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An Exploration of Treatment Burden and Patient Capacity in People with Stroke

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Submitted in fulfilment of the requirements for the Degree of
Doctor of Philosophy (PhD)

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October 2016

2 VOLUMES

VOLUME 1 - THESIS

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Abstract

Background and aims: Advances in modern medicine have led to improved outcomes after stroke, yet an increased treatment burden has been placed on patients. Treatment burden is the workload of health care for people with chronic illness and the impact that this has on functioning and well-being. Those with comorbidities are likely to be particularly burdened. Excessive treatment burden can negatively affect outcomes. Individuals are likely to differ in their ability to manage health problems and follow treatments, defined as patient capacity. The aim of this thesis was to explore the experience of treatment burden for people who have had a stroke and the factors that influence patient capacity.

Methods: There were four phases of research. 1) A systematic review of the qualitative literature that explored the experience of treatment burden for those with stroke. Data were analysed using framework synthesis, underpinned by Normalisation Process Theory (NPT). 2) A cross-sectional study of 1,424,378 participants ≥ 18 years, demographically representative of the Scottish population. Binary logistic regression was used to analyse the relationship between stroke and the presence of comorbidities and prescribed medications. 3) Interviews with twenty-nine individuals with stroke, fifteen analysed by framework analysis underpinned by NPT and fourteen by thematic analysis. The experience of treatment burden was explored in depth along with factors that influence patient capacity. 4) Integration of findings in order to create a conceptual model of treatment burden and patient capacity in stroke.

Results: Phase 1) A taxonomy of treatment burden in stroke was created. The following broad areas of treatment burden were identified: making sense of stroke management and planning care; interacting with others including health professionals, family and other stroke patients; enacting management strategies; and reflecting on management. Phase 2) 35,690 people (2.5%) had a diagnosis of stroke and of the 39 co-morbidities examined, 35 were significantly more common in those with stroke. The proportion of those with stroke that had ≥ 1 additional morbidities present (94.2%) was almost twice that of controls (48%) (odds ratio (OR) adjusted for age, gender and socioeconomic deprivation; 95% confidence interval: 5.18; 4.95-5.43) and 34.5% had 4-6 comorbidities compared

to 7.2% of controls (8.59; 8.17-9.04). In the stroke group, 12.6% of people had a record of ≥ 11 repeat prescriptions compared to only 1.5% of the control group (OR adjusted for age, gender, deprivation and morbidity count: 15.84; 14.86-16.88). Phase 3) The taxonomy of treatment burden from Phase 1 was verified and expanded. Additionally, treatment burdens were identified as arising from either: the workload of healthcare; or the endurance of care deficiencies. A taxonomy of patient capacity was created. Six factors were identified that influence patient capacity: personal attributes and skills; physical and cognitive abilities; support network; financial status; life workload, and environment. A conceptual model of treatment burden was created. Healthcare workload and the presence of care deficiencies can influence and be influenced by patient capacity. The quality and configuration of health and social care services influences healthcare workload, care deficiencies and patient capacity.

Conclusions: This thesis provides important insights into the considerable treatment burden experienced by people who have had a stroke and the factors that affect their capacity to manage health. Multimorbidity and polypharmacy are common in those with stroke and levels of these are high. Findings have important implications for the design of clinical guidelines and healthcare delivery, for example co-ordination of care should be improved, shared decision-making enhanced, and patients better supported following discharge from hospital.

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“It is easy to get a thousand prescriptions but hard to get one single remedy.”
(Chinese Proverb)

Acknowledgement

I would like to thank my principle supervisor Prof Frances Mair for all her time, knowledge, support, enthusiasm and patience. I would also like to thank my other supervisors: Prof Carl May was an unending supply of wisdom during the qualitative studies; Dr David Batty provided invaluable statistical advice; and Prof Peter Langhorne provided great expertise in stroke research.

Thanks to Dr Gary McLean for his help with statistics and patience with my never ending emails. Thanks to Dr Sara Macdonald for her help with the systematic review and kinds words of encouragement. A huge thanks to those in GPPC who have provided friendship and support over the years, in particular Deborah Morrison, Bhautesh Jani and David Blane who I not only shared an office with but also the experience of completing a PhD whilst raising a young family and trying to get enough sleep. Huge thanks to Michelle McKelvie, Michere Beaumont, Linda Easton and Christine Fitzpatrick who provided endless administrative assistance, and to Jane Goodfellow for all her expert help with figures and posters.

I would like to profoundly thank all the participants that took part in this research, and also Janice Reid, Yvonne McIlvenna, Tracy Ibbotson, Ruth Graham, Lesley McDonald and Belinda Manak for all their help with recruitment.

Thanks to my colleagues in the International Minimally Disruptive Medicine Workgroup for conceptual assistance (Frances S Mair, Carl R May, Victor M Montori, Sara Macdonald, David T Eton, Nathan Shippee, Deborah Morrison, Bhautesh Jani, Susan Browne, David Blane, Nilay Shah, Patricia Erwin, Kathleen Yost, Alison Richardson, and Sara Demain).

I am indebted to my family and friends for their support. To my husband John Paul, thank you for patience and for missing so much football in order to watch the children while I wrote this never ending thesis. To Dylan and Rory, I started this thesis before you arrived and although you somewhat delayed the process you have kept my spirits up, so thank you! Thanks to my Dad for reading (most) of this thesis and not just pretending to. I dedicate this thesis to my mum, who is in my thoughts every day, and who encouraged me to never give up on a project.

Author's declaration

The work described in this thesis was performed during my period as a Clinical Academic Fellow and this was funded by the Chief Scientist Office Scotland (CAF/10/03). I declare that I am the sole author of this thesis and was responsible for the conception, design and undertaking of all aspects of the research under guidance from my supervisors. A number of colleagues collaborated at various stages and they are formally acknowledged below.

Qualitative Systematic Review

A formal search strategy was employed and updated by Prof Patricia Erwin from the Mayo Clinic Rochester. Candida Fenton from the Social and Public Health Sciences Unit in the University of Glasgow also contributed to discussions about creating a search strategy.

I acted as first reviewer during all stages of the review including paper screening, data extraction, quality appraisal and data coding. The following colleagues acted as second reviewers: Prof Frances Mair, Prof Carl May, Dr Deborah Morrison, Dr Bhautesh Jani, Dr Sara Macdonald, Dr Alastair Rankin, Dr Jennifer Maxwell. The following medical students also screened papers: Andrew Leitch, Louise Bradshaw, Nikole Runciman, Sylvia Kamyra, Aishah Coyte, Yasmin Grant, Ahad Jan, Colette Kenman, Jamie Hooker, Megan Harwood, Patrick Collins. I carried out all higher levels of data analysis.

Cross-sectional study

The data originally planned for use (but deemed unsuitable) was extracted by Julie Boyd from NHS Greater Glasgow and Clyde Information Services and cleaned by Dr David Purves from the Robertson Centre for Biostatistics.

The data used for analysis was collated by Katie Wilde and Fiona Chaloner of the Primary Care Informatics Unit at the University of Aberdeen. Prof Stewart Mercer and Prof Bruce Guthrie carried out initial data management to define morbidities. The use of this data was funded by the Chief Scientist Office 'Living Well with Multimorbidity' programme (ARPG/07/1). I performed all statistical

analysis with guidance from Dr Gary McLean. Jane Goodfellow helped to create Figures 2 and 3.

Qualitative analysis of interviews

Recruitment of participants from primary care was supported by Janice Reid, Yvonne McIlvenna and Tracy Ibbotson of the Scottish Primary Care Recruitment Network. This involved searching GP databases and generating letters.

Recruitment of participants from secondary care was supported by Ruth Graham, Lesley McDonald and Belinda Manak of the Stroke Research Network. This involved identifying potentially appropriate participants in the stroke wards and clinics and handing out information packs. I then carried out screening of interested participants.

Michere Beaumont transcribed the participant interviews. I carried out all data analyses, and Prof Frances Mair double coded four transcripts.

Publications and presentations

Publications arising from this research

1. **Gallacher K**, Morrison D, Jani B, Macdonald S, May CR, Montori VM, Erwin PJ, Batty GD, Eton DT, Langhorne P, Mair F. (2013) Uncovering Treatment Burden as a Key Concept for Stroke Care: A Systematic Review of Qualitative Research. *PLoS Med*; 10(6): e1001473.
2. **Gallacher K**, Jani B, Morrison D, Macdonald S, Blane D, Erwin PJ, May CR, Montori VM, Eton DT, Smith F, Batty GD, Mair FS. (2013) Qualitative Systematic Reviews of Treatment Burden in Stroke, Heart Failure and Diabetes - Methodological Challenges and Solutions. *BMC Medical Research Methodology*; 13:10
3. **Gallacher KI**, Batty GD, McLean G, Mercer SW, Guthrie B, May CR, Langhorne P, Mair FS. (2014) Stroke, multimorbidity and polypharmacy in a nationally-representative sample of 1,424,378 patients in Scotland: implications for treatment burden. *BMC Med*;12:151.

Publications related to this research

1. Abu Dabrh AM, **Gallacher K**, Boehmer KR, Hargraves IG, and Mair, FS (2015) Minimally disruptive medicine: the evidence and conceptual progress supporting a new era of healthcare. *Journal of the Royal College of Physicians of Edinburgh*; 45(2), pp. 114-117.
2. May CR, Eton DT, Boehmer K, **Gallacher K**, Hunt K, MacDonald S, Mair FS, May CM, Montori VM, Richardson A, Rogers AE and Shippee N(2014) Rethinking the patient: using Burden of Treatment Theory to understand the changing dynamics of illness. *BMC Health Services Research*; 14(281).
3. Leppin AL, Gionfriddo MR, Kessler M, Brito JP, Mair FS, **Gallacher K**, Wang Z, Erwin PJ, Sylveste T, Boehmer K, Ting, HH, Murad MH, Shippee ND, Montori VM. (2014) Preventing 30-day hospital readmissions. *JAMA Internal Medicine*; 174(7). pp. 1095-1107.
4. **Gallacher, K. I.**, Montori, V. M., May, C. R., and Mair, F. S. (2014) Treatment burden and multimorbidity. In: Mercer, S. W., Salisbury, C. and Fortin, M. (eds.) *ABC of Multimorbidity*. Series: ABC Series. Wiley-Blackwell: Oxford, pp. 30-33.

Presentations arising from this research

1. Uncovering the treatment burden of chronic illness. Three qualitative systematic reviews exploring the patient experience of stroke, chronic heart failure and diabetes management. Scottish School of Primary Care (SSPC) Annual Meeting 2011.
2. Exploring the Burden of Treatments for Stroke Patients, a Qualitative Systematic Review. Society for Academic Primary Care (SAPC) Annual Scientific Meeting, 2011.
3. The patient experience of treatment burden in stroke, a Qualitative Systematic Review. Institute of Health and Well-being Conference, University of Glasgow, 2012.
4. Qualitative Systematic Reviews of Treatment Burden in Stroke, Heart Failure and Diabetes - Methodological Challenges and Solutions. North American Primary Care Research Group (NAPCRG) Annual Meeting, 2012.
5. How stroke patients describe their treatment burden, a qualitative study. SAPC Annual Scientific Meeting, 2013.
6. The patient experience of treatment burden in stroke management. International Society for Quality in Healthcare (ISQua) Annual Scientific Meeting, 2013.
7. Treatment Burden in Stroke - a Novel Concept that Should Change Our Practice. NADEGS Annual Meeting, 2014.
8. Comorbidity and polypharmacy in stroke - a cross sectional study. SAPC Annual Meeting, 2014.
9. Stroke, comorbidity and polypharmacy in a nationally-representative sample of 1,424,378 patients in Scotland: implications for treatment burden. NAPCRG Annual Meeting, 2014.
10. Uncovering treatment burden in stroke. NAPCRG Annual Meeting, 2014.
11. Treatment burden and patient capacity in stroke: a qualitative study. European Stroke Conference 2016.
12. The experience of treatment burden for those with stroke: a qualitative study. Northern Irish Stroke Conference 2016.

Abbreviations

BoTT	Burden of Treatment Theory
CaSM	Confidence after Stroke Measure
CCI	Charlson Comorbidity Index
CHF	Chronic Heart failure
CIRS	Cumulative Illness Rating Scale
CIRS-G	Cumulative Illness Rating Scale adapted for geriatric populations
CuCoM	Cumulative Complexity Model
CVA	Cerebrovascular Accident
DLSES	Daily Living Self-Efficacy Scale
ESSI	ENRICH Social Support Inventory
GP	General Practitioner
ICD-9	9th revision of the International Statistical Classification of Diseases and Related Health Problems
ICD-10	10th revision of the International Statistical Classification of Diseases and Related Health Problems
ISSB	Inventory of Socially Supportive Behaviour
MDM	Minimally Disruptive Medicine
NHS	National Health Service
NPM	Normalisation Process Model
NPT	Normalisation Process Theory
OR	Odds Ratio
PAM	Patient Activation Measure
PCCIU	Primary Care Clinical Informatics Unit
PRECiS	Patient-reported Evaluation of Cognitive State
PSSS	Perceived Social Support Scale
QOF	Quality and Outcomes Framework
QOL	Quality-of-life
RCT	Randomised Control Trial
SNQ	The Social Network Questionnaire
SSEQ	Stroke Self-Efficacy Questionnaire
SSSMQ	Southampton Stroke Self-Management Questionnaire
TIA	Transient Ischaemic Attack
US	United States

Glossary

Cardiovascular disease	All diseases of the blood vessels and heart including stroke, TIA, angina, coronary heart disease, hypertension, myocardial infarction, congenital heart disease, heart valve disease and cardiomyopathy.
Cerebrovascular disease	A collection of diseases that involve damage to the brain due to altered blood supply. This includes stroke and TIA.
Co-morbidity	The presence of one or more long-term conditions in addition to an index condition.
Conceptual Model	A conceptual model is a model made of the composition of concepts, which are used to help people know, understand, or simulate a subject the model represents.
Cross-sectional	Data collected at one point in time.
Framework analysis	A type of qualitative analysis involving the use of a framework to sift, chart and sort data.
Framework synthesis	A type of qualitative synthesis involving the use of a framework to analyse data from multiple qualitative studies.
Illness burden	The impact of illness on an individual, e.g. symptoms or financial cost.
Multimorbidity	The presence of one or more long-term conditions within one individual.
Non-adherence	Not following medical advice.
Normalisation Process Theory	A middle range theory that can be used to understand the processes involved in the implementation and embedding of a set of tasks.
Patient activation	The knowledge, skills and confidence a person has in managing their own health and health care.
Patient capacity	The ability of an individual to manage their health and follow treatments.
Polypharmacy	The prescribing of multiple medications
Qualitative synthesis	Combining results of multiple qualitative studies.
Scottish Stroke Care Standards	Standards of stroke care set by the Scottish Government.
Scottish Stroke Improvement Plan	A Scottish Government policy document that aims to improve stroke care in Scotland.
Self-efficacy	Belief in one's ability to succeed in specific situations or accomplish a task.

Self-management	Managing one's own health.
Stroke	Damage to the brain due to a lack of blood supply or bleeding into the brain. Symptoms last over 24 hours. Includes ischaemic stroke (blocked blood vessel), intracerebral haemorrhage (bleeding inside the brain) and subarachnoid haemorrhage (bleeding on the surface of the brain).
Taxonomy	An ordered arrangement / list of groups or categories
Thematic analysis	A type of qualitative analysis that involves pinpointing, examining, and recording patterns (or "themes") within data
Transient Ischaemic Attack	A temporary blood vessel blockage resulting in symptoms similar to stroke but lasting less than 24 hours.
Treatment burden	The workload of healthcare for patients and the effects of this on their well-being
Treatment workload	The set of tasks that patients must carry out to manage their health.

Chapter 1 - Introduction

1.1 Aims of this chapter

To introduce the concept of treatment burden; describe stroke and its management; explain the aims and objectives of this thesis; and provide a brief overview of subsequent chapters.

1.2 Background - the concept of treatment burden

In this thesis, I explore how people who have had a stroke experience and may be burdened by the processes of stroke care, and what factors influence their capacity to follow treatments and manage health problems. Advances in science and technology have led to improved treatments for those who have suffered a stroke, including therapies that aid recovery and prevent further disease^{1;2}. This has led to an upward trend in survival rates in most westernised countries including the UK²⁻⁴, and therefore increasing numbers of people living with the long-term sequelae of stroke and its management. Although advances have led to improvements in some outcomes⁵⁻⁷, there has been increasing burden of treatment demands placed on patients required to follow complex regimes set by healthcare providers^{8;9}. Additionally, advances in other areas of healthcare and an increasing life expectancy contribute to the problem of comorbidity in stroke¹⁰, further increasing burden on patients as they attempt to manage more than one condition simultaneously.

Treatment burden is a relatively new term, defined as the workload of healthcare for patients and the effects of this on their well-being^{11;12}. Excessive treatment burden can lead to negative outcomes such as reduced quality-of-life, non-adherence, less effective treatment and wasted resources^{8;9}. Patients vary in their abilities to follow treatments and engage with health professionals depending on a variety of physical, psychological and social factors, and this is defined as patient capacity¹³⁻¹⁵. Aspects of treatment burden may be worsened by guidelines and policies set by governing bodies as well as the organisation of health services. This is a significant problem for patients that could be amenable to change through proper exploration and action by those who provide healthcare^{8;9}. For example, over the last two decades there has been a move

towards empowerment of the patient through initiatives such as supported self-management programmes; however these can result in a considerable healthcare workload for the patient^{9;16-18}. This move has been driven by increasing evidence that such strategies for patient engagement can both improve outcomes and reduce healthcare costs¹⁹. As responsibility for disease management has shifted from healthcare providers to patients and their caregivers, careful consideration must be given to the implications of this on their well-being⁹. In the UK, a six week 'expert patient programme' for those with long-term conditions was rolled out nationally in 2002. This was subsequently evaluated using three high quality studies: 1) a process evaluation; 2) a randomised control trial; and 3) a qualitative study. Findings showed a moderate positive impact on self-efficacy (belief in oneself to successfully manage the long-term condition), a smaller impact on reported energy, and an improvement in health-related quality-of-life, with little impact on routine health services utilisation. Participants reported an increase in social support through improved social networks and a reduction in social isolation, and the programme was found to be cost effective. Although these findings were encouraging, one concerning finding was that patients reported an increase in out of pocket expenses, and the process evaluation concluded that the programme appealed most to those who were affluent and able to manage their health already, therefore it was unlikely that it would reach the majority of people living with long-term conditions in the UK. Another concern was that participants reported a lack of input with regard to setting outcome targets, for example the focus on improving self-efficacy at times detracted from other goals that were more meaningful to them. Those who undertook the evaluation concluded that resources for self-management support would be better directed elsewhere, ideally at multiple levels that include patients, health professionals and organisations, to foster improved self-management support²⁰. This evaluation demonstrates a requirement for healthcare providers to gain insight into the patient experience of chronic disease management in order to inform the design of suitable health services.

In 2009 a pivotal paper introduced the concept of treatment burden and recommended the following clinical and research priorities to tackle this issue: clinicians and researchers should establish the weight of treatment burden

experienced by those with long-term conditions; governing bodies should incentivise co-ordination in clinical practice; co-morbidity (the presence of one or more conditions in addition to an index condition) should be acknowledged in clinical evidence; and health care providers should prioritize the patient perspective⁹. The initial ideas for this thesis stemmed from this important paper. Thus far, treatment burden in stroke has not been comprehensively examined in the literature. Investigation of this is vital in order to fully understand how changes in practice and policy can minimise burden on patients and improve outcomes.

1.3 What is stroke and how is it managed?

1.3.1 Stroke

Stroke or cerebrovascular accident (CVA) is defined as ‘a serious medical condition where one part of the brain is damaged by a lack of blood supply or bleeding into the brain from a burst blood vessel’²¹. Stroke can result in death, permanent or temporary disability, and is classified as one of the cerebrovascular diseases alongside Transient Ischaemic Attack (TIA), a temporary blood vessel blockage resulting in similar symptoms to stroke but lasting no more than 24 hours²¹⁻²³.

In the UK, around 150,000 people suffer a stroke each year with around 15,000 of these occurring in Scotland^{24;25}. The Scottish incidence rate is estimated to have decreased by approximately 22% over the past decade due to improvements in prevention strategies²². On a global basis the incidence of stroke has also fallen, mainly due to improvements in high income countries, with low and middle income countries showing a moderate increase over a similar time period²⁶. Despite this downward trend in incidence, a decrease in mortality due to improved treatments has resulted in an overall increase in the number of people living with stroke²⁶. In the UK, prevalence has increased by 26% over the past decade, resulting in an estimated 1.2 million people surviving stroke²³. In Scotland, the prevalence is estimated to be slightly higher than in other parts of the UK, currently at 3.3% in men and 2.7% in women²². The World Health Organization has predicted that the number of stroke events will increase in the European Union over the next decade due to an ageing population²⁷.

1.3.2 Stroke management

Over the past two decades, improving stroke outcomes has been a priority for UK governments, for example in Scotland there has been implementation of the Scottish Stroke Care Standards²⁸ and Stroke Improvement Plan²⁹. An update of the national clinical guidelines^{30;31} alongside rigorous audit of clinical standards²⁴ has resulted in widespread implementation of organised specialist stroke management, for example stroke unit care, which has contributed to reductions in mortality from stroke in Scotland^{22;23}.

Treatments for stroke vary depending on symptoms and disabilities. Current clinical guidelines recommend prompt clinical assessment, with subsequent medical and surgical intervention as appropriate, then early, co-ordinated multidisciplinary rehabilitation started in an acute stroke unit and completed either on a rehabilitation ward or at home as part of an early supported discharge package³⁰⁻³². Rehabilitation is often intensive and arduous for patients^{23;33}. Alongside rehabilitative treatments, patients are required to attend follow up appointments at their doctor and take secondary preventative medication^{30;31;34}. Despite evidence that such medications are effective, adherence is estimated to be sub-optimal³⁵. Reasons for this include a lack of information and support from health professionals^{36;37}, confusion due to generic medication switches by pharmacists³⁸ and expense of medication^{37;39;40}.

Newly recommended treatments include upper limb electrical stimulation³⁴ and endovascular thrombectomy⁴¹. Although 'gold standard' care has become more readily available in the UK and stroke services have improved greatly over the past two decades, aspects are still substandard. For example, in Scotland the delivery of thrombolysis within an appropriate timeframe is currently below the desired target²⁴.

Self-management is a fairly new concept in stroke care; however, there is emerging good quality evidence that supported self-management can improve functional outcomes, participation, dependency and mortality^{42;43}. Training in self-management for patients is now recommended as part of routine care in UK national stroke guidelines⁴⁴. However, concerns have been raised about the use of traditional programmes¹⁸ in the context of stroke given the cognitive,

physical, psychological, social and financial difficulties faced by many stroke patients^{45;46}. Optimal methods of delivery are therefore still uncertain, and an emphasis on supporting the adjustment process rather than imposing behaviour change may be more appropriate⁴⁵.

The trend towards early supported discharge from hospital⁴⁷ and self-management of stroke at home⁴² has implications for treatment burden, as responsibility has shifted from healthcare provider to patient. Despite this, current government documents such as the Scottish Stroke Care Standard²⁸ and the Scottish Stroke Improvement Plan²⁹ are very heavily weighted towards acute care, with less focus on the longer term therapies and possible burdens faced by those in the community. For example, issues such as multimorbidity, adherence to long-term medications, and drug interactions are all missing, despite those with stroke being at high risk of suffering from co-morbid conditions⁴⁸ and an increase of 17% in the number of drugs prescribed in cardiovascular disease over the past decade²². There is therefore considerable room for improvement in the guidance set by governing bodies for those with stroke.

1.4 Aims and objectives of this thesis

The research questions explored in this thesis are: What are the treatment burdens experienced by those who have had a stroke? What factors influence patient capacity to follow treatments? These questions have been answered through a mixed methods approach consisting of: systematic review of the qualitative literature; analysis of a nationally-representative primary care data set; and interviews with people who have had a stroke.

The explicit objectives were:

1. To carry out a systematic review of the qualitative literature that explores how those who have had a stroke experience treatment burden.
2. To quantify comorbidity and prescribing in those who have had a stroke in Scotland.

3. To explore in depth, the experience of treatment burden and factors that influence patient capacity by interviewing those who have suffered a stroke.
4. To integrate findings of the above to create a conceptual model of treatment burden and patient capacity in stroke.

1.5 Overview of chapters

This chapter is a brief introduction and overview of the thesis. In the second chapter a synopsis is provided of the theoretical underpinnings of the thesis, with a description of how treatment burden and related concepts have been conceptualised thus far in the medical and sociological literature. The third chapter will provide a description of the background literature on treatment burden, patient capacity and comorbidity in stroke. In the fourth chapter, methodology is discussed and this is followed by three results chapters divided into: the systematic review; quantitative analyses of primary care data; and qualitative analyses of interviews with those who have had a stroke. In the last chapter, a conceptual model is presented, overall findings discussed and hypotheses generated about potential changes to healthcare practice and policy that could minimise treatment burden and maximise patient capacity. Strengths and limitations of the thesis and directions for future research will then be provided.

This thesis tells a story: a summary of theoretical underpinnings and background literature; an exploration of what we know about treatment burden in stroke from the international literature; a quantification of comorbidity and prescribing for those living with stroke in Scotland; an exploration of how people living with stroke describe treatment burden and their capacity to follow treatments in a real life setting; and a discussion of how these findings can inform practice and policy. Each phase of the study has undoubtedly influenced the next, for example, findings from the systematic review had considerable impact on the objectives in the quantitative section and interview guide for the semi-structured interviews, and the interview schedule and method of data analysis in the qualitative section evolved in response to findings. The processes of planning, analysing, writing and reflecting have therefore been iterative in

nature and informed by the evolving literature. In the next chapter, the theoretical underpinnings of the thesis will be discussed.

Chapter 2 - Theoretical Background

2.1 Introduction

2.1.1 Aims of this chapter

To explain the underlying concepts, existing definitions and theoretical underpinnings of the work described in this thesis.

2.1.2 Rationale

This thesis describes an exploration of the experience of treatment burden for those with stroke. Treatment burden is a relatively new term, defined as the workload of healthcare for patients and the effects of this on their well-being. Treatment burden is important because it leads to negative outcomes such as poor quality-of-life, reduced adherence, ineffective treatment and wasted resources^{9;49;50}. Although data on adherence to therapies following stroke are limited, estimations vary from 50-85%, with a general consensus that adherence is suboptimal^{51;52}.

In this chapter, conceptualisation of treatment burden in the literature is described along with exploration of other relevant concepts such as treatment workload, patient capacity, multimorbidity and minimally disruptive medicine. The aim is not to give an exhaustive review of the literature but to explore the important concepts and hypotheses that underpin this thesis. These ideas have been conceptualised in those with chronic illness and therefore are not specific to stroke. However, all are relevant to the stroke population, who undergo arduous rehabilitation followed by lifelong secondary preventative treatments for their condition. A description of the literature that has examined treatment burden in those with stroke is given in the next chapter.

2.2 Methods

As my supervisors were published experts in this field of research, an initial discussion with them directed me towards key reading materials. Further relevant papers were found through a search of: online databases such as Ovid; Google scholar; and the references and citations of papers found to be of

interest. Search terms included: treatment burden; treatment workload; patient capacity; resilience; multimorbidity; patient experience; chronic disease; and patient reported measure.

2.3 Background literature on treatment burden

2.3.1 The patient experience of illness

As it has become increasingly accepted that health professionals have a responsibility to understand their patients' experiences and put medical management into a wider social context, interest in the patient perspective has proliferated over the past four decades^{53;54}. This interest, however, has frequently focussed on the hardships of illness rather than on the burdens that arise as a consequence of treatments. It is important to note that treatment burden is distinct but inevitably related to the burden of illness, which encompasses factors such as physical and psychological symptoms, time lost in employment and financial consequences. Both treatment burden and illness burden include physical, psychological, social and financial dimensions. For example, physical disability would be classified as an illness burden and polypharmacy (the prescribing of multiple medications) a treatment burden. As mentioned above, these two types of burden are unequivocally linked and have considerable overlap, yet are important to consider as separate entities, as although they have strong influences on each other, they are also likely to have separate origins that deserve exploration.

As burden of illness is related to burden of treatment, a few of the more salient pieces that have examined the patient experience of illness will be briefly discussed before a more in-depth discussion of the treatment burden literature. The first conceptual model of the patient experience of illness was Parsons' 'sick role', within what he termed 'sickness behaviour'⁵⁵. This model described sickness as a deviant status for the individual (deviant from the 'well' population), and therefore exempted the patient from normal social roles along with any responsibility for their condition, with the agreed obligations on the part of the patient to try to get well, seek technically competent help and cooperate with the medical professional. This model has been criticised due to its creation in reference to acute rather than chronic illness, its failure to

recognise preventative health care, its lack of appreciation for the broader social and psychological aspects of illness, and because it appears to provide insight through the lens of the healthcare provider rather than the patient⁵⁶⁻⁵⁹. However, despite these limitations, Parson's studies are accepted as pioneering work that subsequently became a framework for sociological research on sickness behaviour⁵⁹. The 'obligations' described by Parsons could be considered an early recognition of treatment burden, as explored in this thesis.

One limitation of Parsons' sick role⁵⁵ was that it was framed around the liaison between patient and health professional. Mechanic subsequently coined the concept of 'illness behaviour' which extended beyond this liaison, by encompassing the medically related activities and concerns of persons which take place outside the clinical setting^{60;61}. This concept lent itself more suitably to chronic illness management. Mechanic described illness behaviour as 'the manner in which individuals monitor their bodies, define and interpret their symptoms, take remedial action, and utilize sources of help as well as the more formal health care system. It is also concerned with how people monitor and respond to symptoms and symptom change over the course of an illness and how this affects behaviour, remedial action taken and responses to treatment'. Similar to Parson's work⁵⁵, Mechanic's early studies⁶⁰ have been criticised as providing insight through the lens of the healthcare provider rather than the patient themselves⁵⁹. However, his later work was more focussed on the patient perspective⁶², and explored the personal, social and sociocultural factors that influence the response of an individual to their illness. Although he did not define these processes as burdensome, Mechanic certainly recognized the complex range of actions required of patients when managing their illness⁶².

In 1975, Glaser and Strauss along with their students published high quality, pioneering work that explored the patient experience of chronic illness in the community⁶³. In this they sought to gain a broader understanding of the patient perspective including the social and psychological experiences of chronic illness. Although not named as treatment burden, several concepts were described that could be considered as such, for example, the management of crises, symptom control, and the implementation of daily treatment regimens⁶³. This research uncovered important issues for those with chronic illness, many of which are likely to hold true for patients today. The framework created was fairly basic;

however, some of the concepts hypothesised were further developed many years later in pivotal work by Corbin and Strauss that described the concept of the illness trajectory⁶⁵. They defined trajectory as the course of an illness over time, plus the actions of clients, families and healthcare professionals to manage that course. Another term used in their model was biography, meaning previous personal experiences and beliefs that may shape the management of illness, and this supports the concept that patients vary in their capacity to cope with treatments, discussed later in this chapter. The illness trajectory framework is highly acclaimed and has subsequently evolved over decades of research, having been applied to numerous conditions including stroke⁶⁵.

Salient work by Bury sought to explore the wider social context of chronic illness and its management through analysis of interviews with rheumatoid arthritis patients. Three types of 'biographical disruption' caused by illness were found: disruption of taken-for-granted assumptions and behaviours and the decision to seek help; a fundamental rethinking of the person's biography and self-concept; and the mobilisation of resources⁶⁶. Bury's work has been highly acclaimed and gave valuable insight into the chronic illness experience. However, similar to the work above it focussed on the intrusions of illness rather than treatments and therefore gave little insight into treatment burden. Many other highly regarded studies have similarly investigated the burdens of illness, for example the experience of symptoms and bodily dysfunction⁶⁷; the psychosocial influences of illness⁶⁸⁻⁷⁰; and patients' understanding of their illness⁷¹. In summary, numerous pieces of highly acclaimed research have conceptualised the patient experience of illness; however, these studies share a lack of focus on treatment burden.

2.3.2 Treatment burden

2.3.2.1 Treatment workload

The earliest conceptualisation of treatment workload was in 1985 when Corbin and Strauss published pivotal research that recognised the workload of illness management for patients. In this work they conceptualised three types of work associated with chronic illness: illness trajectory work; everyday life work; and biographical work^{72;73}. Illness trajectory work consisted of the work that goes into managing the course of illness, such as regimen work and crisis

management. Everyday lifework encapsulated the daily tasks that are required to run the household and manage everyday living, such as grocery shopping and childcare. Biographical work involved retaining a sense of self-identity amidst the reconstruction of life which has been altered by the illness and its management. All types of work involved interactions and negotiations with others such as family, friends and healthcare workers. The authors described the conditions under which the work is being carried out as a constantly fluctuating 'structure in process'. Each line of work creates a 'reciprocal impact' on the others, as the patient balances workloads, efforts and resources to maintain equilibrium. This work has been highly acclaimed as it used inductive methods of analysis to conceptualise the hard work of managing a chronic illness from the patient perspective, and places this in the context of attending to the everyday demands of life. The illness trajectory work described by Corbin and Strauss underpins the concept of treatment burden described in this thesis. They described a set of tasks carried out by the patient including: sense-making; decision making; working with others; organisational work; securing finances; establishing routines; troubleshooting; and monitoring outcomes. This set of tasks resonates with the framework informed by Normalisation Process Theory (NPT) used for analysis of data in subsequent chapters.

Following the publication of Corbin and Strauss's research, the notion that the management of chronic illness creates 'work' for patients has slowly emerged in the literature, with studies exploring, for example, how patients: seek information about their condition ⁷⁴; carry out everyday decision making ¹⁷; undertake self-care ⁵⁰; take medications ^{75;76}; develop coping strategies ⁷⁷; mobilise resources ⁷⁸; and interact with health professionals ⁷⁹. These studies have all examined healthcare from the service-user perspective and have supported the premise that managing health requires considerable time and effort from patients. However, they have all focussed on narrow aspects of the patient experience, therefore a holistic outlook is lacking. Studies that have examined treatment workload specifically in relation to stroke are examined in detail in Chapters 3 and 5.

Further expanding on the concept of treatment workload, May recently theorized the hard work of patient-hood for those with chronic illness. He described the clinical encounter as a field within which work is carried out by

both health professionals and patients, alongside a wider framework of individuals within the patient's social network⁸⁰. He noted that the work of being ill has changed over recent times in the developed world, due not only to the epidemiological shift from acute to chronic illness, but also the rapid socio-technical advances in healthcare organisation and delivery⁵⁸. Motivation on behalf of the patient was described as crucial to the management of chronic illness, with the following attitudinal expectations of the patient from healthcare providers: prudence (willingness to minimize the load placed on formal healthcare provision); resourcefulness (capacity to operationalize knowledge and link it to existing patterns of service provision); agency (active engagement in shared decision-making and treatment processes); expertise (possession of knowledge and skills for appraising management advice and self-management outcomes)⁵⁸. This theoretical work therefore recognized that managing health is hard work, and that this can be exacerbated by the expectations and demands of healthcare providers. It also recognized that the abilities of the patient and their social network to respond to these demands can heavily influence whether the work of patient-hood is successfully completed. These observations are echoed in more recent work on patient capacity, which is discussed later in this chapter.

The research above has therefore conceptualised the workload of health care that people with chronic illness are required to perform in response to the requirements of their healthcare providers and systems. Treatment burden is a novel concept that stems from this work, defined as the impact of healthcare workload on the functioning and well-being of the patient^{11;12}.

2.3.2.2 Conceptualisation of treatment burden

Treatment burden is likely to be affected by many factors, including the nature of illness and treatments available, the presence of comorbidities, and the organization of health services and practices of healthcare practitioners^{9;14;81}. For example, the prescription of polypharmacy (multiple medications) can directly increase workload and also increase the risk of adverse drug events and hospitalisations⁸²⁻⁹⁰. However, many medications⁸²⁻⁹⁰ are known to have therapeutic advantages⁹¹ and one large good quality study of primary care patients in Scotland concluded that although polypharmacy was associated with unplanned

hospital admissions in those with chronic illness, the effect was reduced in those with higher numbers of co-morbidities, with only the most extreme levels of polypharmacy being associated with hospitalization in that group⁸⁹. Assessment of treatment burden is therefore undoubtedly complex, and many factors must be considered.

There has been interest in the qualitative exploration of treatment burden from the patient perspective. A recent study explored treatment burden among those with chronic illness and their informal carers in Australia and this uncovered financial burden, time and travel burden, medication burden and healthcare access burden⁹². This was a high quality study that inductively analysed interviews with 97 patients. However, findings mainly concentrated on management in the community with less information on the hospital experience. Financial burden was a particular problem, as were waiting times for those without private healthcare. Both of these burdens are likely attributable to the healthcare system in Australia, where publicly funded and private healthcare systems co-exist. The authors also reported that those with co-morbidities and polypharmacy described feeling particularly burdened by their treatments. Most participants in this study had multiple chronic conditions and therefore some stroke patients were included. However, treatment burden in stroke was not the focus of the study. A systematic review and concept analysis by the same research team explored the conceptualization of treatment burden in chronic disease⁹³. This review examined attributes, antecedents and consequences of treatment burden. Treatment burden was reported as a dynamic process that changes over time in response to disease severity and control. Burdens uncovered included: physical side effects; financial burden; time required to obtain, administer and manage treatment; and psychosocial aspects including impact on family and lifestyle. The authors described a combination of objective and subjective treatment burdens, the former being aspects that lend themselves more freely to measurement such as number of medications, and the latter being less measurable aspects of burden such as fear and guilt. They also described antecedents of treatment burden that included: patient characteristics; disease condition; treatment characteristics; family support and engagement; and design of healthcare system. Lastly they examined the consequences of treatment burden which included: adherence; health and well-

being; resource use; employment; and impact on family and carers. Although this was a high quality systematic review, most studies included were quantitative in nature and covered a wide range of different chronic diseases, without differentiation between these in the results. An interesting overview of the concepts of treatment burden was provided, rather than a deeper exploration of disease specific aspects of treatment burden. None of the studies found examined people who had suffered a stroke.

Two recent high quality papers described the creation of a conceptual framework of treatment burden in complex patients with chronic disease in the United States (US) ^{12 94}. Semi-structured interviews were carried out in group of 50 patients followed by focus groups to confirm themes. The conceptual framework created consisted of three distinct themes: 1) work patients must do to care for their health; 2) challenges / stressors that exacerbate burden; and 3) impacts of burden. Interestingly, the authors removed from their model aspects of health-related work that they felt were 'voluntary activities that a person may undertake to make self-care easier' such as information seeking, and they reported these findings elsewhere along with other factors that lessen treatment burden ⁹⁵. Factors reported to lessen treatment burden were: 1) the use of problem-focused strategies e.g. gaining the support of others or using technology; 2) the use of emotion-focused coping strategies e.g. maintaining a positive attitude or spirituality/faith; 3) questioning the notion of treatment burden as a function of adapting to self-care and comparing oneself to others; 4) having social support (informational, tangible, and emotional assistance); and 5) experiencing positive aspects of health care e.g. coordination of care and beneficial relationships with providers. These findings therefore encompassed voluntary strategies employed by patients themselves to minimise treatment burden, aspects of healthcare provision that may positively influence their experience, and the influence of support networks on increasing the capacity of an individual to cope with their treatments. Similar to in the Australian study, there was a notable emphasis on the financial challenges of healthcare from patients, likely to be partly attributable to the US health care system which often requires patients to negotiate with insurers and face financial challenges that are more profound than in countries who run a healthcare system free at the point of care. The conceptual frameworks produced provided a

comprehensive exploration of treatment burden in those with chronic illness in the US; however, stroke-specific difficulties were not addressed.

A taxonomy of treatment burden in those with chronic disease has recently been created using a multi-country online survey in a sample of 1053 participants from 34 different countries⁹⁶. This taxonomy included a wide range of healthcare tasks, aggravators of treatment burden and patient-reported consequences of treatment burden. Benefits of the methodology included the ability to obtain data from a large, diverse sample of individuals. However, this was at the cost of losing richness in the data when compared to face-to-face interviews and sampling bias (only those who could use the internet could take part; therefore, those who were well educated and affluent were over represented). Despite these drawbacks, the taxonomy provides a useful insight into treatment burden for those with chronic disease.

2.3.2.3 Measures of treatment burden

Despite a growing interest in the exploration of treatment burden for those with long-term conditions globally, until recently comprehensive measures have been lacking. Current patient-reported Quality of life (QOL) measures typically lack information on treatment burden, although a few do include some questions on treatment side effects or difficulties, for example the Illness Intrusiveness Rating Scale (IIRS), which measures how much illness and its treatments interfere with various aspects of everyday life⁹⁷. Some published studies have quantified particular aspects of treatment burden using patient-reported measures in those with various long-term conditions. Examples of conditions studied are diabetes, cancer, and cystic fibrosis⁹⁸⁻¹⁰⁰. Types of treatment burden measured include time and effort spent following medication regimes¹⁰⁰⁻¹⁰⁷, side effects of treatment^{99;108}, adhering to a specific diet^{103;109} monitoring blood glucose levels in diabetes¹⁰³ and out-of-pocket expenditure¹¹⁰. A recent high quality systematic review examined patient-reported measures of treatment burden in chronic heart failure, diabetes and chronic kidney disease. Studies found were mostly for use in those with diabetes, and the authors highlighted the methodological challenges encountered due to a lack of conceptualisation of treatment burden in the literature. Findings demonstrated a lack of patient

input during development of the measures, poor evidence of reliability and validity, and a lack of holistic outlook ¹¹¹.

There has been a recent interest in the development of reliable, comprehensive patient-reported measures involving input from service-users. One measure of treatment burden in multimorbid patients was developed through a review of the literature and semi-structured interviews with patients in France ^{112;113}. Validation of the measure was described in full but detailed description of any underlying conceptual model of treatment burden was lacking. Additionally, the measure was fairly rudimentary, omitting aspects of treatment burden such as learning about treatments, goal setting, side effects of medications, and accessing equipment.

Another study described the development of a measure of healthcare task difficulty amongst older multimorbid patients ¹¹⁴. One drawback of this measure is a lack of service-user input during its development, and its focus on a narrow range of burdens. For example, difficult interactions with health professionals are not included. However, the authors state that it is a 'worthwhile foundation from which the broader concept of treatment burden in medical decision making might be further explored'. Findings showed that healthcare task difficulty was associated with worse mental and physical health as well as poorer patient-reported quality of chronic illness care. The study also found that healthcare task difficulty was more common in those who were less activated, meaning they had less knowledge, skills and confidence in managing their health.

Another patient-reported measure was developed for diabetic patients, to be utilised during the clinical encounter by healthcare practitioners ⁹⁸. This was developed following a review of current QOL instruments and discussion groups with providers and patients. The measure created was comprehensive, and included questions on treatment burden as well as physical health and social factors that may influence ability to cope with treatments. Importantly, it allows patients to direct the consultation towards issues that are important to them at that point in time, and a visual guide accompanies the questions along with a set of 'suggested actions' available to the healthcare team dependent on how the patient responds. One benefit of this measure is that it has been designed specifically for use within the clinical consultation and it is therefore

shorter than traditional patient-reported measures. However, the authors acknowledged that implementation in a clinical setting may still be impractical, and pilot testing is currently underway.

No comprehensive measures of treatment burden in stroke could be found at the time of writing this thesis. However, areas that have been examined include time spent with therapists in hospital ¹¹⁵, waiting times for acute care ¹¹⁶ and adherence to preventative therapies ⁴⁰. These will be discussed in detail in Chapter 3.

2.3.2.4 Normalisation Process Theory

One of the major theoretical underpinnings of data analysis in this thesis is Normalization Process Theory (NPT) -this underpins the framework synthesis described in Chapter 5 and the framework analysis described in Chapter 7. Methodology is described in more detail in Chapter 4, but NPT will be introduced here and a description given of how it ties in with the other important concepts and theories that support this thesis. NPT seeks to explain how the work of enacting an ensemble of tasks or practices is accomplished through the operation of four mechanisms: ‘coherence’ (sense-making work); ‘cognitive participation’ (relationship work); ‘collective action’ (enacting work); and ‘reflexive monitoring’ (appraisal work)^{117;118}. Treatment burden is defined as the ‘workload’ of healthcare for those with chronic illness and the impact of this on well-being. If we conceptualise this ‘workload’ as a set of practices performed by patients during their chronic disease management that must be implemented, embedded and sustained in their life, NPT fits well as a conceptual framework. NPT was generated from Normalization Process Model (NPM), a formal grounded theory generated over time from a series of inductive qualitative studies that explains the routine incorporation of complex healthcare interventions into practice ^{118;119}. NPT is a middle range and generic theory (meaning that it explains a set of phenomena and can be applied to different contexts) that has broader uses than its predecessor. For the purposes of health service research, the ensemble of tasks or practices that NPT pertains to could be, for example, those relating to the implementation of complex interventions ¹²⁰, health technologies ¹²¹, sickness careers ⁵⁸ or treatment burden ¹²². These practices may be carried out by health professionals, patients themselves, or both ¹¹⁸. Several

studies have used NPT to explore the patient perspective of treatment burden in specific diseases such as heart failure^{11 122;123} and chronic kidney disease¹²⁴, and have found it to be an extremely useful conceptual framework.

As described above, NPT comprises 4 domains. Within these domains there are 16 subdomains. The following is a description of these:

Coherence: Sense-making work, investing in making tasks meaningful.

- *Differentiation.* Defining, dividing up and categorising tasks.
- *Communal Specification.* Making sense of ‘shared’ versions of tasks.
- *Individual Specification.* Making sense of ‘personal’ versions of tasks.
- *Internalization.* Learning how to do tasks in context.

Cognitive Participation: Relationship work, investing personal and interpersonal commitment to tasks.

- *Enrolment.* Recruiting the self and others to tasks.
- *Activation.* Organising a ‘shared’ contribution to tasks.
- *Initiation.* Organising an individual contribution to tasks.
- *Legitimation.* Making tasks the right thing to do.

Collective Action: Enacting work, investing effort and resources in tasks.

- *Skill Set Workability.* Allocating tasks and performances.
- *Contextual Integration.* Supporting and resourcing tasks in their social contexts.
- *Interactional Workability.* Doing tasks, and achieving outcomes, in practice.

- *Relational Integration*. Making and communicating reliable knowledge about tasks.

Reflexive Monitoring: Appraisal work, investing in comprehending.

- *Reconfiguration*. Changing tasks.
- *Communal Appraisal*. Shared evaluation of contributions to tasks.
- *Individual Appraisal*. Individual evaluation of contributions and tasks.
- *Systematization*. Organising a reliable stock of knowledge about tasks.

Alternative theories were examined for their possible relevance. Several behavioural change models have been used in the medical, sociological and psychological literature to explain the uptake of treatments and health-related behaviours, including Theory of Planned Behaviour¹²⁵, Diffusion of Innovations Theory^{126;127}, Health Belief Model¹²⁸, Social Cognitive Theory¹²⁹, and Self-regulation Theory¹³⁰. However, these models have been developed to explain the reasons behind the adoption of behaviours rather than the work that goes into the processes of adoption, therefore none were deemed suitable for underpinning the investigation of treatment burden. NPT was considered suitable as a conceptual framework, and its use in data analysis is described in Chapter 4.

2.3.3 Patient capacity

Alongside the literature on treatment burden, there has been an interest in patient capacity, defined as the ability of those with chronic illness to manage their health and respond to the requirements of healthcare providers, whilst continuing to cope with the demands of everyday life^{13;131}. It should be noted that this is not the same as ‘mental capacity’, a legal term used in the healthcare setting that means ‘the ability of patients to make their own decisions’. However, an individuals’ mental capacity does contribute to their overall ability to manage health problems, so these terms are related but separate. Corbin and Strauss alluded to the importance of patient capacity in their studies of illness work when they described the ‘internal and external

resources that come into play, enabling (patients) to work at illness management' ^{72;73}. A recent good quality systematic review concluded that supporting patient capacity through interventions was associated with greater effectiveness in reducing 30-day hospital readmissions ¹³². These results show promise with regard to the ability of health and social care services to improve patient capacity and to subsequently improve health-related outcomes; however, further exploration is required.

A qualitative study from the UK involved interviews with both multimorbid patients and healthcare practitioners to explore views on factors that influence engagement in self-management ¹³¹. This high quality study concluded that the following factors influenced patient engagement: access and availability of socio-economic resources and time; knowledge; emotional and physical energy; the degree to which patients and practitioners agreed about the division of labour for chronic disease management; and willingness to take-up types of self-management practices. This was a small study of 20 patients and 20 doctors; however, it gave valuable insight into the possible factors that may affect patient capacity in those with multimorbidity.

The Self-integrity Model demonstrates that maintenance of an individual's self-integrity and biography in the face of illness relies on 'supportive capacity', including the use of coping techniques and emotional support from others ¹³³. This model, created through phenomenographic analysis of interviews with palliative care patients, gives important insights into capacity related factors that influence patient distress.

Findings from the studies above suggest that both internal and external factors have an influence on patient capacity. Internal factors can be defined as factors within an individual such as personality and physical functioning, and external factors defined as influences outside of this such as social networks and environmental influences. Examples of these will now be explored.

2.3.3.1 Internal factors that may affect patient capacity

Internal factors such as cognition, literacy and education are likely to influence patient capacity through effects on the processing of health-related information

and interactions with others. A qualitative study conducted in New Zealand used focus groups with patients and health professionals to examine the errors that patients make when managing illness. Findings revealed that some errors were made due to low literacy, low numeracy, or inability to comprehend instructions. This study was limited by sampling from only one community and although more patients than health professionals were interviewed, findings between these two groups were not differentiated. However, despite these limitations, this study gave valuable insight into the generation of patient errors which was a previously understudied phenomenon ¹³⁴. A qualitative study from the UK that involved interviews and focus groups with individuals who had literacy difficulties demonstrated that the stigma and consequences of low literacy can impair interactions with health professionals and the ability to self-manage health ¹³⁵. This was a well-conducted study that examined a hard to reach population; however, one limitation was that those who participated were likely to be more confident and motivated than the typical population of those with low literacy.

There has been a particular interest in the examination of resilience in those with chronic disease, meaning the ability to rebound from crisis or adversity and move on with life ¹³⁶⁻¹³⁸. A recent high quality systematic review concluded that in the context of physical disease, resilience involves maintaining high levels of physical functioning following adversity, and that it is a dynamic process rather than a personality trait. High quality studies of resilience were found to be lacking. However, the authors acknowledged methodological difficulties with their search strategy due to variability in the conceptualisation of resilience in the relevant literature.

Another concept that has been recently proposed as influential on chronic disease management is self-efficacy, defined as belief in oneself to successfully complete a task, or in the case of chronic disease management, to successfully manage health ¹³⁹. There has been a widespread interest in the influence of self-efficacy on health-related behaviour change ¹⁴⁰ and recently there has been a particular interest in the influence of self-efficacy on self-management in stroke ¹⁴¹. This will be discussed further in Chapter 3.

2.3.3.2 External resources

Financial status is likely to affect an individual's capacity to manage their health, although this may vary depending on healthcare system. A study conducted in the US explored the barriers faced by low-income parents when accessing health care for their children through analysis of an open-ended question on a postal questionnaire. Findings showed that families reported lack of insurance coverage, poor access to services, and unaffordable costs as barriers to healthcare. This was a large, well-conducted study of 722 participants who were a subgroup of a larger study of 2681 (they had completed the open ended question at the end of the questionnaire). Limitations of the use of postal questionnaires include a loss in richness of the data compared to face-to-face interviews, possible bias in the wording of the questionnaire, and possible response bias. Additionally, the larger study was recruited from those enrolled in a food stamp system, therefore they were already connected to a system of public benefits, and those not engaged with such services were not reached ¹⁴².

One large study of 300 individuals with either chronic heart failure or diabetes in England demonstrated the importance of social networks in the self-management of chronic conditions ¹⁴³. Postal questionnaires and face-to-face interviews were used to collect information about personal social networks. Results demonstrated that (1) social involvement with a wider variety of people and groups supports personal self-management and physical and mental well-being; (2) support work undertaken by personal networks expands in accordance with health needs helping people to cope with their condition; (3) network support substitutes for formal care and can produce substantial savings in traditional health service utilization costs. This was a well-conducted study that gave insightful information about the importance of personal social networks with regard to capacity to manage long-term conditions.

A qualitative study carried out in the UK involved interviews with 20 multimorbid patients to ascertain the nature of medicine-taking work that people with long-term conditions undertake and how members of their social network are involved ⁷⁵. Findings revealed that considerable medication work existed for patients and that most participants had some kind of support from their social

network with regard to taking their medicines, ranging from intermittent and ad hoc help to routine and wide-ranging involvement. This was a small study therefore generalizability is limited; however, insightful information was gained about the influence of social networks on medicine taking.

2.3.3.3 Conceptualisation of patient capacity alongside treatment burden

Only recently has consideration been given to the importance of patient capacity with regard to the investigation of treatment burden. A theoretical paper described a patient-centred model named the Cumulative Complexity Model (CuCoM) that portrays the balance of patient *workload* and *capacity* as influencing both self-care and healthcare utilization and, therefore, health outcomes¹³. *Workload* is defined as all demands in an individual's life including healthcare burden and other responsibilities such as employment and family. *Capacity* refers to the resources and limitations affecting an individual's ability or readiness to do the work. Examples of factors suggested to affect capacity include physical/mental functioning, pain, symptoms, fatigue, finances, literacy, and social support. The model denotes that high workload and low capacity can result in detrimental health care utilization such as non-adherence to therapies, negatively affecting health outcomes and leading to a further increase in workload and decrease in capacity. For example, an individual with a complicated medication schedule and poor social support may miss tablets, leading to worsening symptoms (reduced capacity) and the subsequent addition of treatments or clinic visits by health professionals (increased workload). The balance between workload and capacity is described as fluid and sensitive to change both in an individual's internal characteristics, their environment, and the care providers they interact with. An advantage to this model is that it can be applied to a broad range of populations and conditions, and it is the first of its kind to examine treatment workload and patient capacity together. However, its development was supported only by a narrative review of the literature with no direct service-user input, and therefore subsequent verification is required through research using both qualitative and quantitative methods.

A recent systematic review explored models of patient complexity including CuCoM¹⁴⁴. Patient complexity was defined as the complicated interplay between medical and non-medical factors that influence health-related outcomes. Six

other models of complexity were included, and the authors endeavoured to create a new model by amalgamating the models found. Many of the factors identified that contributed to complexity were related to patient capacity, for example social support systems and general health status. CuCoM was the only model to explicitly define treatment workload or burden; however, other models did include quality of healthcare delivery as influential. The final model created has many similarities to CuCoM; it includes a patient workload domain and a time-varying patient capacity and resilience domain, both of which influence health status and access and utilization of services. This review was of reasonably high quality; however, information about methodology in the included studies was lacking, rendering assessment of quality and level of service-user input unattainable.

A recent well-conducted qualitative systematic review examined the qualitative literature on treatment burden using a framework synthesis based on CuCoM¹⁴⁵. The authors explored the treatment-generated disruptions experienced by patients across all chronic diseases and treatments and how these disruptions are accommodated. Disruptions were reported as biographical, relational or biological. 'Biographical disruptions' included loss of independence, restriction of meaningful activities, negative emotions and experience of stigma from others; 'relational disruptions' included strained family and social relationships and feeling isolated; and 'biological disruptions' involved physical side-effects. Additionally, authors reported that patients employed 'adaptive treatment work' e.g. asking others for help or purposively not adhering to therapies in order to minimise treatment disruptions. The review uncovered 11 papers on treatment burden in various chronic diseases; however, none were in those with stroke. As only papers with the terms 'treatment burden' or 'burden of treatment' in the title or abstract were sought, there is a risk that some studies may have been missed that have sought to examine treatment burden but phrased or conceptualised this in a different way. Nonetheless this paper added to the conceptualisation of treatment burden by describing the mechanisms by which the management of chronic illness can cause disturbance to an individual's life.

During the writing of this thesis I was fortunate to co-author a paper that progressed the concepts of workload and capacity through description of Burden

of Treatment Theory (BoTT) ¹⁴. This paper theorised healthcare utilization as an undertaking that is characterized by individuals and their support networks as they navigate through health care systems. This navigation occurs under the controls of health care providers and the social and economic resources available to them, for example funding for nurse liaison services or rehabilitation classes. Along with their support networks, individuals possess the ability to perform healthcare tasks, secure co-operation of others and add to their social capital, thus reinforcing the resilience of their network. The relational aspects of healthcare provision were emphasised as well as the importance of resources for both healthcare providers and patient, and it was theorised that maximum benefits can only be gained from services if patients are given the wherewithal to use them. This was a theoretical paper that draws on relevant work carried out by the authors and others, and therefore, similarly to CuCoM, verification of BoTT should be sought through empirical research in those with chronic disease. Both CuCoM and BoTT emerged during the writing of this thesis and both models influenced the qualitative analysis described in Chapter 7. This is described in more detail along with methodology in Chapters 4 and 7.

2.3.3.4 Measures of patient capacity

The conceptualisation of patient capacity has preceded the development of methods of its measurement. Therefore, comprehensive measures of capacity in those with chronic disease are lacking, but there are measures available that capture aspects of patient capacity. Certain patient-reported quality-of-life measures consider aspects such as self-efficacy [104], the intrusion of illness on everyday life ¹⁴⁶ and the effects of disabilities such as visual or hearing impairments ¹⁴⁷. There are measures of self-efficacy that have been validated in those with chronic disease, but these omit wider socio-demographic factors that may influence patient capacity ¹⁴⁸. The Patient Activation Measure (PAM) gauges the knowledge, skills and confidence a person has in managing their own health and health care, but similarly omits broader socio-demographic factors ¹⁴⁹. A recent good quality systematic review found a significant association between low PAM scores in those who were chronically ill and increased hospitalization rates as well as emergency room utilisation ¹⁵⁰, supporting the premise that those with low levels of patient capacity have worse health-related outcomes.

However, the relationship between PAM score and medication adherence was deemed inconclusive due to heterogeneity of methods within included studies, and another limitation was that the majority of included studies had been conducted by developers of PAM, so further research is needed.

Lastly, there are measures of social support that have been validated for use in those with chronic disease, for example the ENRICH Social Support Inventory (ESSI) ¹⁵¹ and the Inventory of Socially Supportive Behaviour (ISSB) ¹⁵². These have potential to be useful, yet focus only on social support, so omit other factors that influence patient capacity. Measures validated for use in those with stroke are discussed in Chapter 3.

2.3.4 The relevance of multimorbidity

Many of the conceptual frameworks described above include comorbidity or multimorbidity as influential on treatment burden and patient capacity ^{13;98;112;114;144}. In this thesis, comorbidity refers to the presence of one or more morbidities in addition to an index condition such as stroke ¹⁵³, whereas multimorbidity describes the presence of two or more conditions within one individual, with no index condition specified ¹⁵⁴. In their work on illness trajectories, Corbin and Strauss acknowledged the additional difficulties posed by the presence of multiple conditions by stating ‘chronic diseases are often multiple diseases: not uncommonly a person has two or more illnesses simultaneously. This complicates the formulation of the treatment scheme because the physician must take into consideration the number of regimens a person is on, their possible interactive effects, and the ability of the ill person to carry them out’⁷³. An increase in life expectancy and improvement in acute treatments have led to an increase in the number of people living with long-term conditions ¹⁵⁵. Improvement in services for these individuals has become a priority for governing and funding bodies ^{156;157}.

Multimorbidity has been shown to be perceived by patients as a barrier to self-care ^{13;50;81;92}, and one large, high quality study in England showed that those with multiple long-term conditions more frequently report worse experiences in primary care ¹⁵⁸. Multimorbidity may increase treatment burden in several ways. Firstly, volume of treatments such as number of medications increases with

number of conditions ¹⁵⁹⁻¹⁶¹. Secondly, treatments or encounters may interfere or interact with one another, for example medications may interact or medical appointments may be poorly co-ordinated ^{12;112;162;163}. This has the potential to further increase the volume of work, for example as new treatments are given to compensate for interactions ¹⁶⁴. Thirdly, co-morbidities can affect the capabilities of the individual to follow therapeutic regimes due to physical or mental impairment, for example those with arthritis may find physiotherapy sessions more challenging ^{165;166}. Fourthly, multimorbid patients who become overburdened, for example by complex medication regimes, may be less likely to adhere to therapies, leading to poor disease control and a further escalation of treatments by health professionals, increasing treatment burden further ^{9;13;167}. During the examination of treatment burden in stroke, it is therefore important for us to investigate the presence and extent of multimorbidity, as this is likely to have a significant impact on the patient experience.

Two studies recently evaluated the applicability of clinical guidelines to those with multimorbidity. Findings showed that current guidelines do not consistently take account of multimorbidity and as a result patients are placed at risk of considerable treatment burden, including adverse interactions between drugs and diseases ^{168;169}. Both were exploratory studies that examined a selection of clinical guidelines and created hypothetical patients to highlight these issues; therefore, further research is needed in this area.

2.3.5 The influence of healthcare provision on treatment burden and patient capacity

It is likely that the design and provision of health services is highly influential on the patient experience of treatment burden ^{11;123}, yet until recently this had remained unacknowledged in the medical literature. A videographic analysis of consultations suggested that treatment burden is dealt with poorly by clinicians ¹⁷⁰. In this well-conducted study, videos of 46 consultations between clinicians and those with type 2 diabetes were analysed. However, the authors acknowledged that a lack of conceptualisation of treatment burden at the time the study was conducted may have affected reliability of coding.

A new patient-centred way of practising medicine was proposed in a theoretical paper in 2009, aimed at reducing treatment burden and increasing patient capacity. This was coined *minimally disruptive medicine (MDM)*⁹. The authors stated that the patient should be placed at the centre of their management plan, with careful consideration of the workload of healthcare and the individual's capacity to cope with that workload. Shared decision-making between patient and practitioner and better co-ordination between health care providers were also cited as important.

A theoretical paper advancing the concept of MDM was published in 2015, which described the MDM Care Model¹⁷¹. This paper set out pragmatic solutions to practicing MDM, by first 'identifying the right care' and then 'making the right care happen'. To identify the right care, the authors recommended considering both treatment work and capacity, describing patients as 'complex adaptive systems' characterized by a large number of interactive components, with ability to exhibit emergent properties such as a workload-capacity imbalance. To operationalize provision of this care, the authors suggested prioritisation of feasibility and consideration of the paucity of resources available in realistic healthcare settings. They encouraged the use of resources that are already available but perhaps poorly advertised, and emphasized the importance of monitoring fluctuations in the patient's treatment work and capacity over time. A theoretical MDM toolkit was proposed, with tools such as 'goal elicitation', 'capacity assessments', and 'workload assessments' to identify the right care and 'resource registries', and 'medication therapy management'.

Over the past decade, there has been a call for the practice of more generalist care for patients^{172;173 174;175}, and a drive towards minimally disruptive medicine complements this, with health care providers being encouraged to provide holistic patient-centred care that realistically considers the burdens imposed on patients from healthcare systems and other aspects of their life.

2.4 Conclusion

Above a description has been given of the underlying concepts, existing definitions and theoretical underpinnings of the work described in this thesis. These concepts have been developed in relation to those with chronic disease, and in Chapter 3 a description is given of the literature that has provided

information on treatment burden and capacity specifically in relation to those with stroke. Conceptualisation of treatment burden and patient capacity in those with chronic disease was in the very early stages of development when the work described in this thesis began. Much of the above literature has been published in parallel to my own studies and this has been helpful in some ways yet difficult in others, for example the evolving concepts have informed my methodologies, but this has meant maintaining a degree of flexibility and the need for an iterative approach to this work. The influence of the above literature on methodology is described in Chapter 4.

In summary, the idea that healthcare imposes work on patients dates back to 1985 when Corbin and Strauss published their well-known paper on 'three lines of work' for those with chronic disease⁷². Treatment burden is a more recent notion, and thus far it has been conceptualised as the workload of healthcare for those with chronic disease, the negative impacts of this on well-being and the disruptions caused to everyday life^{8;11;14;81;93}. Additionally, factors that both exacerbate and lessen treatment burden have been explored including the influence of healthcare providers, the compensatory work that patients do to accommodate burdens and their individual capacity to cope with treatments, including both internal resources such as literacy and external resources such as social support^{14;93-95;145}.

As conceptualisation is still young, further exploration of treatment burden and capacity is required. Additionally, many of the above concepts will be generalisable to those with stroke and other chronic diseases, yet there are also likely to be disease specific aspects of treatment burden that are important to understand.

Chapter 3 - Treatment burden in stroke

3.1 Introduction

3.1.1 Aims of this chapter

To provide background information on what is already known about treatment burden in stroke.

3.1.2 Rationale

The aim of this thesis is to explore the experience of treatment burden for those who have suffered a stroke. As discussed in Chapter 2, treatment burden is defined as the impact of treatment workload on wellbeing. It is important to note that treatment burden is not exclusive to those with stroke; indeed, it is a phenomenon that is pertinent to those with a wide range of illnesses. However, exploration of this matter in those with stroke is important because these individuals are required to undergo intensive and arduous treatments, many of which continue life long, and their capacity to cope with treatments may be low due to cognitive and physical difficulties or social isolation.

Traditionally in stroke research, the term ‘burden of care’ has tended to describe the financial costs of healthcare to the state or the burden on carers of stroke patients¹⁷⁶⁻¹⁸². Pound et al. acknowledged this failing when they remarked that ‘stroke is seen as the misfortune of almost everyone except the person who has actually had the stroke.’¹⁸³ This historical lack of insight into the burdens endured by those with stroke has been exaggerated by a lack of funding in stroke research compared to other conditions such as cancer and coronary heart disease²³. However, over the past two decades, researchers have developed an interest in understanding the perspective of those with stroke and the burdens they endure.

A description is given below of the qualitative and quantitative literature that has explored treatment burden in stroke. The aim is not to provide an exhaustive review of the literature but rather to offer a discussion of relevant papers with the intention of placing the work described in this thesis in context.

3.2 Methods

Relevant articles were sought through a search of: online databases such as Ovid; Google scholar; and the references and citations of pertinent papers. Experts in the field were also contacted and asked to provide references of interest. Search terms included: stroke; cerebrovascular disease; treatment burden; treatment workload; patient capacity; comorbidity; patient experience; and patient reported measure.

3.3 Background literature of treatment burden in stroke

3.3.1 *The qualitative literature*

As treatment burden is a fairly new concept in the literature, little qualitative work has been published that explicitly explores this in stroke, although information can be gained from studies that have examined the more general patient experience of stroke management. Primary studies that have explored the patient experience of stroke, treatment burden and patient capacity will be described in turn and then relevant qualitative syntheses discussed.

Early studies on the patient experience of stroke

Prior to the early 1990s, few studies had been published on the journey through the recovery process after stroke from the patient perspective¹⁸⁴. In 1974, Hoffman published an interesting paper on the interactions between patients and healthcare providers in a hospital setting in Canada¹⁸⁵. She described how negative attitudes of health care providers affected these interactions and created unrealistic expectations from patients. She concluded that a general hospital setting was not an optimal environment for the rehabilitation of stroke patients, a finding that was echoed later in the literature that supports care for patients on the acute stroke ward¹⁸⁶. Kaufmann and Becker later published a series of papers that explored the experience of stroke rehabilitation in the US, how patients incorporate stroke illness into their lives, how they conceptualise both illness and recovery, and how prejudices from healthcare providers about age and potential for recovery can influence patient care¹⁸⁷⁻¹⁹⁰. Although not explicitly aimed at understanding treatment burden, these studies were among the first to give insight into the experience of stroke management from a patient

perspective, demonstrating, for example, the negative interactions with therapists that patients may endure ^{185;189}. In one study, Kaufmann acknowledged that 'rehabilitation emphasizes the hard work and adaptive capacity of the patient as a whole being in an environmental context'¹⁸⁷. These early studies provided fascinating insights into stroke management from the patient perspective; however, findings are now likely to be outdated due to the considerable progress in treatments and vast improvement in prognosis for patients since their publication.

Studies of treatment burden

Following on from this earlier work, a plethora of qualitative studies has been published on the patient experience of stroke around the world, although many have focussed on the experience of illness rather than the management process ¹⁸⁴. Those that have examined the experience of treatments have often been narrowly focussed, for example on interactions with healthcare providers, the availability of information provision, and the experience of hospital care ¹⁹¹⁻¹⁹⁵. In 1996 an interesting study investigated stroke patients' views of services in England ¹⁹⁶. Although the generalizability of this study is limited due to its small size and restricted information about participants, the authors used their results as a platform to discuss the importance of patient-centred care and participant-led research. They concluded that care was fragmented, information provision poor and communication between staff and patients substandard, yet overall satisfaction with services appeared to be high. It was concluded that patient involvement in research was vital to unpick findings and plan stroke services. A later study explored the experiences of those undergoing stroke rehabilitation in the US, which concluded that care was not individually tailored to patient needs and that discharge into the community was inadequately supported ¹⁹⁷. This study was undertaken on a small convenience sample from one stroke support group which again limits generalizability, however it was well-conducted and provided useful information on deficiencies in care that can be encountered by those with stroke.

An insightful study published in 2011 concluded that failings in health and social care provision or 'system-induced setbacks' can burden those with stroke ¹⁹⁸. During this study, stroke patients that had been involved in a pilot community

stroke service in the UK were interviewed. 'System-induced setbacks' found included negative attitudes by staff, poorly supported discharge, long waiting times for social care, poor communication between services and neglectful care. In this paper it is stated that 'people's responses to living with a stroke involve far more than simply a response to their condition, however creative and active, but also involve a response to the way health and social care services are organised and delivered'. Although undertaken in the context of a pilot study, many of these findings related to routine care, and findings support the concept that the organisation of health services has an impact on treatment burden.

Another paper introduced the concept that those with stroke shoulder responsibility for the work of recovery in a well-designed study involving in-depth interviews with patients 10 months after their stroke¹⁸³. This paper gave valuable insight into the positive actions that those with stroke take to manage their everyday lives in the face of illness, supporting the concept of illness work described in Chapter 2. However, an examination of the limitations of coping strategies and resources were not examined¹⁸³.

Studies of patient capacity

Studies that have examined stroke patient capacity to follow management plans are also small in number. Since the mid-1990s, many rigorous studies have been published that examine the influence of stroke on the patient's lifeworld, for example the impact on cognitive and physical functioning, personal identity and social roles¹⁹⁹⁻²⁰³. However, these fail to examine how the consequences of stroke may affect a patient's capacity to undertake treatments.

The work discussed above by Becker and Kaufman on U.S. stroke patients explored how patient expectations of recovery can be shaped by a variety of factors such as age, nature of impairments, depression and acceptance of biomedical perspectives^{188;189}. This supports the premise that a wide range of bio-psycho-social factors may influence patient capacity and engagement with treatments; however, this is not explicitly explored in this work. A small good quality study of stroke patients was undertaken in the UK in which both low and high adherers were interviewed³⁷. Findings suggested that ease of medication regime, knowledge about treatments, support from health professionals and ability to adopt coping strategies all influenced adherence, again suggesting that

a wide variety of factors may affect capacity in those with stroke. Another insightful study explored adherence in stroke patients living in France. This study reported similar findings to the one conducted in the UK, although social support also promoted adherence ³⁶.

Another study carried out in the UK explored confidence in stroke survivors. Ten individuals who had suffered a stroke and participated in a trial of outdoor mobility rehabilitation were interviewed about the meaning of confidence. Although small, this study gave valuable insight into the personal, social and psychological aspects of capacity that influence confidence, for example loss of identity, fear, social roles and personal attitudes and beliefs ²⁰⁴.

Relevant qualitative syntheses on treatment burden and patient capacity

Qualitative syntheses on treatment burden and patient capacity in stroke are lacking. No syntheses were found that sought to explicitly examine these topics, but several were found in related subject areas that give valuable information. Table 1 provides a summary of qualitative systematic reviews carried out in relevant subject areas and the knowledge they provide about treatment burden. Additionally, a quality appraisal of each review was undertaken using an adapted version of R-AMSTAR ²⁰⁵ and scores are shown in Table 1. A full breakdown of scores is given in Appendix 1. A common finding was that rehabilitation lacks patient centeredness, and there is a mismatch in ideas about goal setting between patients and health professionals. Additionally, recovery was described as a long journey of adaptation to new circumstances, and psychological support reported as lacking, particularly once the initial phase of rehabilitation has ended and patients are discharged from services. Information from health professionals was described as poor, with patients relying heavily on family members to support them. These findings give us some indication of the hard work of recovery from stroke and the difficulties encountered by patients; however, a full exploration is lacking of the patient experience of treatment burden and patient capacity.

Table 1 – Relevant qualitative systematic reviews that give information about treatment burden and patient capacity in stroke.**(All qualitative except *quantitative; ** mixed methods)**

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Eilersten et al 2012 ²⁰⁶	12	To interpret and synthesise stroke survivors' experiences of post stroke fatigue.	Stroke patients.	Patients are given inadequate information about fatigue prior to discharge. Healthcare providers minimized the importance of post stroke fatigue. Stroke survivors exert considerable mental energy searching for validation of fatigue. They cope with unrealistic expectations from others and try and hide fatigue. They adopt strategies to cope with fatigue.	25
Hafsteinsdotter et al 2011 ²⁰⁷	11	To systematically review the research on stroke patients' and caregivers' educational needs.	Stroke patients and caregivers.	The educational needs of stroke patients and caregivers may be unmet. Unmet needs include knowledge about the clinical aspects of stroke, prevention, treatment and functional recovery. The most commonly reported needs of caregivers involved patients' moving and lifting, exercises, psychological changes and nutritional issues.	29

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Hole et al 2014 ²⁰⁸	13	To consider how a patient's experience of stroke rehabilitation influences and evolves their identity and to consider the different psychosocial concepts and interactions that may influence this.	Stroke patients.	Broader human needs were not met and patients were not acknowledged as individuals. Transition, adjustment and learning occurs during episodes of change and self-realisation, patients problem solve and practise tasks at these times. They depend on professionals and family members. They adjust to their new circumstances and integrate into their social world. Tasks in rehab have a lack of meaning. Positive experiences are shaped by key psychosocial concepts such as hope, social support, and rely on good self-efficacy which is influenced by both clinical staff and external support.	22
Lamb et al 2008 ²⁰⁹	27	To appraise and synthesise the evidence on the psychosocial / spiritual experience of elderly stroke patients.	Stroke patients over 65.	Reconstructing life after stroke requires considerable physical and psychological work. Patients adopt strategies to adapt to their new life e.g. re-learning, becoming active in their own care, allowing more time to complete tasks and using physical aids. They draw on their sense of hope and inner strength. Feeling connected to others including health professionals is important. There is a lack of psychological support available and information for patient is lacking. Some found a lack of respect from health professionals.	32

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Luker et al 2015 ²¹⁰	31	To report and synthesize the perspectives, experiences, and preferences of stroke survivors undertaking inpatient physical rehabilitation through a systematic review of qualitative studies.	Stroke patients.	Patients reported a lack of physical therapies and lack of opportunity to practice outside of formal therapy sessions. Patients felt bored and alone on the ward. Therapies often appeared boring and meaningless. Mismatch in goal setting between patient and health professional was reported. Physical rehabilitation can be difficult, stressful and frightening. Disempowering staff attitudes and organisational barriers to autonomy were strong negative influences. Poor communication and mixed messages from staff led to misunderstanding and frustration. Patients used humour and hope to fuel motivation.	33
McKevitt et al 2004 ¹⁸⁴	95	To identify the scope of published qualitative studies of stroke, consider their relevance to development and delivery of services for people with stroke and make recommendations for future work.	Stroke patients, caregivers, health professionals.	There is a mismatch between patient and health professionals' expectations of recovery and views of goal setting. Paternalistic care prevents patients being adequately prepared for discharge. Some patients do not like to use adaptive aids due to stigma. Communication between therapists and patients could improve and be more patient centred. Patients develop coping strategies and use motivation to aid recovery. Information provision is poor and services can be poorly co-ordinated.	24

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Mold et al 2003 ²¹¹	55	To assess how well the processes which might lead to inequity in the delivery and uptake of stroke services are currently understood by reviewing the qualitative literature in the area.	Stroke patients and caregivers (some papers that examined more general patient populations were included).	Healthcare providers' prejudices towards older patients or those deemed less motivated may influence the care provided. Such perceptions differ between patient and health professional, and between different health professionals. Socio-economic factors, resource limitations and information provision may influence service delivery and uptake.	15
Murray et al 2003 ²¹²	23	To identify the most frequently encountered longer-term problems experienced by stroke patients and their informal carers. To provide a platform for the development of a patient-centred, primary-care based stroke service.	Stroke patients and caregivers.	Service deficiencies accounted for 29% of all problem areas reported. These included limited access to therapies, unclear goal setting and poor general care whilst in hospital, poorly co-ordinated discharge, abandonment by services, lack of patient involvement, lack of information, delays in obtaining services, poor home care, lack of input from GP, mismatch in ideas of recovery between patient and professional, absence of longer term reviews.	30

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Peoples et al 2011 ²¹³	12	To obtain the best available knowledge on stroke survivors' experiences of rehabilitation.	Stroke patients	Patients find it difficult to deal with the consequences of stroke whilst in hospital due to unfamiliarity, inflexible ward routines and a lack of privacy. They seek information, which can be difficult to obtain. Patients identified a failure of health professionals to identify non-physical needs. Dignity and respect was challenged through negative interactions between staff and patients. Feelings were mixed on collaboration with health professionals, some prefer paternalism and others shared decision-making. Similarly, some enjoyed taking an active part in rehab and others felt overwhelmed.	26
Reed et al 2012 ²¹⁴	18	To identify the key factors to account for in planning and developing rehabilitation and community services for stroke based on users' perspectives.	Stroke patients, caregivers, health professionals.	Recovery from stroke is long term. Those with stroke develop innovative strategies to deal with the effects of stroke in the context of their lives as they strive to maintain control and independence. Patients depend on friends and family for a 'web of support'. There were difficulties reported in obtaining formal support for carers. Stroke survivors face physical, economic and psychological barriers in accessing the world outside their home. They use strategies to enhance social interaction and support. Developing a positive outcome was dependent on interaction between the person, their close social networks and the environment they lived in.	35

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Rosewilliam et al 2011 ²¹⁵	18 8 * 1**	To explore and map out from the literature the nature and extent of application of the patient-centred goal-setting concept in current stroke rehabilitation practice and to examine the evidence for any effects (outcomes) of application of the concept.	Stroke patients and healthcare professionals.	Stroke patients don't feel involved enough in the goal setting process. There is a mismatch in ideas between patients and health professionals about perceptions of level of patient involvement, recovery, and the focus of rehabilitation. Suggestions about how to improve patient centeredness are made.	31
Salter et al 2008 ²¹⁶	9	To examine the contribution of the published qualitative literature to our understanding of the experience of living with stroke.	Stroke patients.	Patients re-interpret the self. They also cope with uncertainty of recovery. They rely on their social networks, although they are often socially isolated. Some re-focus on positive aspects of their lives and demonstrate resiliency. They adapt to their new lives slowly. Optimism diminishes over time.	30

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Sarre et al 2013 ²¹⁷	40	To synthesize qualitative studies on adjusting after stroke, from stroke survivors' and carers' perspectives, and to outline their potential contribution to an understanding of resilience.	Stroke patients more than 6 months post stroke and caregivers.	Patients undergo recovery of function; finding practical ways of dealing with impairment (practical adjustment); and psychosocial recovery despite impairment. Factors that affect ability to adjust were: personal characteristics; adjustment practices (physical and mental); social support; built environment, health care delivery and structure, information, public awareness, employment and welfare practices and policies.	28
Satink et al 2013 ²¹⁸	33	To synthesize patients' views on the impact of stroke on their roles and self.	Stroke patients.	Discharge into the community is a difficult time for patients, they can feel abandoned and 'dumped' back home. Patient identify and adapt to their new roles post stroke. Hope is a major strategy and an important element of emotional recovery. Patients gain support from family, friends and other patients, although some report overprotection from family and paternalism from health care professionals. There was a mismatch in goals between patients and healthcare professionals.	31

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Sugavanam et al 2013 ²¹⁹	10 7*	To systematically integrate and appraise the evidence for effects and experiences of goal setting in stroke rehabilitation.	Stroke patients, caregivers and health professionals.	The extent of patient involvement in the goal setting process was not made clear. Patients were often unclear about their role in this process. Professionals reported higher levels of collaboration during goal setting than patients. Patients and professionals differed on how they set goals, types of goals set, and on how they perceived goal attainment. Barriers to goal setting outnumbered the facilitators.	29
Walsh et al 2014 ²²⁰	18	To examine the barriers and facilitators of community reintegration in the first year after stroke from the perspective of people with stroke.	Stroke patients.	As well as the stroke itself, other factors influence community reintegration. Personal factors were: perseverance; emotional challenges; meaning attached to activities; and the adaptability of the individual. Influential social factors were: sense of belonging versus perceived stigmatisation; support and dependency; and environmental factors. With regards stroke services, the following were deemed as barriers: treatment delays; poorly organised discharge; a lack of information; rehabilitation that was not deemed meaningful; and a lack of patient centeredness.	30

Author and year	No of studies	Aim	Population studied	Findings that relate to treatment burden	Amstar score (out of 44)
Williams et al 2013 ²²¹	6	To explore the experience of engaging in occupation following a stroke for older people in the community.	Stroke patients.	Patients establish new routines and learn new ways of doing things. They use adaptations to their environment and assistive devices as well as the help of others to engage in occupations. There is a need to reflect and plan more than before the stroke.	29
Woodman et al 2014 ²²²	11	To identify, appraise and synthesise qualitative research on stroke survivors' views of their experiences of social participation.	Stroke patients.	Patients adapt to and accepted their new lifestyles post stroke using determination, perseverance, resilience and courage. Patients draw on a range of skills, set personal targets, problem solve, learn from people, utilise supportive networks and take action. They re-evaluate the personal meaning of activities and make decisions about which to let go or hold onto.	33

A recent high quality meta-review of qualitative systematic reviews was published that sought to summarise the qualitative literature on self-management and the lived experience of stroke, in order to identify how self-management might be effectively supported in stroke survivors. The authors used an exhaustive search strategy and found 14 systematic reviews comprising 232 primary studies. Although meta-review carries a risk of distancing the reader from the primary studies, this was a useful way to explore the vast amount of literature in this area, and the following key recommendations were made relating to the provision of self-management in stroke: 'a) recognition that the support needs of stroke survivors change over the trajectory of recovery; b) the importance of collaborative relationships with healthcare professionals who offer guidance and information specific to the stage of recovery and enable patients to feel respected, valued, and in control of decisions about their lives; c) the provision of individually tailored psychological, emotional and behavioural support from the early stages after suffering a stroke to proactively help stroke survivors manage the long-term challenges of reintegration into society by increasing adaptive coping strategies and help them adjust to their new self by focusing on new or developing skills; and d) social groups with other stroke survivors and groups of people who are understanding and supportive.' The authors recommended that no further qualitative research is required that explores the lived experience of stroke, and that research should now focus on the design and implementation of interventions to aid self-management²²³.

Summary of qualitative studies

In summary, over the past decade, many primary qualitative studies and qualitative syntheses on the patient experience of stroke management have been published. Although comprehensive examination of treatment burden and patient capacity in those with stroke is lacking, valuable nuggets of information are available amongst the findings available. As qualitative work tends to be carried out in a small group of participants, generalizability of primary studies must be interpreted with caution. However, studies from a variety of settings can improve our knowledge of the possible burdens faced by patients, and many syntheses are available that are perhaps more generalizable. A systematic review of the qualitative literature on treatment burden in stroke is described in Chapter 5. This review does not explore patient capacity, and the reasons

behind this are discussed in Chapter 4. However patient capacity is explored in the analysis of qualitative interviews described in Chapter 7.

Alongside the work described above there is a body of literature that explores the experiences and needs of the informal carers of those with stroke ¹⁸¹.

Examination of this literature was deemed to be out with the scope of this thesis, however these individuals are known to experience their own burdens that arise as a consequence of caregiving, and this is an important area of on-going research.

3.3.2 The quantitative literature

Measurement of treatment burden

As discussed in Chapter 2, there have been recent advances in the development of patient-reported measures of treatment burden; however, none could be found specifically for use in those with stroke. There are measures intended for those with multimorbidity where no index condition is specified ^{12;112;114}, and these could be used for those with stroke, although their use risks missing stroke-specific difficulties that may not apply to other conditions, for example the hardships endured by those with aphasia. One merit of using generic measures is that they are patient rather than disease focussed, and additionally they allow comparisons to be made across a range of conditions. However, treatment burden is likely to involve disease-specific burdens as well as those that are common to various conditions and those that arise as a consequence of multimorbidity. Examination of treatment burden within individual conditions is therefore an important first step in ascertainment of the full scope of treatment burdens experienced by those with multimorbidity.

Although no stroke-specific measures of treatment burden could be found, a few studies were located that have quantified certain aspects of stroke care through simple counts, for example time spent with therapists in hospital ¹¹⁵, delays in acute care ¹¹⁶, number of days in hospital with initial stroke ¹⁰ and costs of medical care ²²⁴. Data collected on GP consultations in Scotland have shown that the number of patients consulting their GP in relation to stroke has risen over the past decade ²².

A few small studies have quantified patient satisfaction with stroke services and varying results have been found. A common finding was that dissatisfaction was associated with poor functional outcome after stroke²²⁵⁻²²⁷. One study carried out in the UK examined the satisfaction of 93 stroke patients in one health care district in England with regard to discharge from hospital and follow up²²⁸. This study reported low levels of satisfaction, particularly regarding information provision from healthcare professionals, communication between staff and the scope of rehabilitation provided²²⁸. However, as this study was carried out in the late 1990s, findings are likely to be out-dated, for example no stroke specialist services were available at that time, and these are now commonly available in the UK. No more recent studies could be found.

As discussed in Chapter 2, the prescribing of polypharmacy (multiple medications) has been highlighted as one burden faced by those with chronic disease in terms of increased workload and increased risk of adverse drug events and hospitalisations⁸²⁻⁹⁰. Adherence to medications by those with stroke is generally thought to be substandard, with studies reporting adherence at 1 year as between 24% and 90%, depending on the medications examined^{35;51;229}. Several trials have tested interventions such as text message reminders and motivational interviewing to improve adherence with varying levels of success²³⁰⁻²³². A small number of observational studies have quantified prescribing in those with stroke and these are described in Table 2. The mean number of medications observed was reported as between 5-11^{90;233;234}, however all studies had a small sample size, limiting generalizability.

Despite the burdens that polypharmacy can produce, there is evidence that the prescribing of certain medications such as statins, angiotensin-converting enzyme inhibitors and antiplatelet medications improve health-related outcomes for those with stroke⁹¹ and nonadherence has been shown to be associated with worse stroke outcomes^{235;236}. Advantages of medication use must be taken into consideration when measuring overall treatment burden, with reduced access to effective treatments in vulnerable groups also being an important burden to consider²³⁷.

Table 2 – Studies of prescribing in stroke

First author and year	Country	Aim	Sample	Sample size	Outcomes relevant to prescribing	Results that relate to polypharmacy	Limitations
Ostwald 2006 ²³³	US	To 1) identify the types of medications prescribed for stroke survivors who are being discharged home from rehabilitation, 2) explore correlations between medication prescriptions and the number of stroke-related comorbidities and medical complications, 3) identify the cost of medications and potential impact of medication costs on stroke survivors, and 4) discuss the nurses' role in preparing stroke survivors and their caregivers for medication use after discharge.	Stroke survivors of at least 50 years of age, who were discharged home from one of five hospital systems between November, 2001 and December, 2003	97	Discharge medications abstracted from patient's chart by trained nurses and occupational therapists	Stroke survivors were discharged home with an average of 11.3 medications per person from 5.4 different drug classifications. Most commonly prescribed drugs were antihypertensives, antiplatelets, antihyperlipidaemia and antidepressant.	Small sample size so limited generalizability. Relied on case notes.

First author and year	Country	Aim	Sample	Sample size	Outcomes relevant to prescribing	Results that relate to polypharmacy	Limitations
Sweileh 2009 ²³⁴	Palestine	To analyze the types and cost of medications prescribed at discharge for ischaemic stroke survivors.	Stroke survivors diagnosed with ischaemic stroke subtype	78	Medications prior to admission and upon discharge were ascertained from the medical records. Medications prescribed to stroke survivors at discharge were classified based on their therapeutic class.	Stroke survivors were discharged with an average of 4.9 medications per patient from 4.3 different drug classes. Most commonly prescribed drugs were antiplatelet, anti-ulcer, antihypertensive, antibiotics.	Excluded those who died during hospitalization. Small sample size so limited generalizability. Relied on case notes.

First author and year	Country	Aim	Sample	Sample size	Outcomes relevant to prescribing	Results that relate to polypharmacy	Limitations
Classen 2007 ⁹⁰	US	To determine prevalence and incidence of polypharmacy, inappropriately prescribed drugs, and potential drug-drug interactions, in a cohort of home-based older adults with self-reported stroke.	Home-based older adults (60 years and older) with self-reported stroke who had participated in a larger study 1993-1996 in one district and 2000 in another.	191	Self-reported prescription medications. Data collected during larger study by trained occupational therapists and nurses who administered structured in-home interviews, lasting 2.5 hours. They verified reported prescription medications with actual medications. Polypharmacy was classified as no polypharmacy (0-1 drug), mild (2-3 drugs), moderate (4-6 drugs), and severe (7+ drugs).	They used an average of 6.2 medications, and 75% had moderate or severe (4-7+ drugs) polypharmacy.	Small sample size so limited generalizability.

Measurement of patient capacity

In line with the cultural shift towards patient self-management discussed in Chapter 2, there has been an interest in measuring the ability of stroke patients to self-manage their health and several patient-reported measures have been developed. The Southampton Stroke Self-Management Questionnaire (SSSMQ) was developed in the UK using focus groups with stroke patients, and validated in a nationally recruited sample of patients²³⁸. This measure focuses on the patient's beliefs, personal abilities and interactions with health professionals; however, it omits the wider social influences on capacity such as financial status, social support and other personal commitments. As discussed in Chapter 2, The Patient Activation Measure (PAM) is a measure of readiness and ability with regard to self-management that has been validated in varying populations and conditions, but it fails to measure social aspects of capacity¹⁴⁹. One Scottish study that evaluated its use within a complex self-management support intervention for stroke patients found that those with stroke did not find it specific enough to their situation or easy to understand⁶⁴.

Three measures of self-efficacy after stroke have recently been developed, all underpinned by Bandura's self-efficacy theory¹³⁹. The Stroke Self Efficacy Questionnaire (SSEQ) was developed in the UK and this measures perceived confidence in functional performance following stroke²³⁹. Although shown to be valid and reliable in a stroke population, this measure again fails to include the broader psychosocial aspects of recovery, and also fails to differentiate between poor functional performance that has arisen due to physical impairments and that which has arisen due to a lack of confidence. The Daily Living Self-Efficacy Scale (DLSES)²⁴⁰ was developed and validated in a good quality study of those with stroke in Australia, and this measure captures self-efficacy in a broader sense including psychosocial function and activities of daily living. Another advantage is that unlike the SSEQ it can be used to assess self-efficacy in stroke patients regardless of level of physical functioning. More recently, the Confidence after Stroke Measure (CaSM) was developed in the UK, and again this measure has the advantages of capturing broader the psycho-social aspects of recovery. CaSM has been shown to be valid and reliable in a stroke population, and therefore has the potential to identify those that would benefit from intervention to improve confidence following stroke²⁴¹.

There has also been a recent interest in the exploration of impaired cognition following stroke, with the Cognition Failures Questionnaire (CFQ) being the measure most frequently used in clinical trials²⁴². Drawbacks to this include its focus on memory difficulties and a lack of service-user input during its development, therefore a new patient-reported measure was recently developed in the UK named the Patient Evaluated Report of Cognitive State (PRECiS)²⁴³. This useful measure was developed with stroke patient input, has been validated in a stroke population and captures a broad variety of aspects of life that may be affected by impaired cognition. It therefore has potential to be very useful in the assessment of cognition in those with stroke.

It has been suggested that social isolation in those with stroke is associated with worse health-related outcomes²⁴⁴ yet there is no consensus on the best way to measure social support. In addition to the generic measures described in Chapter 2, The Stroke Social Network Scale (SSNS) is available for use in those with stroke²⁴⁵. This was developed with input from stroke patients and validated in a UK stroke population including those with aphasia. It therefore shows potential to be a useful tool with regard to measuring the social aspects of patient capacity in those with stroke.

In addition to the measures described above, several quality-of-life (QOL) measures capture aspects of capacity. A systematic review was carried out by the Patient-reported Outcome Measurement Group at the University of Oxford that examined patient-reported QOL instruments for those with stroke²⁴⁶. This comprehensive review found nine measures that were stroke-specific (e.g. Burden of Stroke Scale, Stroke Impact Scale) and six that were generic but validated in a stroke population (e.g. Nottingham Health Profile, Health Utilities Index). Aspects of capacity covered by these measures included physical function, cognition, psychological well-being and social well-being.

Measurement of co-morbidity

There is evidence to support the premise that those with higher numbers of long-term conditions to manage are likely to experience higher levels of treatment workload, such as higher numbers of medications and more frequent hospital admissions^{9;159-161;233;247-249}. Measurement of multimorbidity is therefore important in the investigation of treatment burden in chronic disease; however little consensus has been reached in the literature about the best way to do this. There is, however, an acknowledgement of the heterogeneity of existing methods, and an acceptance that different methods are likely to be appropriate for different outcomes^{250;251}. This holds true for the measurement of multimorbidity in stroke. Numerous methods have been scrutinised with regard to adjustment for co-morbidity during the examination of outcomes^{252 253-256}, yet little consensus has been reached about the optimal method available.

As described in Chapter 3, comorbidity is defined as the presence of one or more morbidities in addition to an index condition such as stroke, and multimorbidity as the presence of two or more conditions where no index condition is specified. A small number of studies have examined the prevalence of comorbidity in stroke and these are described in Table 3. Some of these have also examined health-related outcomes^{10;257-263}, with results generally indicating that those with higher levels of co-morbidity have worse outcomes. However, discussion of this was deemed outwith the scope of this thesis, and only results reporting prevalence of co-morbidity are shown. All studies concluded that co-morbidity is common in stroke; however comparison between studies is difficult due to a broad variation in methods of measurement and co-morbidities examined. Studies generally had a small sample size or examined a narrow range of co-morbidities; limitations are described in more detail in Table 3.

Table 3 – Studies of prevalence of co-morbidity in stroke

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Arnold 2008 264	Switzerland	To compare younger and older patients with first-ever ischaemic strokes in a large cohort of consecutive patients.	Patients older than 16 years who suffered a first ever acute ischaemic stroke and had been admitted to The Berne Stroke Unit from January 2000 to July 2006.	1004	Charlson co-morbidity index (CCI) was calculated from self-reported information and clinical examination.	19	Mean CCI Index in those under 45 years was 0.18 and in those over 45 years was 0.84.	Aim was to compare groups rather than assess overall prevalence. No count of co-morbidities given. Limited to those morbidities accounted for in CCI.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Bergman 2015 ²⁶⁵	Sweden	To investigate the association between comorbidity and stroke in young adults.	Those in the Swedish Stroke Register 2001-2009, aged 15-44 years.	2599	Co-morbidities recorded at hospital discharge were obtained and grouped into ICD-10 chapters.	All ICD-10 chapters excluding pregnancy.	Prevalence of all ICD-10 chapters, (excluding pregnancy) were more frequent amongst stroke than non-stroke patients. Independent associations were found between stroke and 8 chapters: neoplasms, blood, endocrine, psychiatric, nervous, eye, circulatory, and symptoms.	No count of co-morbidities. Relied on case notes. Only younger patients examined.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Caballero 2012 ²⁵⁷	Spain	To investigate the association between CCI score and the functional outcome and mortality 6 months after ischaemic stroke or intracerebral haemorrhage.	Patients with spontaneous intracerebral haemorrhage and ischaemic stroke admitted to the stroke unit during 18 months.	175	CCI was ascertained on admission.	19	The CCI mean score was 1.38. Most common co-morbidities were cerebrovascular disease (29.1%) diabetes (23.4%), congestive heart failure (23.4%).	Unclear how co-morbidities were ascertained at admission. No count of co-morbidities given. Limited to those morbidities in CCI. Small number of participants, limited generalizability.
Carod-Artal 2014 ⁴⁸	Spain and Brazil	To assess cross-cultural differences in the prevalence of comorbidity and stroke subtypes in ischaemic stroke patients from 2 regions of the world.	Ischaemic stroke patients consecutively admitted to 2 different general neurology wards over 1 year period.	500	Cumulative Illness Rating Scale adapted for geriatric populations (CIRS-G) was calculated from self-reported information and clinical examination.	14 organ systems	Mean CIRS-G score 7.6, mean number of affected organs 3.8. Comorbidity was more common in the Spanish group.	Small number of participants, limited generalizability. No count of co-morbidities. Limited to those morbidities accounted for in CIRS-G.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Fischer 2006 ²⁶⁰	Switzerland	To analyse comorbid conditions of patients in a two hospitals and different specializations and to evaluate the overall impact of comorbidities on stroke outcome.	Consecutive patients with an acute ischaemic stroke admitted to two hospitals from December 2001 to December 2002, with symptoms of under 48 hours (TIAs excluded).	266	CCI was ascertained on admission.	19	67.7% of patients had CCI scores of 0 or 1. The most frequent comorbid condition was a previous cerebrovascular event, followed by coronary artery disease, diabetes and tumor. There were no patients with lymphoma, moderate or severe liver disease or AIDS, and there were only few patients with dementia, metastatic solid tumor, hemiplegia, peptic ulcer, mild liver disease or leukemia.	No count of co-morbidities given. Limited to those morbidities accounted for in CCI. Small number of participants, limited generalizability.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Giaquinto 2003 ²⁶¹	Italy	To evaluate the impact of comorbidity on functional independence and gain after stroke.	Stroke patients consecutively admitted to a rehabilitation centre.	93	Cumulative illness rating scale (CIRS).	14 organ systems	The CIRS item scoring the highest value was the neurological (item 12), followed by cardiac (item 1) and hypertension (item 2).	Unclear how co-morbidities were ascertained at admission. No count of co-morbidities given. Limited to those morbidities accounted for in CIRS. Small number of participants, limited generalizability.
Johansen 2006 ¹⁰	Canada	To estimate the incidence of hospitalization for stroke and describe the impact of age, sex and comorbidity on in-hospital mortality, length of stay and readmission rates.	Discharges where a hospital diagnosis of cerebrovascular disease was the dominant diagnosis were used to identify patients 20 years and older, in 1999/2000.	32,107	ICD-9 diagnoses in hospital discharge records.	Unclear	Comorbid conditions were prevalent among stroke patients: hypertension was diagnosed in 35% of patients; diabetes in 17% of patients; arrhythmia in 15% of patients; ischaemic heart disease in 14% of patients; and congestive heart failure in 5% of patients.	Unclear what co-morbidities were examined. No count of co-morbidities. Relied on case notes.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Karatepe 2008 ²⁵⁸	Turkey	To evaluate the incidence of co-morbid diseases and their impact on functional outcome in patients after stroke.	Within one week of a stroke event during an inpatient period at the neurology service.	94	Type, incidence and severity of co-morbidities were studied from patient history, physical exam and a structured form. Liu co-morbidity index was used to assess relationship of co-morbidities and outcomes.	41	Median number of co-morbidities per person was 5. Co-morbid conditions commonly reported: hypertension, constipation, hyperlipidaemia, diabetes, ecg abnormality, osteoarthritis, visual impairment, shoulder pain, depression, neurogenic bladder, gastritis.	Small number of participants, limited generalizability.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Kesarwani 2009 ²⁶⁶	US	To examine the association of cardiovascular co-morbidities with the likelihood of being a stroke survivor and to determine the prevalence, treatment, and control of hypertension in this population.	Those who self-reported stroke in a larger study that was a stratified multistage probability sample of the civilian non-institutional population in the US.	438	Self-reporting of cardiovascular co-morbidities and medical examination.	Unclear	79.3% had additional comorbidities, including diabetes mellitus (24.7%), coronary artery disease (28.8%), chronic kidney disease (25.3%), heart failure (16.5%), and peripheral arterial disease (10.9%). The odds (and 95% confidence intervals) of prevalent stroke were 2.2 (1.5-3.2), 5.0 (3.2-7.8), 4.1 (2.1-7.8), and 10.0 (4.8-20.9) with one, two, three, and four or more comorbidities, respectively.	Unclear what morbidities were examined. Small number of participants, limited generalizability.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Maduagwau 2012 ²⁶⁷	Nigeria	To investigate some co-morbidities, and age, gender, and occupational distribution of stroke survivors seen in the physiotherapy clinic.	Stroke survivors who received physiotherapy in one hospital.	236	Record of co-morbidity in case notes at physiotherapy clinic was obtained.	Unclear	7 co-morbidities reported: hypertension, diabetes, HIV, hyperlipidaemia, chronic heart disease, obesity.	Small number of participants, limited generalizability. Unclear what morbidities were examined, no count of morbidities. Relied on case notes.
Sangha 2015 ²⁶⁸	UK	To compare risk factors and mortality for subdural haematoma, subarachnoid haemorrhage, and ischaemic and haemorrhagic stroke.	Patients admitted with these conditions in one hospital 2000-2007.	4804	Co-morbidities in hospital health records was obtained.	Unclear	Cardiovascular co-morbidities and epilepsy were more common in those with ischaemic stroke. Ischaemic heart disease was less common in those with subarachnoid haemorrhage.	Unclear what co-morbidities were examined. No count of co-morbidities. Relied on case notes.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Schmidt 2011 263	Denmark	To examine 18-year trends in short-term and long-term stroke mortality and the prognostic influence of comorbidity.	All first-time inpatient hospitalizations for ischaemic stroke and intracerebral haemorrhage among Danishborn inhabitants aged 15 years or older during the period January 1, 1994 to December 31, 2011.	219,354	CCI calculated from information on comorbid conditions using inpatient and outpatient hospital diagnoses recorded in the health records during the 15 years preceding the stroke. Defined 4 categories of comorbidity, i.e., total scores of 0 (none), 1 (moderate), 2 (severe), and 3 or higher (very severe).	19	The most prevalent comorbidities at the time of stroke diagnosis were atrial fibrillation or flutter (11.0%), cancer (10.9%), diabetes (9.0%), congestive heart failure (8.1%), chronic pulmonary disease (8.1%), peripheral vascular disease (7.7%), myocardial infarction (7.7%), ulcer disease (5.8%), connective tissue disease (3.4%), dementia (2.5%), and severe renal disease (2.3%). Prevalence of severe co-morbidity had increased over the 18 year period examined.	No count of co-morbidities given. Limited to those morbidities accounted for in CCI. Relied on health records.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Turhan 2006 259	Turkey	To investigate how comorbidity and serum albumin levels, two strong prognostic indicators in geriatric stroke, relate to rehabilitation outcome in this patient group. We also assessed whether stroke aetiology (ischaemic or hemorrhagic) influences these links.	Geriatric stroke (ischaemic and haemorrhagic) patients who were admitted to two separate rehabilitation clinics affiliated with a University Hospital between 2001 and 2003.	80	CCI was ascertained from medical records on admission.	19	Mean co-morbidity index was 3.04.	No count of co-morbidities given. Limited to those morbidities accounted for in CCI. Small number of participants, limited generalizability. Relied on health records. Only examined older stroke patients.

First author, year, country	Country	Aim	Inclusion criteria	Sample size	Outcomes relevant to co-morbidity	No of diseases examined	Results that relate to prevalence of co-morbidity	Limitations
Yikilkan 2013 ²⁶⁹	Turkey	To investigate co-morbid diseases and the actual cholesterol levels of elderly home-care stroke patients.	Stroke patients visited by home health care centre.	112	Record of co-morbidity in case notes was obtained.	Unclear	11 co-morbidities reported: hypertension, diabetes, congestive heart failure, Alzheimer disease, coronary artery disease, prostate problems, epilepsy, chronic obstructive lung disease, cancer, dementia, osteoporosis.	Small number of participants, limited generalizability, no count of morbidities, relied on case notes.

Summary

In summary, a small number of studies have examined co-morbidity and prescribing in stroke, but large, generalizable studies are lacking. No measures of treatment workload or burden in stroke were found, with only very narrow aspects of care having been quantified in the medical literature. Similarly, there are several measures that are useful for capturing aspects of patient capacity, but none that cover this comprehensively. The most all-embracing measure found was the SSSMQ²³⁸; however this omits wider social influences on capacity such as social support and socioeconomic status.

3.4 Conclusion

In this chapter I have explored the background literature on treatment burden and patient capacity in those with stroke in order to place the work described in the succeeding chapters in context. The aim was not to provide an exhaustive literature review, although attempts have been made to be as inclusive as possible. There are clear opportunities for future research, for example a systematic review of available measures of treatment burden and capacity in those with stroke would be worthwhile. A systematic review of the qualitative literature that explores treatment burden in stroke is described in Chapter 5.

Chapter 4 - Methodology

4.1 Introduction

4.1.1 *Aims of this chapter*

To discuss the rationale behind the methods used in this thesis; and the potential strengths and weaknesses of the methods chosen.

4.1.2 *Rationale*

Governing bodies have recently demanded better use of evidence in policy making, and as a result there has been an expansion in the range of research methods used to provide the necessary evidence base²⁷⁰. It has become clear that different questions are better answered by different types of methodology, with some questions simply not best answered by experimental studies such as randomised control trials (RCTs)²⁷⁰. As well as evidence of effectiveness, other evidence must be sought for adequate health care, for example whether health care meets the patient's self-perceived needs²⁷¹. Qualitative research is an appropriate methodology for answering such questions, and is increasingly used to inform practice and policy. There has been a recent explosion of multi-method health service research, with qualitative methods being used as a way of corroborating, facilitating and complementing quantitative research²⁷².

A multi methods approach has been chosen to explore the experience of treatment burden for those who have had a stroke. This comprises: a qualitative systematic review of research exploring the stroke patient experience of their chronic disease management; quantitative analysis of a large dataset taken from primary care records; and qualitative analysis of interviews with twenty nine stroke patients.

4.2 Methods

The methods described in this thesis were chosen following discussion with my supervisors and an exploration of the literature. Relevant articles were sought through a search of: online databases such as Ovid; Google Scholar; and the references and citations of important papers.

I will first discuss my epistemological and ontological assumptions and how these relate to mixed methods research. I will then go on to discuss methodological considerations for each phase of the research, with most attention being given to the qualitative systematic review, as this is the most novel and controversial method used.

4.3 Epistemology and Ontology

Careful consideration must be given to the epistemological and ontological assumptions made throughout this thesis, which could be considered as conflicting due to the use of a mixed methods approach. Quantitative research is generally associated with a realist positivist stance, which assumes that knowledge is objective and true and accessible through what can be observed. This approach assumes that the investigator and those being researched are independent of one another. Qualitative work however has strong links with interpretivism. This assumes that there are multiple interpretations of reality, and that knowledge is a socially produced construct. The investigator and subjects are linked as there are no realities separate from the mind ²⁷³⁻²⁷⁶.

It has been argued that the use of a mixed methods approach may not be valid due to the wide differences in deep seated assumptions between the quantitative and qualitative paradigms ²⁷⁷. Others have taken this further and suggested that even mixing methods within the same paradigm may be inappropriate ²⁷⁸. However, there has been a recent movement towards using multi method approaches as a means of better answering complex research questions ^{272;273}. Pioneers of multi method research reject the idea that strong divisions between paradigms exist and believe that differences can be overcome ^{272;273}.

Modified versions of realism have been proposed such as Hammersley's subtle realism ²⁷⁹⁻²⁸¹ which allows us to hold on to the search for truth as a "regulative ideal" ²⁸² while at the same time accepting that it is impossible to be absolutely certain that such truth has been attained. These beliefs lend themselves well to the collection of evidence from different sources. There are three key elements to his argument ²⁷³:

1. Truth should be reinterpreted as beliefs about whose validity we are reasonably confident.
2. There are phenomena which are independent of our claims about them.
3. The aim of social research is seen as representing rather than reproducing reality. Phenomena can be represented from multiple perspectives, but there are not multiple realities as anti-realists believe.

Others have since endorsed similar modified realist positions²⁸³⁻²⁸⁵.

Such a modified realist approach was taken when conducting the research described in this thesis. The view was taken that research uncovers phenomena that represent the reality of living with the management of stroke, whose validity we can be reasonably confident about, using information obtained from multiple perspectives, using multiple methods. Three different methods that complement one another were used. A qualitative systematic review aimed to uncover what is known about the stroke patient experience of treatment burden in different settings and contexts around the world. Analyses of primary care data aimed to quantify multimorbidity and prescribing in order to gain insight into the likely extent of these aspects of treatment burden for individuals living with stroke in Scotland. Interviews with stroke patients then gave a more detailed account of treatment burden for those living in the Greater Glasgow and Clyde area, as well as insight into their capacity to cope with treatments.

I am a white Scottish female general practitioner in my mid-thirties with some limited experience of carrying out both qualitative and quantitative studies. I also have clinical experience of treating those with stroke in primary care, and opted to read the relevant literature before and during my studies. This a priori knowledge is likely to have had some influence on my work and I have reflected on this whilst writing this thesis.

4.4 Qualitative Systematic Review

A qualitative systematic review was carried out to fulfil the following objective:

1. To carry out a systematic review of the qualitative literature that explores how treatment burden is experienced by those who have had a stroke.

4.4.1 Is Qualitative Synthesis Appropriate?

The increasing numbers of qualitative studies and their use in informing health policy has led to a demand for the synthesis of qualitative research, similar to that of the systematic review and meta-analysis of quantitative studies^{273;276}. There are opposing views on whether this is appropriate or even possible in qualitative research, due to the epistemological and ontological differences between quantitative and qualitative ideals as discussed above²⁷¹.

An interpretivist viewpoint makes the synthesis of studies in order to understand a particular phenomenon challenging, the argument being that there is no 'truth' to be discovered, only a collection of different stories that all have their own truths, with synthesis destroying the integrity of individual projects. Sandelowski stated "Just as it goes against the nature of poetry to attempt to summarize even one poem about love, so it seems both epistemologically and ethically inappropriate to attempt to summarize findings from one or more qualitative studies about human experiences of health and illness"²⁸⁶.

This viewpoint has however been contested by other qualitative researchers who believe that by synthesising multiple qualitative studies, it is possible to produce more powerful theory generation, and that by not doing so we risk isolation from policy makers and clinicians^{270;275;287;288}. In their early work Glaser and Strauss warned that the continued failure to link local grounded theories into formal theories would relegate the findings of individual studies to "little islands of knowledge" which may never be utilised if kept in separation^{286;289}. Walsh suggested that "it may be helpful to view the process as opening up spaces for new insights and understandings to emerge, rather than one in which totalizing concepts are valued over richness and thickness of description"²⁷⁵. Recently, several reviews of methods for qualitative synthesis²⁹⁰⁻²⁹² and guidance on methodology and reporting have been published^{205;293;294} in order to encourage transparent reporting of methodology and guide novice researchers as to the key steps involved.

There is evidence that the synthesis of qualitative research can add to our knowledge of the patient experience of healthcare^{287;295}. This type of research suitably lends itself to uncovering and exploring patients' perceived needs and behaviours, providing conceptual depth about the patient experience. It can collate data found in different contexts, seek gaps in the available research and inform the design of healthcare systems and policies. In this thesis, analysis is approached using a modified realist stance with sensitivity to the heterogeneous nature of the studies involved, and with the understanding that what we seek to understand is a variety of representations of the reality of living with and managing stroke. In fact, it has been argued that this type of research is perhaps particularly relevant for topics that are scarcely found in the literature²⁷², such as the patient experience of treatment burden.

4.4.2 Deciding what to review

When creating the review question, the first consideration was how focussed this should be. Too broad and the process could become unmanageable, particularly as study diversity can make qualitative analysis difficult²⁸⁷. Too focussed and relevant papers may be missed, a particular worry being the omission of important papers that oppose results from the other studies found²⁹⁶. The research question decided on was 'what are the components of treatment burden that patients with stroke experience during the management of their illness?'

Once the review question was set, the type and extent of the review was then decided. There are several broad options for approaching the synthesis of qualitative studies²⁸⁷:

1. Qualitative only systematic review.
2. Mixed systematic review (quantitative and qualitative).
3. Narrative review (an informal review of the literature, as opposed to the transparent and reproducible process of a systematic review).
4. Secondary analysis of original data from primary studies.

A systematic review of the qualitative literature was chosen for the following reasons: qualitative as opposed to quantitative research seemed the most appropriate lens for examining the patient experience of disease management; narrative review seemed neither rigorous nor transparent enough for my purposes; and secondary analysis was not appropriate as the aim was to aggregate and understand what had thus far been concluded from the literature.

The next consideration was whether to allow modification of the question in response to retrieved studies (similar to the methods used in primary qualitative research), or whether the research question should be fixed from the outset²⁹⁷. The latter was chosen in order to stick to the requirements of conventional systematic reviews and therefore enhance transparency and reproducibility.

4.4.3 Locating Relevant Papers

There are two main schools of thought with regard to searching for the relevant literature during a qualitative systematic review:

1. That it is unrealistic to claim to be able to find and adequately analyse everything relevant ever published; therefore purposeful sampling is used to retrieve materials until data saturation is reached²⁸⁶. This is the approach often taken by authors of narrative reviews, or of reviews deemed as interpretive rather than aggregative (aimed at developing concepts and theories rather than summarizing data)²⁹⁷. This is the method recommended by Pawson for realist synthesis of complex interventions, which usually involves using an extremely large and diverse set of resources, and seeks to uncover theories about complex interventions to aid their future development²⁷⁰.
2. That a robust search should be exhaustive, aiming to retrieve all of the relevant studies in a field rather than simply a sample of them. This is similar to the method used in traditional systematic review or meta-analysis. Papers are then sorted into relevant and irrelevant using a list of inclusion and exclusion criteria^{275;298}.

The second methodology was chosen in this case, as the aim was to carry out a comprehensive review of the literature in order to identify what had already been studied on this topic, and transparency in reporting was desired. Purposive sampling was not deemed suitable due to a perceived risk of potentially missing relevant studies.

One challenge when carrying out a qualitative systematic review is the creation of a comprehensive and rigorous database search using predefined index /subject heading / free text terms^{275;297-299}. Although this technique usually lends itself well to traditional quantitative systematic reviews, there has been much less adequate refinement of the electronic indexing of qualitative articles to date, making the search for these more taxing²⁹⁷. For example, the subject heading “qualitative research” was only introduced to MEDLINE in 2003. Those papers found in journals also often lack abstracts, making it difficult to establish the relevance of these papers²⁹⁷. Several papers have been published that outline strategies for searching through well-known databases for relevant qualitative studies³⁰⁰⁻³⁰³.

Due to the difficulties of database searching, other techniques have also become established as helpful in the searching process, all of which can involve either electronic or hand searching^{299;304}:

- Snowballing. This can involve 1) Reference or footnote tracking (looking back at studies referenced in articles found) or 2) Citation tracking (looking forward at studies that have subsequently cited articles found, using a citation database).
- Journal run. Looking through the contents of every issue of a journal between specified dates.
- Author searching. Searching by author rather than topic.
- Internet browsing.
- Contacting experts in the field.

These methods can be used in addition to database searching to enhance the search. One way of doing this is to use the “berry picking” technique. This is described as “a series of selections of individual references and bits of information at each stage of the ever-modifying search. A bit-at-a-time retrieval ... (similar) to picking huckleberries or blueberries in the forest. The berries are scattered on the bushes; they do not come in bunches. One must pick them one at a time.” Bates argues that berry picking is closer to the actual behaviour of searchers than traditional models of information retrieval ³⁰⁴.

In the review, a combination of methods was chosen including: formal database searching; internet searching using the berry picking method; the ‘related articles’ function in PubMed and Web of Science; reference tracking; citation tracking; personal files; and professional contacts. It was felt that this approach utilised a good mix of methods to optimise article retrieval.

Details of the search strategy are described in Chapter 5, however it is worth noting here that two information scientists were involved in the project. A search strategy was initially created in consultation with the first information scientist, informed by key words and phrases found during a scoping search. The formal search was centred on three main concepts: stroke; treatment burden; and patient experience. There was difficulty in refining the search as results appeared to lack specificity with findings of over 30,000 papers; and sensitivity was also lacking as some key papers were not retrieved. Several searches were created but none gave optimal results, causing a delay in the project. This information scientist then withdrew from the project due to time constraints, and a second information scientist was recruited. A second search strategy was created in consultation with this information scientist, again informed by key words and phrases found during the scoping search. The concept ‘qualitative methods’ was added into the search strategy along with the other three concepts: stroke; treatment burden; and patient experience ^{300-303;305;306}. This appeared to increase both sensitivity and specificity of the search, judged by the number of papers returned and key papers found, although no formal measurement of this was made. Final results (shown in Chapter 5) showed that 96% of papers were identified by the predefined database search, despite scoping, reference and citation searching being carried out. This contrasts with the findings of Greenhalgh et al ²⁹⁹ who found only 30% of papers using this

method. This could be explained by differences in the topic under review as well as in inclusion criteria, or it could be an indication of differing sensitivities of the search strategies.

Initially, the search was carried out to include all publications up to and including March 2011 and this was subsequently updated to February 2013. A formal update was not deemed necessary after this, as the aim was to create a taxonomy of treatment burden in stroke, and data saturation was reached following the subsequent qualitative work described in Chapter 7. It was therefore decided that updating the search further was very unlikely to add any new information. Instead, any pertinent new studies on treatment burden in stroke were sought, and none found. This is discussed further in Chapter 5.

4.4.4 Quality Appraisal of Qualitative Studies

The rise of the qualitative systematic review has led to discussion of the development of quality criteria for inclusion or exclusion into such a review. There are numerous agreed checklists available for quantitative research³⁰⁷⁻³¹⁰. There is however, no consensus on similar criteria for qualitative studies. In the following section I will discuss the various viewpoints on quality appraisal in the literature.

Firstly, there are opposing perspectives on whether appraisal of quality in qualitative research is suitable at all. Those who support it feel that it is integral to the interpretation and synthesis of studies²⁸⁷, as well as for promoting qualitative research as credible and fundable³¹¹. This camp expresses the view that due to the increased presence of qualitative work, it is necessary for policy makers, researchers and health care providers (who are not always experts in qualitative methodology) to be discriminatory in order to make adequate decisions^{271;273}. It has also been argued that without quality standards it is possible that qualitative work could be thought of as inferior to other research disciplines, particularly by those who believe in consigning research methods to a hierarchy with randomized control trials at the top²⁷¹.

Even those in favour of quality assessment, however, have highlighted the difficulties in deciding on the best method. Qualitative research is often seen as

a creative discipline³¹² with an absence of an agreed hierarchy of evidence, and great variation between different methodologies reflecting different theoretical perspectives. The result is a huge variation in opinion amongst experts and a plethora of proposals for appraisal with little consensus^{272;313-315}. Another issue is that publishing restrictions on length of reports often make it difficult for qualitative researchers to state their methodology in enough detail to allow a rigorous assessment by the reader^{271;276}. It is also important to note that an underlying assumption of quality appraisal is that qualitative research can be flawed, an assumption that is strongly opposed by anti-realists who state that each study is a particular story, and that accepting one version of events as correct is too authoritative^{276 273;316}. However, strong anti-realist viewpoints such as these are relatively recent, and traditional standards for appraising quality in qualitative studies were, as in quantitative appraisal, created from a positivist stance³¹⁷:

- Internal validity. The degree to which findings correctly map the phenomenon in question.
- External validity. The degree to which findings can be generalized to other settings similar to the one in which the study occurred.
- Reliability. The extent to which findings can be replicated or reproduced by another investigator.
- Objectivity. The extent to which findings are free from bias.

In the late 1970s, some qualitative researchers began to challenge the use of positivist criteria to evaluate qualitative work³¹⁷. This rejection of naïve realism led to a plethora of authors attempting to create an alternative set of criteria suitable for qualitative work, with underpinning paradigms ranging from critical realism, through constructionism, to relativism^{273;317-325}.

One example is Lincoln and Guba's landmark work³¹⁹ that proposed the need to establish "trustworthiness" of findings from studies using qualitative methods, in terms of their:

- **Credibility.** The "truth" of the findings, as viewed through the eyes of those being observed or interviewed and within the context in which the research is carried out.
- **Transferability.** The extent to which findings can be transferred to other settings. In order for findings to be transferable, the contexts must be similar. Therefore, it is the role of the researcher to identify key aspects of the context from which the findings emerge and the extent to which they may be applicable to other contexts.
- **Dependability.** The extent to which the research would produce similar or consistent findings if carried out as described, including taking into account any factors that may have affected the research results.
- **Confirmability.** Researchers need to provide evidence that corroborates the findings. Such evidence should come directly from subjects and research context, rather than the researcher's biases, motivations, or perspectives.

Aspects to be considered when using these criteria for the appraisal of qualitative work include the following:

Credibility

There is an agreement that clear explanation and transparency of methods is vital for the reader to gain an understanding of credibility. This should detail: access to participants; data collection; the researcher's role; data analysis; and how conclusions are drawn²⁷³. A demonstration of reflexivity by the researcher is helpful, in that they understand their own role in the research process and how their a priori assumptions have shaped analysis. Attention to and explanation of negative cases can add to validity and demonstrate fair dealing with all those studied²⁷³.

Transferability

Qualitative research tends to use a non-probabilistic sampling strategy aimed at reflecting diversity rather than generalizability³²⁶. The researcher may use their sampling method to compare different patient groups³²⁷. Generalizability can be difficult and often inappropriate to demonstrate in qualitative work, with the assessment of the transferability of findings to other contexts being more appropriate, and perhaps the onus should be on the reader to do this³¹⁹. In order for this to be possible, however, the author must provide sufficient detail or 'thick description' of methods, definitions and theoretical frameworks²⁷³.

Dependability

This can be either internal (by other researchers on the same project) or external (in a different project in a similar setting)^{326;328}. It has been argued that the use of internal reliability testing violates the process of induction as a second rater or coder is not likely to have the same background information as the first, who will usually have carried out the interview and therefore picked up non-verbal cues or subtleties³²⁹. It has also been demonstrated that measurement can be extremely challenging as although researchers may agree on basic themes, it is likely that they will 'package' these differently. As mentioned earlier, external reliability is also likely to be difficult to achieve in qualitative rather than quantitative work due to the natural settings used. Detail in the paper of whether methods of analysis were inductive or deductive, or whether computer software was used, are argued to be extremely helpful in promoting reliability³²⁶.

Confirmability

With regard to confirming results through other sources, triangulation is one option. This was originally introduced into social research by Campbell and Fiske³³⁰ and is an approach that uses different methods, data sources, investigators or theories to study a phenomenon²⁷³. Although thought of as useful, conclusions can be difficult to achieve, as data collected in different forms by different methods can be difficult to compare. It is also argued that using different methods to validate one explanation does not lend itself to the interpretivist approach often taken in qualitative research³²⁷. Another method often used is respondent validation, meaning that researchers feedback their findings to

participants to establish if they agree that these are a reasonable account of the phenomenon observed³²⁶. Using this method for validation, however, assumes that participants can devote enough time and energy to giving sufficient feedback, and that they do not have their own agenda when doing so²⁷³. It may therefore be that triangulation and respondent validation should both be thought of as ways of limiting error rather than as absolute proof of confirmability.

In recent times, a plethora of authors have published guidance on assessment of quality in qualitative research^{271;273;280;285;307;307;313;317;326-328;331-333;333-335}. Some are based on extensive reviews funded by governing bodies^{273;332} and others are what could be termed opinion pieces, although these are based on many years of experience on behalf of the authors^{271;307}. Some are formal checklists^{336;337}, others more general guidance that encourage the reader to bear in mind a few key principles before making an overall judgement of quality^{285;331}. Although it is likely that all methods are somewhat subjective^{270;273;338} checklists are likely to be easier for less experienced researchers to use and also more transparent to the reader.

After careful examination of the options and discussion with experienced researchers, a checklist was developed for quality review based on criteria suggested by Popay, Williams and Rogers²⁷¹. These criteria had been created by the authors based on their vast collective experience, and stem from a subtle realist approach similar to the one underpinning this thesis. The authors stated there is no absolute list of criteria as to what constitutes good qualitative research, and that epistemological and ontological differences must be acknowledged and judgement applied in context. This fits well with the assumptions in this thesis as described above.

Another decision was whether to exclude papers from the review based on quality appraisal. There are some researchers who advocate the exclusion of studies deemed 'poor quality' as the best course of action, along with a sensitivity analysis to assess if exclusion of these studies affects the overall results³³⁹. However, one risk of excluding papers due to poor quality is that a paper may be excluded based on failure of one criterion not seminal to the overall integrity of the paper^{313;328}, or it may fail assessment as a whole paper

yet the part of it required for inclusion in the review would pass when considered on its own. This may be the case in a rarely researched topic such as treatment burden. Additionally it is difficult to compare papers that describe a variety of methodologies^{270;273}. Another difficulty is that research design frequently involves a trade-off between enhancing validity and reliability due to budgetary and practical constraints²⁷³. Furthermore, as mentioned earlier, studies are usually evaluated through the published report itself, which are often limited in word count by publishers³¹³. It was therefore decided that the checklist would be used as a reflective rather than a prescriptive tool^{327 271} and studies would not be excluded based on quality appraisal.

4.4.5 Data synthesis

The term 'qualitative meta-synthesis' was first coined by Stern and Harris in 1985, in reference to amalgamating qualitative research in order to develop an explanatory theory to summarise and explore the findings of a group of qualitative studies³⁴⁰. This process involves analysing the outcomes of studies rather than primary data, and therefore is distinct from qualitative secondary analysis. As with the other aspects of qualitative systematic review described above, there is no clear consensus on how to carry out data synthesis, with great debate over methods and somewhat confusing terminology.

There are many different documented methods of synthesis^{290-292;341}. Most appear to consist of a 'compare and contrast' exercise, which can range from descriptive to interpretive. Descriptive techniques at their most basic aim to summarize similarities and differences between studies. Interpretive techniques additionally aim to add new understandings and perspectives while preserving meaning from the original studies^{275;298}. Examples of some commonly used methods are shown in Table 4. In this case, a framework synthesis approach was chosen^{295;342-345}, a method derived from qualitative framework analysis^{346;347 348;349}. This method is frequently used in applied policy research, where the aim is to gather predefined information with the potential to create actionable outcomes^{346;349}. Framework synthesis, like framework analysis, is an appropriate method for researchers with some degree of knowledge in their chosen area, with a predefined framework being applied to data to gain a deeper understanding of a particular phenomenon^{346;347;350}. Although

traditionally there has been a preference from qualitative researchers to use purely inductive methods of analysis^{351;352}, there has been a recent interest in the use of existing theories and *a priori* concepts to guide methodologies such as framework analysis / synthesis^{353;354}. Care must be taken, however, not to 'shoe horn' findings into the framework, and this is one challenge of using such a method³¹⁸. To prevent this from occurring, a constant questioning of the suitability of the framework used must occur³⁵⁵ which in turn aids the development of thick description and conceptual density during analysis³⁵³.

There are 5 stages of framework analysis (and therefore synthesis)³⁴⁶: familiarisation; identifying a thematic framework; indexing; charting; mapping and interpretation. This is described in more detail in Chapter 5. Framework synthesis seemed appropriate for this systematic review, not only due to the preconceived ideas formed through clinical experience and knowledge of the literature, but also because it fits with the modified realist approach. Following AMSTAR guidance²⁰⁵, another reviewer also independently carried out every phase of the review, and any disagreements were resolved with third party involvement. Inter-rater reliability was not calculated as the benefits of this in qualitative research are unclear³⁵⁶. A particularly novel aspect of this review is the approach to data analysis: using a framework informed by Normalization Process Theory (NPT)^{117;357}.

Table 4 – Commonly used methods for qualitative synthesis

Method	Approach	Advantages	Disadvantages
Meta-ethnography 272;287;296;358-360	<p>1) Reciprocal translational analysis. This involves identifying key themes, concepts or metaphors in each study and translating these into each other.</p> <p>2) Refutational synthesis. This involves describing differences between key themes, concepts or metaphors. Differences are examined and an attempt is made to explain their existence.</p> <p>3) Lines of argument synthesis. This involves building a general interpretation grounded in the findings of the separate studies.</p>	<p>Can generate theory beyond those in original studies.</p> <p>Useful for inductive methods of synthesis.</p> <p>Systematic, transparent approach.</p>	<p>Possibly strips context from the original studies.</p> <p>Some believe that this method is integrative rather than interpretive.</p> <p>Dispute over which order studies should be synthesised in.</p> <p>No guidance on sampling.</p>
Thematic analysis / synthesis 272;361	<p>Can use exhaustive or purposive sampling.</p> <p>1) Free line-by-line coding of the findings of primary studies</p> <p>2) Organisation of these 'free codes' into related areas to construct 'descriptive themes'</p> <p>3) Development of 'analytical themes' (the result of placing the synthesis within an external theoretical framework derived from a priori assumptions).</p>	<p>Allows clear identification of major themes.</p> <p>Useful if a specific research question is set.</p> <p>Flexible approach.</p> <p>Can cope with diverse evidence types.</p>	<p>Care must be taken to explain data-driven and theory-driven themes.</p>

Method	Approach	Advantages	Disadvantages
Critical Interpretive Synthesis ³⁶²	<p>Purposive sampling.</p> <p>Places emphasis on critique in a broader sense, with acknowledgement of the research tradition guiding the research in question and critical analysis of particular forms of discourses.</p> <p>Iterative process, empirically and theoretically grounded, with theoretical categories being generated from the available evidence and submitted to rigorous scrutiny as the review progresses.</p>	<p>Good for large studies using a diverse range of literature.</p> <p>Flexible approach.</p>	<p>Lack of transparency and reproducibility.</p> <p>Purposive sampling may miss some papers.</p>
Narrative synthesis ³⁶³	<p>Broad guidelines for improving transparency and reproducibility in qualitative data synthesis as well as reducing bias, with the acknowledgement that there are numerous and diverse ways of synthesising data, the most appropriate choice depending on the research question asked.</p> <ul style="list-style-type: none"> - Developing a theory of how the intervention works, why and for whom - Developing a preliminary synthesis of findings of included studies - Exploring relationships in the data - Assessing the robustness of the synthesis <p>Iterative rather than in stages. Individual techniques and elements can be selected or the whole process can be followed.</p>	<p>Can be applied to various methods of synthesis and also to quantitative research.</p> <p>Can be tailored to suit the needs of the researcher.</p>	<p>Individual tailoring means this is not a suitable method for novice researchers.</p>

Method	Approach	Advantages	Disadvantages
Grounded theory <small>272;272;351;364</small>	Constant comparison to identify patterns and relationships within data. Iterative process. Includes guidance on sampling (which can be theoretical), data collection, analysis and theoretical saturation	Generates theory. Can qualitise quantitative research and include in review.	Detail can be lost from original study. Lack of transparency.
Meta-narrative review <small>365</small>	Uses the unfolding 'storyline' of a research tradition over time as the initial unit of analysis. The quality of studies within each research tradition can then be quality assessed using criteria appropriate for that paradigm, and findings from each research tradition can then be synthesised.	Tailors method to research tradition examined.	Some subjectivity required when categorising research traditions. Synthesis is difficult.
Framework synthesis <small>342;343</small>	Based on framework analysis, offers a structured approach to organising and analysing data. Iterative literature searching, a priori coding. A predefined framework is applied to the data.	Organises large and unwieldy amounts of data. Good for those with a priori knowledge in their field. Good for projects with predefined objectives.	Risk of 'shoehorning' findings into the framework. Not suitable for more exploratory work.

Method	Approach	Advantages	Disadvantages
Realist synthesis ²⁷⁰	<p>Purposive sampling.</p> <p>Designed as an approach to reviewing research evidence on complex social interventions. Tests 'theories' rather than 'interventions', by defining the underlying theory or assumptions about how an intervention is supposed to work, then seeks to gather evidence in a systematic way to test and refine this theory.</p>	<p>Suitable if the sources used to inform the review are substantial and diverse.</p> <p>Generates theory.</p>	<p>Needs experience and expertise.</p> <p>Lack of transparency and reproducibility.</p>
Miles and Huberman ³⁶⁶	<p>Cross-case analysis which compares multiple cases in multiple ways.</p> <p>A meta matrix can be constructed then the researcher is encouraged to go beyond initial impressions by looking at the cases with numerous and diverse lenses, for example by comparing within-group similarities and inter groups differences, then by pairing up cases and comparing them this way, then perhaps comparing data from different sources.</p>	<p>Systematic and transparent.</p> <p>Can include quantitative data also.</p>	<p>No guidance on sampling.</p>
Meta-synthesis / meta-aggregation ³⁶⁷	<p>Mirrors Cochrane reviews of effectiveness whilst taking account of the important differences between qualitative and quantitative research.</p> <p>Exhaustive search strategy, quality appraisal and data extraction using software designed by Joanna Briggs Institute, then data synthesis consisting of categorising findings and creating synthesised findings from these categories.</p>	<p>Systematic and transparent.</p>	<p>Need software from Joanna Briggs Institute.</p>

Method	Approach	Advantages	Disadvantages
Metastudy ³⁶⁸	<p>1) Metatheory - examination of any theories that underpin research topics and questions.</p> <p>2) Metamethod - examination of the of the methodological approach used.</p> <p>3) Metadata analysis – reinterpretation of the findings from each study taking into account findings from other studies.</p>	<p>New theory generation.</p> <p>Can qualitate quantitative research and include in review.</p>	<p>Difficult, time-consuming process.</p>

4.4.6 Normalization Process Theory

As discussed in Chapter 2, Normalization Process Theory (NPT) explains how the work of enacting an ensemble of tasks or practices is accomplished through the operation of four mechanisms: ‘coherence’ (sense-making work); ‘cognitive participation’ (relationship work); ‘collective action’ (enacting work); and ‘reflexive monitoring’ (appraisal work)^{117;118}. If we conceptualise the workload of healthcare as a set of practices performed by patients during their chronic disease management that must be implemented, embedded and sustained in their life, NPT appears to fit well as a conceptual framework. It is important to note, however, that although NPT is a predefined theory, the treatment-burden-specific meaning of the domains are not predefined, as NPT was originally created to understand the processes of service implementation³⁵³. Helpfully, NPT had been utilised recently to inform a framework analysis that conceptualised treatment burden in those with chronic heart failure, and in this work NPT was found to be an extremely useful and insightful tool^{11;122}. NPT was chosen rather than a ‘stroke-specific’ conceptual framework for two reasons: 1) no stroke-specific conceptual frameworks were found; 2) use of NPT enables the possibility of future comparisons between patient experiences across a range of chronic diseases.

NPT also informed the framework analysis of patient interviews described in Chapter 7, and this is discussed further below. The same framework was used in the systematic review and qualitative study, adapted and refined as analyses progressed. The method was therefore iterative in nature, and the framework synthesis to some extent informed the framework analysis. Due to the relatively novel use of NPT, the suitability or ‘fit’ of this conceptual framework was continually assessed throughout the process.

4.5 Quantitative analysis of primary care data

A large cross-sectional study of primary care data was carried out to fulfil the following objective:

2. To quantify comorbidity and polypharmacy in those who have had a stroke in Scotland.

4.5.1 Change in dataset and objectives

When originally planning these studies, an arrangement had been made to access a dataset from Greater Glasgow and Clyde Health Board that had been developed as part of their work in the sphere of enhanced services for primary care. This was a large data set providing information on approximately 26000 primary care patients with stroke, collected by nursing staff in face-to-face consultations carried out annually as part of routine care. It included epidemiological data along with information about treatment burden in the form of hospital clinic visits, admissions, visits to support groups, visits to allied health professionals and therapists, investigations done, medications, and interventions for alcohol excess and smoking. My intention was to quantify aspects of treatment burden in primary care stroke patients, relate treatment burden to outcomes by linking to hospital admission and mortality data, and analyse if a higher level of treatment burden was associated with factors such as sociodemographics, number of co-morbidities, functional capacity and non-adherence.

However, after the dataset had been obtained and cleaned, it became apparent that it was unsuitable due to large amounts of missing data. This setback resulted in a reorganisation of the project timeline to allow time to be spent researching other available datasets such as the Scottish Stroke Care Audit ²⁴, Scottish Health Survey ³⁶⁹, Twenty07 Study ³⁷⁰, UKBiobank ³⁷¹ and Clinical Practice Research Datalink ³⁷². This reordering of studies is described in more detail below. With regard to finding a dataset, the main factors considered were type of data available, number of participants, access, and cost. It was decided that primary care data collated by the Primary Care Clinical Informatics Unit (PCCIU) at the University of Aberdeen provided an exciting opportunity. This dataset consisted of data from the primary care records of approximately 1.5 million Scottish patients (representative of the Scottish population), and was cleaned and available for immediate use at no cost, in collaboration with colleagues in primary care who had access to the data as part of a large multimorbidity project (CSO Living with Multimorbidity Programme ARPG/07/1). The data included information on the presence of long-term conditions such as stroke and also on prescribed medications, allowing exploration of multimorbidity and prescribing in those with and without stroke. Although

different to the original objectives, these new aims fitted in well with the project, as the literature on treatment burden in chronic illness had recently highlighted the important effects of comorbidity on the patient experience of treatment burden^{112;114}, and prescribing was deemed an important influence on treatment burden worth exploration. A search of the literature revealed that studies examining multimorbidity and prescribing in stroke to date had involved either small numbers of participants or limited numbers of morbidities (see Chapter 3). Unfortunately due to the anonymous nature of the dataset, data linkage to assess outcomes was not possible. However it was felt that examination of multimorbidity and prescribing in a large, nationally-representative dataset would make a worthwhile contribution to the stroke and treatment burden literature, and tie in well with the other studies in this thesis.

4.5.2 The use of routinely collected data

The use of routinely collected data from primary care records has limitations in that it risks missing conditions not reported to clinicians, and some data may be unreliable or missing as was the case in the original dataset deemed unusable. Additionally, the selection and definition of morbidities counted is unavoidably dependent on the data available, and a discussion of this is given below¹⁵⁴. However, demographic variables such as age, gender and socioeconomic status (based on postcode) are likely to be reliably recorded for the purposes of everyday care, as are prescriptions issued (although hand written prescriptions could potentially be missed and an issued prescription does not give us information about whether the patient has had this dispensed from the pharmacy or taken the medication).

Despite these limitations, I found that using routinely collected data had advantages in that it allowed examination of a large dataset representative of the Scottish population. Additionally, data on the most socioeconomically deprived patients were available, often missing when methods such as self-reported questionnaires are used, due to difficulties recruiting these groups.

4.5.3 Measuring multimorbidity

In this thesis, comorbidity refers to the presence of one or more morbidities in addition to an index condition such as stroke ¹⁵³, whereas multimorbidity describes the presence of two or more conditions within one individual, with no index condition specified ¹⁵⁴. There is currently no consensus on the best way to measure multimorbidity in those with long-term conditions ²⁵¹; however a simple count is deemed appropriate for descriptive studies ¹⁵⁴. One limitation of using a simple count is that this weighs all disorders equally, and therefore does not account for variations in effects on the individual depending on type and severity of disease ¹⁵⁴.

In order to measure the prevalence of comorbidity in stroke, a simple count was chosen for two reasons. The first is that the aim was to examine the prevalence of multimorbidity and not outcomes; therefore a count was deemed suitable. The second is that colleagues collaborating on the project had recently published a highly regarded paper that described an epidemiological study of multimorbidity using the same dataset, for which they had created a list of 40 morbidities that could be used as a reference for a simple count. This list had been defined by recent systematic review, expert consensus, Quality and Outcomes Framework (QOF) and National Health Service (NHS) Scotland priority areas ^{154;250;373;374}. Others have since used this dataset and count to examine multimorbidity in those with other long-term conditions ³⁷⁵⁻³⁷⁸. The process by which each morbidity was defined is described in detail in the original paper ¹⁵⁴ and summarized in Appendix 2 (taken directly from the original paper). Read codes, the standard clinical terminology system used in General Practice in the United Kingdom, were used to help identify morbidities. Regarding morbidities that have lifelong implications, e.g. stroke, definition was based on a read code ever having been recorded; however for conditions where cure or remission is possible, e.g. cancer, definition was based on a read code being present within a defined period or at any point if relevant prescriptions had been recently issued. Regarding morbidities that are likely to be under-recorded in the notes e.g. depression, the presence of either a read code or recent relevant prescriptions were accepted. The definition of certain morbidities were more subjective than others, for example 'painful condition' and 'anxiety and other neurotic, stress related and somatoform disorders' are both likely to be heterogeneous in

nature; however these are meaningful categories in practice. Despite these limitations, this list of 40 morbidities was considerably longer than that used in other counts of comorbidity in stroke (see chapter 3), and the authors' detailed description of how they defined each condition ¹⁵⁴ is refreshing.

4.5.4 Measuring prescribing

There are no standard measures of prescribing, and in this thesis, a count of current regular prescriptions, including tablets, inhalers, stoma care and topical therapies ^{379;380} was chosen. Regular prescriptions ('repeat') are clearly distinguished in UK general practice electronic medical records from one-off ('acute') prescriptions such as those for most antibiotics. As there are no formal definitions of regularly prescribed treatments, any regular prescription was counted as current if it was still active (i.e. available for issue on request) on the date of extraction and it had been prescribed in the last 84 days (the longest time possible between active prescriptions). Polypharmacy is often defined as the use of multiple (sometimes five or ten) prescribed medications ^{83;84;86}, although again there is no standard definition. As there is no strong evidence to support the use of any particular cut-off and the risk of drug-related problems seems to increase with each additional medication prescribed ^{379;380}, in this thesis polypharmacy is defined as the prescription of multiple medications.

4.5.5 Statistical techniques

Standard statistical techniques were used for data analyses ³⁸¹ and these are described in Chapter 6. Logistic regression was used to summarize the relationship between stroke and the presence of comorbidities and prescribed medications. Potential confounders were added to regression models, including age, gender, socioeconomic status and morbidity count (when examining medications). Other potential confounders such as ethnicity, smoking status and alcohol consumption were not available, and this is a limitation of the study.

4.6 Qualitative analysis of patient interviews

Interviews with 29 individuals who had suffered a stroke were analysed in order to fulfil the following objective:

3. To explore in depth the experience of treatment burden and patient capacity by interviewing those who have suffered a stroke.

This third phase of these studies was therefore aimed at gaining a deeper insight into the stroke patient experience of treatment burden, by asking patients directly about their experiences of stroke management and their encounters with health services. Analysis was somewhat informed from the findings of the review and cross-sectional study, and also from previous work on treatment burden in heart failure ^{11 382-384}.

4.6.1 Change to order of studies

The original schedule for the studies in this thesis had been: 1) the systematic review; 2) the quantitative analysis of primary care data; 3) the qualitative analysis of patient interviews. However, due to the difficulties in obtaining a suitable dataset described above, this order was altered so that half of the interviews were carried out and analysed before the cross-sectional study, and half after. Although not originally planned, this resulted in a more iterative approach, as the first fifteen interviews had been fully analysed before recruitment of the rest, therefore when data saturation was noted at this point, the interview schedule for the last fourteen participants was altered, and a different method of data analysis used. Ethical approval was sought and approved for this change to the interview schedule. This new interview schedule was informed by findings from the first fifteen interviews and the systematic review, as well as emerging theories on treatment burden and patient capacity in the literature that were discussed in Chapter 2 ^{13;14}. This will be discussed in more detail below. Carrying out the qualitative interviews in two parts did risk the study becoming disjointed, however this was minimised by fully analysing the first set of interviews soon after they were carried out and before starting the quantitative section. Additionally, as both the interview schedules and methods of analysis were different for the two parts of the qualitative study, continuity became less important.

4.6.2 Participants

When sampling for qualitative studies, the aim is to recruit a group of individuals from whom a rich picture of experiences can be gained³⁸⁵. This differs from quantitative research, where sampling methods focus on representativeness of a population, and therefore high numbers are often desirable. Purposive sampling (where individuals are picked due to desirable characteristics) and theoretical sampling (where individuals are picked based on developing theory) are often used, and recruitment may be carried out as analysis progresses, in response to findings³⁸⁵. In this study, I have carried out a form of purposive sampling, picking individuals for interview based on gender, age, deprivation, time since diagnosis and severity of disability in order to obtain as maximum a variation as possible³⁸⁵. To enhance variation, individuals were recruited from both primary and secondary care and exclusion criteria were kept to a minimum. Recruitment in primary care was carried out through the Scottish Primary Care Research Network, and in secondary care through the Scottish Stroke Research Network. Variation was desirable to assist the creation of a diverse and comprehensive taxonomy of treatment burden in stroke, as some burdens may have been specific to individuals with certain characteristics. Sampling was iterative in that those who had already been recruited influenced subsequent recruitment. For example, half way through the process a shortage of women was noted; therefore more women were recruited. This will be discussed further in Chapter 7.

4.6.3 Data collection

As the aim was to gain a deep understanding of the treatment burdens faced by those with stroke, it was decided to interview individuals about their experiences. One-to-one semi-structured interviews were deemed the best way to do this, as this allowed in-depth accounts of treatments that had perhaps happened over a long period of time to be obtained, and also allowed patients to be interviewed in their own home, a benefit for those who had physical disability or difficulties with communication. Other methods such as focus groups have limitations in the elderly and frail population being examined, and observation of treatments was not a suitable method due to the long-term nature of the illness³⁸⁵. The interviews were semi-structured rather than free

flowing due to the a priori ideas described above, yet this method still allowed flexibility of the topic discussed so that participants could direct the conversation towards things that were important to them.

4.6.4 Data analysis

There is a plethora of options available for the analysis of interview data: these vary in their underlying epistemological and ontological assumptions as well as the techniques used for reducing data and generating findings. Some analytical methods such as framework analysis or content analysis tend to be more deductive (meaning pre-defined ideas and theories are tested using the data collected) and others such as grounded theory are more inductive (meaning concepts and theories arise entirely from the data rather than being preconceived by the researcher). Although these analytical processes can be quite different in their techniques, many aspects overlap, with a search for recurring themes in the data the most common goal. Methods range from a count of words or phrases in content analysis, to cyclical generation and testing of new theories in grounded theory³⁸⁵.

Two techniques were used for data analysis: framework analysis of data obtained from the first set of interviews and thematic analysis of data from the second set. NVivo software (version 10) was used for both methods.

Interviews 1-15

The first set of interviews was analysed using a framework informed by NPT that had been developed and refined during the framework synthesis in the systematic review^{346;347;349 348 382}. As well as fitting with a priori knowledge and epistemological / ontological assumptions, this method also allowed findings to be compared to, and amalgamated with, findings from the systematic review. To enhance reliability of coding, a senior researcher double coded four transcripts and any differences were discussed to inform future coding. This was deemed appropriate as the coding frame had already been developed during coding of data in the systematic review³⁸². Similarly to the review, inter-rater reliability was not calculated as the benefits of this in qualitative research are unclear³⁵⁶.

Interviews 16-29

Once data saturation had been reached, one option was to terminate the interviews; however, two factors led to interviews taking place using a new interview schedule and method of analysis. The first was that although no information on *treatment burden* fell outside the NPT-based coding framework during analysis of the first fifteen interviews, information about *patient capacity* did and it was felt this deserved further exploration, particularly as there was an evolving literature on patient capacity at that time, as discussed in Chapter 2^{13;14}. The second reason was that both ethical approval and funding had been secured for further interviews, and this provided an excellent opportunity. Rather than interviewing the first set of participants a second time, it was decided to interview a new set, partly due to the constraints imposed by the ethical approval, and also partly because it widened the breadth of experiences available.

For data analysis of the last 14 interviews, thematic analysis was used^{386;387} in order to allow more flexibility in coding and therefore investigation of patient capacity. There are six stages of thematic analysis: familiarization with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report³⁸⁶. This is described in detail in Chapter 7. This method was more inductive in nature than the framework analysis used for the first set of interviews as there was no preconceived coding framework prior to analysis. However, the concepts formed during the systematic review and first set of interviews along with my a priori knowledge and experience undoubtedly influenced data analysis, therefore this was not a purely inductive process. Additionally, as discussed in Chapter 2, during analysis of the first set of interviews, two pivotal papers on treatment workload and patient capacity were published^{13;14}, therefore my understanding of these issues was evolving separately but alongside the interviews, shaping my thoughts on analysis and planning for the next set of interviews.

Integrative analysis

Lastly, an integrative analysis was carried out, with the components of treatment burden found in the second set of interviews being compared to and merged with the taxonomy created in the first. This taxonomy was then

compared to and merged with the one created in the systematic review. A taxonomy of factors that affect patient capacity was created separately.

4.6.5 My role as a researcher and general practitioner

A researcher's occupation, gender or background are often excluded from the methods or discussion sections of papers, yet these factors are extremely important to consider with regard to qualitative work³⁸⁸⁻³⁹⁰. My role as a general practitioner (GP) is particularly relevant to this project not only because of my clinical knowledge of stroke, but also because some participants were recruited from the practice I was working in^{389;390}.

It has been suggested that there may be negative effects of GPs carrying out qualitative research, for example patients could feel coerced into participation or they may feel they cannot speak honestly about their experiences^{389;390}. It is possible that these negative effects could have occurred in this project not only due to my role as a GP but additionally because some participants were recruited from my practice. Positive effects of GPs carrying out qualitative research include patients feeling more comfortable speaking to a health professional, and the ability for GPs to deal with any distressing events that may arise³⁸⁹.

The practice that I was working in is in a deprived area of Glasgow with a large list size and high prevalence of stroke. I was working there one day a week as a sessional doctor, so was not a named partner. Amongst the practices used for recruitment, my practice had the most replies from patients interested in taking part, which could reflect the influence of my work as a GP in that practice, the high prevalence of stroke in that area, or some other factor such as patient demographics. Recruitment in primary care was carried out through the Scottish Primary Care Research Network. However, the letter of invitation to all patients was written on practice headed notepaper and my contact details were also given, so it is possible that patients in that practice who recognised my name felt obliged to take part. Recruitment was terminated from my practice after seven patients had been interviewed; this was because a wide range of experiences and therefore practices was desired. During subsequent recruitment from secondary care, one reply was returned from my practice. I decided to

recruit this patient into the study because they had been diagnosed with stroke within the last year, a desirable characteristic that was proving to be rare in those agreeing to take part.

Several strategies were employed to minimise any influence of my status as a GP on data collection³⁹⁰. At the start of each interview, rather than disclose that I was a GP, I stated 'today I am here as a researcher who works at the University and I would like to hear about your experiences'. If any patients questioned me directly about being a GP I gave an honest answer, but emphasised that I was not practising that day and was extremely interested in hearing honest views from patients. I also dressed casually and used my first name during introductions. Medical jargon was avoided, as was imparting clinical advice; instead participants were directed towards their own GP. Interviews were carried out in the participant's own home to aid their feeling of empowerment and put them at ease³⁹⁰.

During the interviews, patients from my practice made both positive and negative comments about their stroke care experiences. However, they were more likely to initially make statements such as 'I don't have any complaints' and then make negative comments about their care later on in the interview. I had predicted that participants from my practice may worry more than others about confidentiality, but this did not seem to be an issue that was specific to those from my practice, as several of the participants from varying practices wished to clarify that everything was confidential before making negative statements about their GP. One male working class patient from my practice made reference to the fact that he was calling me by my first name, he seemed pleased to do this, and was the only patient I had seen in a clinical consultation before the interviews.

Similarities between the clinical encounter and research interview have been previously documented, for example the therapeutic properties of both for the participant / patient³⁹⁰. However, I found carrying out interviews for the purposes of research very different to consulting in general practice for three reasons. First, the participant had volunteered their time to take part in the interview and therefore the interaction was for my benefit rather than theirs. Second, as more time was available, the pace of questioning was much slower.

Third, I was not in a position to answer clinical questions asked by the participant and at times I found it difficult to redirect medical questions to the participant's GP ³⁹¹.

4.6.6 Reliability and validity

Earlier in this chapter, the challenges associated with appraising the reliability and validity of qualitative work were discussed along with the methods used for doing so. In order to summarise strengths and weaknesses, I have appraised the qualitative work described in Chapter 7 using the same tool as was used in the systematic review. This is shown in Table 5.

Table 5 - Appraisal of the qualitative work described in Chapter 7, using the quality appraisal tool employed in the systematic review in Chapter 5.

Guideline	Method to try and achieve this.
<p><i>Does the research, as reported, illuminate the subjective meaning, actions, and context of those being researched?</i> (i.e. is it ensured through design and analysis that emphasis is given to the interpretations of those being researched rather than the researcher's or professional's viewpoint?)</p>	<p>Semi-structured interviews can risk researcher - directed interviewing; however during the interviews participants were encouraged to talk freely about any experiences of their treatments to minimise this risk. (Chapters 4 and 7)</p> <p>Framework analysis risks finding researcher - biased results; therefore care was taken to adapt and refine the framework in response to the data, to note any data that fell outside of the framework and to constantly question whether the framework was fit for purpose. (Chapters 4 and 7)</p>
<p><i>Are subjective perceptions and experiences treated as knowledge in their own right?</i> (i.e. does the study treat the data collected directly from the participants, representing their viewpoint, as the basic data for analysis?)</p>	<p>Interviews were taped and transcribed <i>verbatim</i> then analysed. Recordings were listened to during analysis. (Chapter 7)</p>
<p><i>Is there evidence of the adaption and responsiveness of the research design to the circumstances and issues of real-life social settings met during the course of the study?</i> (i.e. is the process of sampling, data collection, data analysis and interpretation iterative? Is there evidence of adaption and redesign as the study has progressed?)</p>	<p>Sampling was purposive to collect a maximum variation sample. The framework used for analysis was adapted and refined during analysis. During thematic analysis, coding was an iterative process with codes being revisited and amended during the process.</p> <p>Data saturation was reached after analysis of 15 interviews, a new research question arose from analysis of the first 15 and a new interview schedule and method of analysis therefore carried out for the last 14. (Chapters 4 and 7)</p>
<p><i>Does the sample produce the type of knowledge necessary to understand the structures and processes within which the individuals or situations are located?</i> (i.e. is sampling appropriate for the aims, objectives, methods and conclusions reached?)</p>	<p>Sampling was purposive to collect a maximum variation sample of people who have had a stroke and live in the Greater Glasgow and Clyde area. This was deemed suitable as the aim was to collect a range of experiences from those living locally. (Chapters 4 and 7)</p>
<p><i>Is the description provided detailed enough to allow the researcher or reader to interpret the meaning and context of what is being researched?</i> (i.e. is a rich picture produced, providing the context of an experience and the intentions and meanings that feed into it, rather than simply a set of facts?)</p>	<p>Taxonomies of treatment burden and patient capacity have been produced (Chapter 7) and a conceptual model created (Chapter 8).</p>

<p><i>Are any different sources of knowledge about the same issue compared and contrasted and how is this done?</i> (i.e. are different methods used to answer the research question and are these examined not only for similarities but for providing different facets of the reality being investigated?)</p>	<p>Two different methods of data analysis were used. Results were compared with results of the systematic review. Cross sectional study complements this qualitative data by quantifying multimorbidity and prescribing in those with stroke. (Chapters 5, 7 and 8)</p>
<p><i>Has the researcher rendered transparent the processes by which data have been collected, analyzed, and presented?</i> (i.e. is the whole process clear to the reader?)</p>	<p>Methods have been outlined clearly. (Chapters 4 and 7).</p>
<p><i>Has the researcher made clear their own possible influence on the data?</i> (i.e. has the researcher stated their own background / experience and ontological / epistemological stance?)</p>	<p>Yes, my epistemological / ontological assumptions, previous research experience and employment as a GP have been discussed. The possible impact of these factors on my role as the researcher are also discussed (Chapter 7)</p>
<p><i>Is it clear how the research moves from a description of the data, through quotation or examples, to an analysis and interpretation of the meaning and significance of it?</i> (i.e. what did the researcher do to reach their conclusions and does this make sense from the original data?)</p>	<p>Method of analysis outlined in detail and examples of coding given. (Chapters 4 and 7)</p>
<p><i>Are claims being made for the generalizability of the findings to either other bodies of knowledge or to other populations or groups and if so what are these claims?</i> (i.e. is it made clear which settings the findings can be applied to and does this seem to fit?)</p>	<p>Details are given of participants e.g. age, level of deprivation, level of multimorbidity etc. Acknowledgement of generalizability is given in the discussion section. Results are compared to the systematic review results to compare this group to the broader findings. (Chapters 7 and 8)</p>
<p><i>Is there any other aspect of the study that may affect the quality e.g. conflict of interest?</i></p>	<p>I work in one of the GP practices that participants were reporting their experiences of, although I took great care to reassure patients that everything was confidential. I had not been directly involved in any of their care. I wore casual clothes and used my first name with participants. (Chapters 4 and 7)</p>

4.7 Creation of the conceptual model

Lastly, a conceptual model was created to fulfil the following objective:

4. To integrate findings and create a conceptual model of treatment burden and patient capacity in stroke.

This process involved examining findings from the systematic review, cross-sectional study and patient interviews in order to scrutinize relationships between components and hypothesize causal processes. The creation of a conceptual model then enabled the identification of suggestions for future areas of research and improvements to health service delivery. The conceptual model created is presented in Chapter 8.

4.8 Conclusion

This chapter has described the rationale behind the methods used in this thesis, along with potential strengths and weaknesses. A multi methods approach has been used, including a qualitative systematic review, quantitative analysis of a large dataset taken from the primary care records, and qualitative analysis of interviews with stroke patients. This approach has allowed exploration of treatment burden and patient capacity in stroke and the creation of a conceptual model. Results and discussion are given in Chapters 5-8.

Chapter 5 – Systematic Review

5.1 Introduction

5.1.1 Aims of this chapter

To explore the experiences of treatment burden for those who have had a stroke through examination of the qualitative literature, and to build a taxonomy of treatment burden in stroke.

5.1.2 Rationale

The first step towards understanding treatment burden in stroke is to examine what has already been investigated and identified in the literature. This chapter describes a systematic review of the qualitative literature that explores the experience of treatment burden for those who have had a stroke. The qualitative literature was chosen as this type of research suitably lends itself to uncovering and exploring patients' perceived needs and behaviours, providing conceptual depth about the patient experience. As discussed in Chapter 4, there is some controversy over appropriate methodology, due to the novelty of this type of research and disagreements about the underlying epistemological and ontological assumptions. Nonetheless there is no doubt that qualitative research provides important information about the patient experience, and if we are to be able to characterise issues such as treatment burden, then there is a clear argument for the synthesis of qualitative studies.

5.1.3 Research question

What are the components of treatment burden that patients with stroke experience during the management of their illness?

5.2 Methods

A protocol was created and the review registered on Prospero, the International Prospective Register of Systematic Reviews

<http://www.crd.york.ac.uk/PROSPERO> (CRD42011001123). This is shown in Appendix 3.

5.2.1 Searching for papers

Qualitative studies seeking to understand the patient experience of stroke management were sought, using techniques involving direct contact with patients such as interviews and focus groups. As discussed in Chapter 4, an exhaustive search strategy was deemed suitable as the aim was to summarise the recent literature. Limitations of English language and year of publication 2000 and onwards were set. The language limit was set due to an unavoidable lack of funding for translation. No geographical restrictions were set. The year of publication as 2000 and onwards was chosen due to the quickly evolving nature of stroke management over recent decades, and the relevancy of current patient experiences to inform current health policy and practice.

A ‘scoping search’ was initially carried out with the aim of finding relevant terms and phrases. This consisted of: searching my own files; internet searching using the ‘berry picking’ method described in Chapter 4³⁰⁴; a preliminary search of databases via Ovid; the use of the ‘related articles’ function in Pubmed (<http://www.ncbi.nlm.nih.gov/pubmed/>) and Web of Science (<http://wok.mimas.ac.uk/>); and consultation with experts in the field. Ten highly relevant or ‘key’ papers were identified during this scoping search³⁹²⁻⁴⁰¹, and key words and phrases were compiled for contribution to the electronic search to follow.

Following the scoping search, electronic searching for relevant papers using a formal search strategy was carried out. A search strategy was created in consultation with an information scientist, informed by key words and phrases found during the scoping search. As discussed in Chapter 4, the search was centred on the following concepts: stroke; treatment burden; patient experience; and qualitative methods. Databases searched were Scopus, CINAHL, Embase, Medline & PsycINFO. Appendix 4 shows the full search strategy created using a combination of free text search terms and subject headings.

Initially, the search was carried out to include all publications up to and including March 2011 and this is indicated in the methods paper published in BMC Medical Research Methodology³⁸². An update to this search (up to and including February 2013) was then carried out at the request of the publisher of the

results paper (Plos Medicine)³⁸⁴. As discussed in Chapter 4, a formal update was not deemed necessary after this; however a search was carried out to ascertain if any pertinent studies had been published i.e. studies in which the exploration of treatment workload or treatment burden was stated as an objective or those which added any new information.

All references and footnotes of included papers were hand searched for relevant papers. Citations were searched of three highly relevant papers, two included in the review and one published just before the time limit^{203;396;402}. No further citation searching was carried out as no studies were identified from the citations of these three papers, which were picked because they had been cited frequently in the other papers, were deemed to be extremely relevant, and were written by well known, well published authors in journals with relatively high impact factors, just before the year 2000.

5.2.2 Paper screening

Distiller software was used for screening papers. This web based software enables all references to be stored then sorted into 'included' or 'excluded' as individual reviewers complete electronic questionnaires based on inclusion criteria (<http://systematic-review.net/>). I and another reviewer screened each title, abstract and full paper, with third party involvement for any disagreements. There were three stages of screening: 1) Title 2) Title and abstract 3) Full paper. Table 6 shows the inclusion and exclusion criteria used. During screening stages 1 and 2, each paper was advanced to the next level of screening unless both reviewers excluded it based on the same criterion. During stage 3, if there were any disagreements then a third party was involved to make the final decision.

Inclusion of studies was limited to those that involved direct patient contact or observation such as interviews or focus groups, and those that used qualitative methods of analysis to seek and identify themes or patterns discussed by participants. Studies using telephone, postal or internet questionnaires were excluded, as were those using document analysis, quantitative patient-reported measures, simple counts of patient responses, and language analysis presented as quantitative results. Studies were included that explored the patient

experience in any setting, but those investigating the patient experience of pilot or experimental studies were excluded, as the aim of the project was to understand the treatment burden that patients face in ‘real world’ settings.

Table 6 – Inclusion and Exclusion criteria for papers found ^{382;384}

Inclusion Criteria	
Types of studies	Publication date 2000 (inclusive)-present.
	Studies from any geographical location.
	English language.
	Studies using qualitative methods of analysis (to describe patterns or themes raised by participants) seeking to understand the patient experience through direct contact with patients or direct observation, describing the processes of illness management experienced by patients and their active contributions towards this. This includes original qualitative studies, studies involving secondary qualitative analysis of qualitative data, and a qualitative study as part of a mixed methods study e.g. the study also has a quantitative component.
Types of participants	Adults (>18 yrs).
	Diagnosed with at least one CVA /CVD / stroke, including ischaemic, intracerebral haemorrhage or subarachnoid haemorrhage, any anatomic location, as per WHO’s definition ‘rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin.’
	Being treated in any ‘usual care’ setting: primary; secondary; tertiary care, e.g. in the hospital, hospice, community, home or rehabilitation.
	Receiving care typical for that geographical location i.e. not part of experimental or pilot studies.
Types of outcome measures	Logistical burdens e.g. interacting with health care organisations, carrying out administrative work involving insurance companies or others, organising appointments or visits from health professionals, organising rehabilitation, arranging transport, funding care.
	Technical burdens e.g. enacting lifestyle changes, performing rehabilitation exercises, modifying environments, taking medications, using assistive technologies.
	Relational burdens e.g. enrolling family, friends and health professionals for support, initiating interactions with possible carers and supporters, maintaining relationships during rehabilitation.

	Sense making burdens e.g. conceptualising problems, understanding and learning about management strategies, knowing when to seek help, differentiating between treatments.
Exclusion Criteria	
Types of studies	Non English language.
	Published pre 2000.
	Grey literature / not published in a peer reviewed journal.
	Dissertations /theses.
	Proceedings.
	Published abstracts.
	Studies using the following methodologies: Lexical studies that analyse natural language data presented as quantitative results; studies without a sampling procedure; qualitative studies using questionnaires or other methods that do not involve direct contact or observation of participants; studies describing the patient experience in an experimental situation rather than 'typical', e.g. during pilot schemes or intervention/experimental trials; any study where qualitative data not analysed i.e. uninterpreted data; case report; any review (systematic, narrative, qualitative); any quantitative study (RCT, non RCT, observational, cohort, case control).
	Treatment guidelines documents.
	Commentary articles, written to convey opinion or stimulate research /discussion, with no research component.
Types of participants	Children (<18 yrs).
	No CVA diagnosis.
	Diagnosis of TIA, subdural haematomas, infarction / haemorrhage due to infection or tumour, cerebral palsy or any other neurological deficit.
	Mixed groups of participants e.g. patients and carers or health care providers, unless results from patients are explicitly separate from other participants.
Types of outcome measures	Anyone other than the patient's perspective of patient work e.g. health professionals.
	Burden on health services / systems or health professionals.
	Economic burden at a society level e.g. costs to government or councils.
	Carer work or burden.
	Standardized, patient-reported measures of treatment burden or illness burden / activities of daily living / quality of life / functional capacity.

5.2.3 Data extraction and quality appraisal

Distiller and Word software were both used during data extraction: Distiller for extracting details of participants and for quality appraisal; and Word for extracting data on treatment burden. For the first 54 papers found (original search up to March 2011), I and another reviewer conducted data extraction and quality appraisal with third party involvement for any disagreements. For data extraction of the 15 papers found during the subsequent search, I myself read through each paper and noted any new themes that arose. This was deemed appropriate because by that stage the coding frame was very well established.

The data extraction instrument developed is shown in Appendix 5. Data extracted for analysis was limited to data describing treatment burden: the self-care practices that patients with chronic illness such as stroke must perform to respond to the requirements of their healthcare providers and the effects of this on well-being^{11;12;112}. Author comments were extracted rather than primary data or verbatim quotes. Due to the large amount of irrelevant data within each paper, clear criteria for inclusion and exclusion of data were used to inform decision making as illustrated in Table 7. The criteria for inclusion of data and the data extraction instruments were created in advance of the review procedure, following discussion between myself, my supervisors and the other reviewers.

Table 7 – Inclusion and exclusion criteria for patient burden found in the data ^{382;384}

Inclusion criteria	Examples
Treatment burdens arising due to the demands of illness management	Several participants reported having multiple contacts with primary care services prior to diagnosis of stroke and hospital admission.
Treatment burdens arising due to service insufficiencies	Mr X (who, in addition to the stroke, suffered heart problems and had one leg amputated below the knee) spent over a thousand nights sleeping in a chair downstairs waiting for the housing department.
Exclusion criteria	Examples
Illness burdens such as symptoms or physical consequences of illness, changes to relationships due to illness, psychological consequences of illness.	Some of them had become physically handicapped and some had become more forgetful, while others suffered from fatigue.
	A number of people said that they tended not to tell anyone about their stroke unless they were family members or close friends because of perceived stigmatizing responses, which added to their psychological and physical isolation.
Lifework burdens such as those caused by circumstances and commitments out with the illness.	Mr x lived in a fairly isolated area with minimal public transport and his mobility was very limited until he was able to drive again. He thus experienced exclusion from his local community.
General comments on services and service deficits where no resultant treatment burden is discussed or no specific negative encounter has been endured.	One participant in the home setting discussed the importance of physiotherapy to her overall rehabilitation.
	Those interviewed expressed a great deal of sympathy and understanding for the health professionals that had cared and rehabilitated them.
Comments on patient perception for the purpose of the research project rather than for the purpose of stroke management.	In contrast to the very exact and detailed descriptions of falling ill most of the patients described very briefly and superficially their time in care.
Patient ideas and expectations.	The informant during his rehabilitation had a need for a reflected understanding of what rehabilitation meant to him when all his experiences were included.

An instrument was created for quality appraisal based upon published guidance by well-known qualitative researchers²⁷¹. This is shown in Table 8 and the rationale behind its use given in Chapter 4. The instrument consisted of eleven questions, each considering an aspect of quality such as rigour, validity, transparency and generalizability. Answers of ‘yes’ ‘no’ or ‘unclear’ were given by reviewers and answers compared. No scoring system or level of set ‘pass mark’ was set, because as discussed in Chapter 4: 1) the aim was to develop as comprehensive a taxonomy of treatment burden as possible and to minimise the risk of missing any key concepts; and 2) there is currently no consensus on the best way to appraise the quality of qualitative research for inclusion in systematic reviews³³⁸.

Table 8 - Quality appraisal instrument ^{382;384}

Appraisal Question (apply each question to the whole study to reach an overall conclusion i.e. aims, sampling, data collection, data analysis, interpretations)
<i>Does the research, as reported, illuminate the subjective meaning, actions, and context of those being researched?</i> i.e. is it ensured through design and analysis that emphasis is given to the interpretations of those being researched rather than the researcher's or professional's viewpoint?
<i>Are subjective perceptions and experiences treated as knowledge in their own right?</i> i.e. does the study treat the data collected directly from the participants, representing their viewpoint, as the basic data for analysis?
<i>Is there evidence of the adaption and responsiveness of the research design to the circumstances and issues of real-life social settings met during the course of the study?</i> i.e. is the process of sampling, data collection, data analysis and interpretation iterative? Is there evidence of adaption and redesign as the study has progressed?
<i>Does the sample produce the type of knowledge necessary to understand the structures and processes within which the individuals or situations are located?</i> i.e. is sampling appropriate for the aims, objectives, methods and conclusions reached?
<i>Is the description provided detailed enough to allow the researcher or reader to interpret the meaning and context of what is being researched?</i> i.e. is a rich picture produced, providing the context of an experience and the intentions and meanings that feed into it, rather than simply a set of facts?
<i>Are any different sources of knowledge about the same issue compared and contrasted and how is this done?</i> i.e. are different methods used to answer the research question and are these examined not only for similarities but for providing different facets of the reality being investigated?
<i>Has the researcher rendered transparent the processes by which data have been collected, analyzed, and presented?</i> i.e. is the whole process clear to the reader?
<i>Has the researcher made clear their own possible influence on the data?</i> i.e. has the researcher stated their own background / experience and ontological / epistemological stance?
<i>Is it clear how the research moves from a description of the data, through quotation or examples, to an analysis and interpretation of the meaning and significance of it?</i> i.e. what did the researcher do to reach their conclusions and does this make sense from the original data?
<i>Are claims being made for the generalizability of the findings to either other bodies of knowledge or to other populations or groups and if so what are these claims?</i> i.e. is it made clear which settings the findings can be applied to and does this seem to fit?
<i>Is there any other aspect of the study that may affect the quality e.g. conflict of interest?</i>

5.2.4 Data synthesis

In Chapter 4, the decision to use a novel method of data analysis - framework synthesis using a framework informed by Normalization Process Theory (NPT) - was discussed. NPT explains how the work of enacting an ensemble of practices (in this case the components of burden of treatment) is accomplished through the operation of four mechanisms: ‘coherence’ (sense-making work); ‘cognitive participation’ (relationship work); ‘collective action’ (enacting work); and ‘reflexive monitoring’ (appraisal work)¹¹⁷. Data were synthesised under the five stages of framework analysis discussed in Chapter 4: familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation^{346;349}.

Familiarisation

This involved reading and rereading included papers to familiarise with the content and become ‘immersed’ in the data.

Identifying a thematic framework

The coding framework was based on one that had been created during a previous study involving the analysis of semi-structured, qualitative interviews with chronic heart failure (CHF) patients¹¹. During this previous study, the coding framework had originally been created using the constructs of NPT and subsequently adapted and refined during framework analysis of the interviews. In the current study, the stroke coding framework was therefore initially created deductively using the previous CHF framework, as well as preconceived ideas from my own clinical knowledge and understanding of the literature. It was subsequently inductively adapted and refined during analysis to create a stroke-specific coding frame for treatment burden. The final framework is shown in Table 9.

Indexing, charting, mapping and interpretation

The coding framework was used to identify, describe and understand the components of treatment burden experienced by patients with stroke. Data was coded under the four NPT domains (coherence, cognitive participation,

collective action, reflexive monitoring) and their subconstructs, shown in Table 9. Several codes were created within each subconstruct, and these were subsequently grouped together under treatment burden headings. A careful note was made of any treatment burdens that fell outside the coding framework, in order to assess if it was ‘fit for purpose’, as one risk of using such a technique is that findings may be ‘shoe horned’ into the framework and having an ‘outside framework’ code aimed at minimising the risk of this.

Data were then organised into framework codes, and themes created within and between codes by looking for regularities and irregularities as well as relationships between components. A pragmatic approach was then taken and themes reorganised into a taxonomy of treatment burden under headings that reflect different processes of stroke care. Findings were then examined again in relation to the theoretical framework underpinned by NPT. This taxonomy reflected the original accounts of the patients being studied, so could be described as ‘grounded’ in the data, with the framework underpinned by NPT being used for extraction and organisation ³⁸².

A good systematic review involves a team of researchers to minimise bias as recommended in guidelines for the conduction and reporting of systematic reviews^{309;403}. As well as regular meetings between the reviewers coding each paper, ‘coding clinics’ were held on several occasions, where coding and differences were discussed. Refinement of the coding frame and analysis was therefore iterative. Later on in the analysis, the emergence of themes and the creation of the taxonomy and conceptual model were also discussed amongst researchers.

Table 9 - NPT-based coding framework ^{11;382;384}

<p>COHERENCE <i>(Sense-making work)</i> Understanding the prospect of having stroke, what this means and how the condition may be managed.</p>	<p>COGNITIVE PARTICIPATION <i>(Relationship work)</i> Investing personal and interpersonal commitment to living with the condition and its management.</p>	<p>COLLECTIVE ACTION <i>(Enacting work)</i> Investing effort and resources in management, carrying out tasks and experiencing the illness.</p>	<p>REFLEXIVE MONITORING <i>(Appraisal work)</i> Reflecting on the effects of therapies in retrospect and determining whether to modify them.</p>
<p>Differentiation Understanding and differentiating between risk factors, investigations, treatments and the roles of different health professionals or services. Prioritising treatments and activities.</p>	<p>Enrolment Engaging with friends, family and health professionals with regard to diagnosis and illness management to enable them to provide support. Adjusting relationships to accommodate new roles as a result of illness management. Protecting family members during management.</p>	<p>Skill set workability Setting a routine/strategy to cope with symptoms, exacerbations, and emergency situations i.e. therapeutic interventions. Enacting activities with a view to achieving goals. Controlling risks associated with recovery. Learning through practice.</p>	<p>Reconfiguration Altering a set routine when required such as medication regimes or appointments, to fit in with daily activities or other arrangements. Learning a new way of doing things after stroke. Altering priorities and ways of thinking due to stroke management.</p>
<p>Communal specification Gaining information about illness management with the help of others, for example friends, family or health professionals. Receiving diagnosis, or misdiagnosis.</p>	<p>Activation Arranging help (e.g. logistical, administrative, or expert) from health professionals, social services or friends and family. Seeking help at onset of stroke.</p>	<p>Contextual Integration Making sure you have the right financial and social resources, and integrating the illness into social circumstances. Managing potential environmental dangers through making resources available. Adjusting to new social role in society or life circumstances such as unemployment. Experiencing good or bad environmental situations such as unemployment.</p>	<p>Communal Appraisal Discussing or altering current management plans already initiated, in discussion with health professionals or friends and family. Recalling previous events with friends and family.</p>

<p>Individual specification Achieving your own understanding illness management in personal terms, through personal research such as reading, or personal life experience.</p>	<p>Initiation Using organisational skills to arrange one’s own contribution to management, such as arranging prescriptions, social care and transport to appointments.</p>	<p>Interactional workability Taking treatments, enacting lifestyle changes, attending appointments, enduring side effects. Enduring poor health care or care that does not meet expectations (e.g. poor interactions) Enduring setbacks in recovery. Learning self-care. The work of rehab. The work after discharge. Enduring intrusions and interventions from family members, including negative interactions such as a lack of support.</p>	<p>Individual appraisal Assessing individually whether to continue or alter current management plans. Recalling previous events. Monitoring symptoms and progress (but not as a routine, see below).</p>
<p>Internalization Relating your experience to illness management, understanding any implications, knowing when to seek help, Understanding one’s own contribution to reducing risk, knowing limitations and risks due to stroke. Calculating safety risks. Maintaining motivation and determination. Overcoming barriers in receiving information. Developing expectations of health services. Making sense of progress in recovery and one’s own contributions to this. Setting goals for recovery.</p>	<p>Legitimation Seeking reassurance about treatments from others about appropriateness of management plans. Gaining confidence in the success of treatments from others. Dealing with stigmatisation or a mismatch in ideas and expectation from others. Reaching an understanding that treatments are ‘the right thing to do’. Comparing yourself to others to validate treatments. Coping with guilt about new role.</p>	<p>Relational Integration Maintaining confidence in health professionals and their interaction with each other. Maintaining confidence in care plan. Coping with multiple caregivers. Enduring system failures caused by poor communication / interaction between service providers. Handing over responsibility of care.</p>	<p>Systematization Developing ways of keeping up to date with newly available treatments. Routine self-monitoring.</p>

5.3 Results

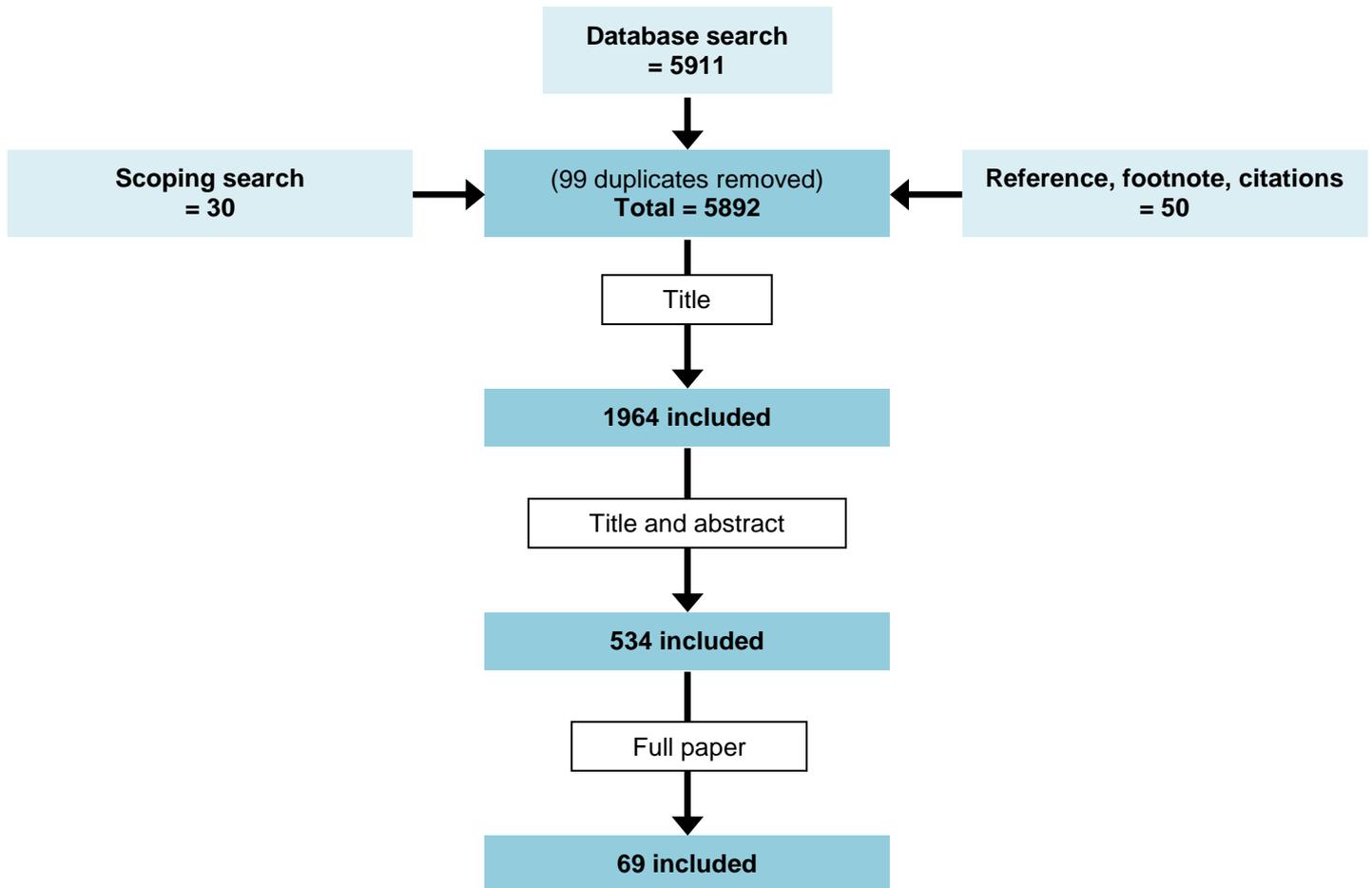
5.3.1 *Included papers*

Of the included studies, none explicitly stated the investigation of treatment burden as a research objective; however, all contained significant amounts of information on treatment burden in the results or discussion sections³⁸².

Research objectives varied significantly between studies, to demonstrate this the included studies have been broadly categorised into the following areas of research (Appendices 6 and 7): recovering from stroke; the interaction between patient and health services; return to work / retirement; nursing home experience; coping strategies; living with aphasia; physiotherapy / exercise; motivation / hope in recovery; reintegration into the patient's lifeworld and community; gender differences; the patient's interpretation; returning to driving; multimorbidity; using a wheelchair; eating difficulties; goal setting; and medications.

During the scoping search, 30 potentially relevant papers were found, 10 of these were deemed to be 'key' papers as described above. 5911 papers were identified from the database searches. Another 50 were identified from reference searching. None were identified from footnote or citation searching. 99 duplicates were removed, resulting in a total of 5892 papers. 69 reached the final stage of data extraction and analysis following the update to February 2013. No pertinent studies were found in the update to February 2016. The PRISMA flowchart is shown in Figure 1. Of the 69 papers included, 66 (96%) were retrieved from the database search. The 3 papers included that were not found from the database search were found from reference searching^{65;404;405}.

Figure 1 – PRISMA flowchart of included papers



5.3.1.1 Study Details

Full details of included papers are given in Appendices 6 and 7. Key descriptive information of included papers is as follows. Country of study: Sweden (n= 19)^{393;397;399;400;402;404;406-418}; UK (n=12)^{37;65;392;396;405;419-425}; Canada (n=11)^{165;401;426-434}; Australia (n=10)^{394;435-443}; US (n=5)⁴⁴⁴⁻⁴⁴⁸; Norway (n=3)^{395;449;450}; Netherlands (n=3)^{398;451;452}; New Zealand (n=2)^{193;453}; Iran (n=1)⁴⁵⁴; Republic of Ireland (n=1)³¹⁴; Nigeria (n=1)⁴⁵⁵; and China (n=1)⁴⁵⁶. Participant numbers ranged from 1 to 113. Setting: community (n=34)^{37;165;314;392;394;399;400;402;404;406;408;409;411;417;419;421;425;426;428-430;432-435;437;440-442;447;450;453;454;456}; outpatient (n=5)^{397;410;413;422;455}; care homes (n=3)^{398;451;452}; hospital (n=6)^{405;407;416;420;445;448}; stroke units (n=8)^{396;412;414;415;423;424;431;436}; stroke medical centre (n=1)³⁹⁵; and mixed setting such as hospital and community (n=12)^{65;193;401;418;427;438;438;439;443;444;446;449}. Gender of participants: males and females (n=56)^{37;165;314;392-396;398-402;405-408;410-419;421;424-430;432;433;435-441;443-445;447-454;456}; male only (n=6)^{65;404;409;422;423;455}; female only (n=2)^{431;442}; unclear (n=5)^{193;397;420;434;446}. Ages of participants ranged from 22 - 100 years, this was unreported in a few studies (n=7)^{193;393;397;420;446;447;450}. Time since stroke (n=41)^{37;314;394;395;399;400;402;404;406;411-413;416-419;422-431;433-436;438;440-445;448;450;454;455} ranged from under 2 weeks - 16 years. Disability since stroke (n=39)^{37;65;314;395-397;399;401;404-406;409;411;413;415-417;419;424-426;428;431-434;436;437;440;441;443-445;447;449;450;453;455;456} was very variable. Ethnicity, when reported (n=13), varied between studies^{396;401;419;424-426;429;430;432;440;444;445;448}. Co-morbidities were seldom mentioned (n=11)^{65;165;393;394;415;421;425;432;440;441;451} nor were medications (n=3)^{37;65;165}. Qualitative data gathering methods: interviews (n=63)^{37;65;165;193;314;393;395-402;404-433;435-443;446;448-456}; focus groups (n=4)^{394;444;445;447}; interviews and focus groups(n=2)^{392;434}; additional field notes (n=5)^{398;417;429;430;455}; additional patient observation (n=1)⁴³⁶. Data analysis: a variety of qualitative methods were used, all sought to identify common themes raised by participants, details are described in Appendix 7. In one study, method of data analysis was not clear (n=1)⁴⁴⁵. Inclusion / exclusion criteria and a summary of findings are also described in Appendix 7.

5.3.1.2 Quality appraisal

Papers were generally of a reasonable quality, aspects of quality that were most poorly demonstrated include acknowledgment of the researchers influence on the analysis; and any note of conflicts of interest. A summary of the quality appraisal is shown in Table 10.

Table 10 – Results of quality appraisal ^{382;384}

Appraisal Question	Yes	No	Unclear
Does the research, as reported, illuminate the subjective meaning, actions, and context of those being researched?	68	0	1
Are subjective perceptions and experiences treated as knowledge in their own right?	68	0	1
Is there evidence of the adaption and responsiveness of the research design to the circumstances and issues of real-life social settings met during the course of the study?	39	27	3
Does the sample produce the type of knowledge necessary to understand the structures and processes within which the individuals or situations are located?	62	3	4
Is the description provided detailed enough to allow the researcher or reader to interpret the meaning and context of what is being researched?	66	3	0
Are any different sources of knowledge about the same issue compared and contrasted and how is this done?	38	31	0
Has the researcher rendered transparent the processes by which data have been collected, analyzed, and presented?	67	2	0
Has the researcher made clear their own possible influence on the data?	24	43	2
Is it clear how the research moves from a description of the data, through quotation or examples, to an analysis and interpretation of the meaning and significance of it?	65	4	0
Are claims being made for the generalizability of the findings to either other bodies of knowledge or to other populations or groups and if so what are these claims?	50	17	2
Is there any other aspect of the study that may affect the quality e.g. conflict of interest?	1	31	37

5.3.2 Treatment burdens

The following areas of treatment burden were identified from the literature, each representing a process of stroke care: 1) making sense of stroke management and planning care; 2) interacting with others including health professionals, family and other stroke patients; 3) enacting management strategies, which includes (a) enduring institutional admissions, (b) managing stroke in the community, (c) reintegrating into society, and (d) adjusting to life after stroke; and 4) reflecting on management. A full taxonomy of treatment burden is shown in Table 11 with exemplar quotations. No treatment burden was identified that fell outside the coding framework. Here only some illustrative quotes are provided.

Table 11 - Taxonomy of treatment burden with exemplar quotations ³⁸⁴

1) Making sense of stroke management and planning care	Making sense of symptoms to aid diagnosis and seek help	The patients ignored the first symptoms of neurological damage although they all were in places where they could easily get in contact with a qualified hospital. M2 was attending a conference. F1 was going to have her car checked. M1 was at his country residence near the town ⁴¹³ .
	Understanding investigations, acute interventions, medications, risk factor modification and negotiating medical terminology	Although the stroke was understood as a serious disease, which they wanted to prevent, they did not seem to be aware of which risk factors were relevant. At least they did not bother to minimize these risk factors ³⁹³ .
	Information gathering from health professionals, enduring poor information provision	Not being adequately informed concerned what the participants described as absent, contradictory or incomprehensible information. Some of them had not received any information other than what was given to them in a brochure about stroke. Others had wanted more detailed information about their brain injury, the reason for examinations performed, the results and the prognosis. Further, contradictory information with regard to the cause of their stroke and about their treatment was described ⁴⁰⁰ .
	Enduring poor information for carers and families from health services	Another perspective on this theme was the call for family education. Participants felt that their families required more information about fatigue, particularly regarding the long-term nature of the problem ⁴⁴⁷ .
	Carrying out research external to health services	Often, the health care system was unable to offer these patients a doctor who fulfilled their demand of competence and behaviour. Instead, they picked information from sources at hand, for instance books and friends ⁴¹³ .
	Understanding the roles of different health professionals	As a result of all the changes, patients feel insecure on admission, describe themselves as lay persons and the health professionals as experts, and find it difficult to judge the work of the health professionals ⁴⁵¹ .
	Working out priorities for rehabilitation	Participants with communication difficulties described these as overwhelming and many became preoccupied with regaining their communication abilities, to the extent that other needs or physical symptoms were ignored ⁴³⁵ .

	Goal setting	Although the major focus is on bodily improvement, the patient also directs attention towards more practical issues. In this phase, the major concern is related to the possibilities of returning home. The patient initiates an appraisal process of what problems he might face and possible ways of handling them ³⁹⁵ .
	Gaining motivation	Managing and maintaining motivation for rehabilitation regimes was difficult for some participants. Some who were unable to muster motivation for an extended time appeared to be hampered by a lack of acceptance about what had happened to them ³⁹⁴ .
	Taking responsibility and using initiative, drawing on former life skills	When the informants experienced that the rehabilitation professionals did not take action, they took control of the situation themselves. The informants expressed pride in their own capacity to take the initiative and in their ability to take action ³⁹⁷ .
	Managing uncertainty of prognosis	Uncertainty about prognosis, along with anxiety about the degree of recovery that would be achieved became predominant concerns during rehabilitation. For some participants, distress arose from overly optimistic expectations about speed of recovery; others perceived that there was some deadline by which they must recover ³⁹⁴ .
	Problem solving	One way in which participants perceived therapy helped to facilitate progress was by responding to problems and solving each difficulty as it arose ⁴²⁴ .
	Developing coping strategies	It is clear from the discussion that patients saw physical limitations as challenges to be overcome by their own individual effort. They believed that it was their job to recover from the physical consequences of stroke, and they developed personal coping strategies in order to do so ⁴⁴⁴ .
	Experiencing negative emotions associated with management strategy e.g. guilt, frustration	Many participants acknowledged that napping during the day was part of their daily routine, although they often expressed feeling guilty about it ⁴⁴⁷ .
	Using spirituality	Spiritual and religious resources were also mentioned by four people as helping them deal with the difficulties in their post-stroke lives ⁴²⁸ .
2) Interacting with others	Seeking advice or reassurance from health professionals	The judgements made by the health care providers about the recovery are important because the stroke survivors use them to validate the progress of their rehabilitation ⁴⁰² .
	Contacting health professionals for practical help	Temporary pain relief was obtained from prescribed medication, which they received after contacting the doctor or nurse, so they were able to get some sleep ⁴⁰⁰ .

	Developing relationships with health professionals	To establish a personal relationship with the staff was useful in several ways. They felt more free to ask for help with personal care and to ask questions about their diagnosis and prognosis ⁴¹⁰ .
	Coping with paternalism from health professionals	Although participants perceived therapy to be an important factor, five participants suggested an inequality within the relationship. They described feeling controlled by the therapists regarding which direction therapy would take and the activities which were to be practiced. Not all participants were comfortable with what they perceived to be a passive role ⁴²⁴ .
	Enduring a lack of understanding from health professionals	Lack of understanding had also to do with attitudes, with what they experienced as unreasonable demands on the part of both the professionals and their next of kin. They described incidents where the professionals had been annoyed with them when they had been in a bad mood or very tired during their physical exercises, or when encountering over-strained professionals. There were also experiences of a feeling of superiority on the part of the professionals, expressed in a comment or a glare ⁴⁰⁰ .
	Coping with a mismatch in ideas about management and recovery with others	For them recovery involved dimensions that were not included in the health care professionals' concept...The goal for them was either to recapture their former social position or to adapt to another life situation ³⁹⁹ .
	Misdiagnosis at initial presentation	Several participants reported having multiple contacts with primary care services prior to diagnosis of stroke and hospital admission ⁴²² .
	Having difficulty accessing services	Patients feel that therapy and supervised exercises in the ward facilitate regaining self-care, but they experience a lack of therapy and supervision, for example, when their therapist is ill or during weekends. In the patients' view, this problem can be solved but patients find it difficult to judge ⁴⁵¹ .
	Experiencing poor communication between services	Some hospital procedures (i.e., ordering medical tests, waiting on transfer from another ward) that involved other hospital departments created uncertainty and made it difficult for some participants to be given information on some topics (i.e., which tests they would be having on a certain day and at what time) ⁴³⁶ .
	Enduring poor continuity of care and consistency of services	Messages—A few low motivation patients described some of the stroke unit professionals as giving out unhelpful "mixed messages." One patient-reported that physiotherapists encouraged her to work at rehabilitation. On returning to the ward, however, she thought the nurses discouraged such effort by putting her to bed. This resulted in confusion regarding the correct way to behave ³⁹⁶ .
	Arranging social care	Home care staff shopped for two participants; this worked well for one after some initial misunderstandings ⁴¹⁹ .
	Gaining emotional support from friends and family	Meaningful relationships – Support: "Don't do it alone." Overwhelmingly, participants highlighted that the support offered through meaningful relationships was a key component contributing to living successfully with aphasia ⁴⁵³ .

	Gaining practical support from family and friends	Being given practical and emotional support by their next of kin was experienced when they received help and the next of kin had performed certain tasks for them. They described help from their spouses in specific activities of daily living, and a few described getting support in their daily exercises. They appreciated being taken out for a drive or a walk. Emotional support was also experienced in connection with being together, mainly with one's spouse. Further there was the concern shown by the next of kin by keeping in contact regularly ⁴⁰⁰ .
	Experiencing a strain on relationships due to management strategies	Negative supports hindered strategies designed to adapt to disabilities. For example, one woman's efforts to adapt to her cognitive disabilities and enhance her sense of mastery and control were repeatedly foiled by her husband's negative attitudes and attempts to remove her adaptive aids ⁴²⁶ .
	Protecting carers from their burden	He was reluctant to go out with his wife, feeling that he was too much of a burden. He did, however, persuade a friend to take him to the local pub once a week in his wheelchair. He felt that this was his way of giving his wife a rest from coping with his stroke ⁶⁵ .
	Gaining support from other stroke patients and support groups	Participants described the unique and important role played by stroke support groups. As well as providing an enjoyable social gathering, participants described feeling understood by others in the group, in a way that family or friends could not understand ⁴³⁵ .
	Experiencing stigmatisation due to management of physical disabilities	Some participants felt that people "felt sorry" for them or were "ignorant" or "nosey," and some felt that people were overly helpful, to a fault ⁴²⁹ .
3a) Enacting management strategies: Institutional admissions	Undergoing acute care	The criticism expressed by the men concerned, for example, the long waiting hours at the emergency department before being admitted to the ward and also the way in which treatment was effectuated ⁴¹⁰ .
	Undergoing inpatient rehabilitation	His stay on the rehabilitation unit was of approximately 3 weeks duration, in which time he received physiotherapy for mobility and arm function, and occupational therapy to improve his ability to dress himself. By the time he was discharged, Robert could transfer between a chair and bed independently, and could mobilize with the help of one person and a walking frame ⁶⁵ .

	Fitting into ward routines	During the few days the participants were in the ward, there were a lot of new things to consider. Apart from facing the fact that they had had a stroke, they had to become aware of the daily routines in the ward and try to understand and follow them. This concerned, for example, hours when meals were served, what time the doctors' rounds took place, what nurse and nurse assistant were responsible for their specific care, how and when it was appropriate to call for help, when the therapists were present at the ward and the staff's expectations of their rehabilitation and outcome ⁴¹⁰ .
	Loss of autonomy and dignity as an inpatient	Loss of control over personal care (toileting, showering, eating) was described as particularly confronting. Almost all participants described being emotionally upset at the 'loss of dignity' they encountered during hospitalization ³⁹⁴ .
	Unfamiliar or unpleasant surroundings on the ward	The participants spoke of the overwhelming boredom they experienced in the rehabilitation setting ⁴²⁰ .
	Admission to a care home	In comparison with hospital, patients experience a personal atmosphere and receive more physiotherapy, occupational therapy and speech therapy which also facilitate autonomy ³⁹⁸ .
	Learning self-care skills to prepare for discharge	Patients take stock of the situation and indicate their priorities in learning. Learning self-care skills requires their own effort ³⁹⁸ .
3b) Enacting management strategies: Managing stroke in the community	Discharge from hospital	The initial period after discharge was, for some of the stroke survivors, filled with practical problems because they did not feel adequately prepared to handle their daily lives and unexpected bodily reactions. As patients they had handed over the responsibility for the care of their stroke and related problems to the health care professionals. After being discharged from hospital to their homes they were left to manage by themselves in their former social context ⁴⁰² .
	Poor access to services in the community	Approximately half of the participants had, at some stage, received support from a psychologist, psychiatrist or counsellor in coping with their stroke, but this support was described as difficult to access and not available when most needed ³⁹⁴ .
	Undergoing rehabilitation programmes in the community	He carried on with the work rehabilitation he had been assigned although he found it exhausting and totally meaningless. He saw no other solution ⁴⁰² .
	Taking and managing risks during rehabilitation	One aspect of rehabbing self that was reported by several participants was taking risks. This was a strategy employed in the phase of rehabbing self. It was identified as trying something without a guarantee that it was possible or would work ⁴³⁴ .

	Reaching goals	Participants described that the process of community reintegration up to one year post stroke, rehabilitation involved transitioning between a series of goals: gaining physical function, establishing independence and adjusting expectations to get back to real living ⁴⁰¹ .
	Establishing and adhering to a medication regime	Almost all participants in the high adherence group recognized the importance of having a stable routine for taking their medication, and most had found a system that worked well for them. Taking their tablets was often spontaneously described as 'routine', 'natural' or a 'habit' and was consistently cued to particular daily activities such as showering or eating meals ³⁷ .
	Enduring medication side effects	Some low adherers also reported bad side effects of their medication. However, unlike high adherers experiencing side effects, who tended to persist with their medication or sought an alternative medicine from their general practitioner, patients in the low adherence group were more likely to alter their dosage or stop taking their tablets altogether to counteract any negative reactions ³⁷ .
	Managing risk factors	A few appeared to have been proactive about controlling their risk and talked about getting information or taking action to control blood pressure. A couple reported having faith in their treatment ⁴²¹ .
	Adjusting diet	The diets of participants varied considerably. Since the stroke, three survivors had adopted cholesterol-lowering diets, one had excluded wheat products and another had espoused a 'healthy' diet (reduced fat, increased fruit and vegetable intake). One now drank less alcohol and had lost weight, another drank more and had gained three stone. Two diabetics described how they now used sugar to 'keep your strength up' ⁴¹⁹ .
	Managing eating difficulties	Preventing things happening could mean to take small bites instead of big ones, to avoid that food getting stuck when too much food was put into the mouth at one time, and discovering which type of food they could choose ⁴¹⁵ .
	Managing psychological difficulties	The use of relaxation exercises and tapes provided relief from emotional distress, particularly in the hospital environment ³⁹⁷ .
	Managing pain	Satisfaction was described as a result of various treatments offered by the professionals, such as aquatic exercise and massage by Transcutaneous Electrical Nerve Stimulation (TENS), also as a result of receiving help in changing their body position at night ⁴⁰⁰ .
	Regaining communication skills	Participants with communication difficulties described these as overwhelming and many became preoccupied with regaining their communication abilities, to the extent that other needs or physical symptoms were ignored ³⁹⁴ .

	Taking physical exercise	Physical exercise was reported by participants with nociceptive pain in order to prevent pain by stretching their shoulder/arm using training equipment, or aquatic exercise. In order to relieve their pain, participants with central pain did perform physical stretching exercises, but were careful to avoid overexertion. The participants with tension-type headache reported that they went out for a walk to get some fresh air in an attempt to relieve the headache ⁴⁰⁶ .
	Managing co-morbidities	Extra coping strategies, such as pharmaceutical use and activity avoidance, were used by participants to deal with the additional difficulties associated with having arthritis while recovering from a stroke, in order to remain engaged ¹⁶⁵ .
	Making adaptations to the home environment or finding new accommodation	Another problem that PEG feeding could pose was the space occupied by supplies and equipment; this hampered mobility of a wheelchair dependent stroke survivor in a tiny bungalow ⁴¹⁹ .
	Enduring inadequate home services	The self-care activities that were not possible for many of the stroke survivors included taking a bath or shower, brushing teeth and having sexual intercourse. This caused frustration and humiliation for them. One described not being able to have enough assistance with taking a shower because of the regulations of the attendant care service ⁴³² .
	Coping with multiple health-related appointments	Returning home was overwhelming. Participants were confused, busy and tired because of health-related appointments and visits from friends and family ⁴⁰¹ .
3c) Enacting management strategies: Reintegrating into society	Returning to driving or negotiating new methods of transport	For those that did resume driving during the first year post rehabilitation, it was critical to regaining control and independence ⁴⁰¹ .
	Returning to work	The occupational therapist was involved in this RTW process and arranged meetings with the workplace, the manager, and in one case also with co-workers. However, only two of the six informants had experienced such a liaison. It was more common that no preparation at all had taken place for return to work when they were discharged from the hospital ³⁹⁷ .
	Acquiring mobility and technical aids	Despite the fear of becoming dependent, however, some participants had been able to change habitual ways with the use of technical aids. Aids for increasing mobility, such as walking canes, walkers, and wheelchairs seemed to have a degree of acceptability and in regard to clothing, participants had also begun to introduce certain adaptations ⁴¹⁶ .

	Negotiating environmental barriers to wheelchair use	The wheelchair helped them with distances when they were tired, but was seen as a nuisance by others because of space restrictions, getting the wheelchair through narrow doorways in the home and community was a problem ⁴³² .
	Managing financial difficulties	The stroke survivors in this study did not have the economic resources to modify their existing living environment, except for a few renovations to their homes. The majority relied on low technology devices to manage in their homes ⁴³² .
	Negotiating government benefit systems	Organizations were frequently viewed as threatening or oppositional, setting up road blocks to needed resources. One of the primary bureaucracies that survivors contended with relates to obtaining disability payments, often an arduous task ⁴⁴⁸ .
3d) Enacting management strategies: Adjusting to life after stroke	New daily structure to accommodate illness management	Initially trying pre-stroke behaviours for occupational performance, the participants in this study soon learned to try modifications of their usual routines as an adaptive response to the challenge of fatigue in their daily roles. The context of their lives had to be reconfigured to accommodate this powerful phenomenon of fatigue ⁴⁴⁷ .
	Relearning ways of doing familiar tasks	Over time, some participants were able to adapt to a new way of life. This entailed learning how to do new things, relearning abilities (such as spelling, communication, walking) and continued commitment to the rehabilitation process ³⁹⁴ .
	Planning activities ahead of time	The study data suggest that problems with performance of habits after stroke, previously used to accomplish daily occupations had been disrupted. The participants had to plan ahead, think, and reflect when carrying out a daily occupation simply to manage their everyday lives. Despite living in a familiar home environment, many of the daily occupations that participants had previously done no longer seemed to be easy to perform and even if repeated often they didn't become habitual. Participants felt that, no matter what they did, they had to think about and plan their daily occupations in advance ⁴¹⁶ .
	Adopting strategies to deal with physical disabilities	Practical solutions to physical limitations, such as carrying a communication card, making lists to assist memory or finding new ways of dressing independently were empowering ³⁹⁴ .
	Adopting strategies to deal with cognitive disabilities	In order to try to adapt to her memory problems following her stroke, Mrs. N.M. developed an extensive filing system of her various interests, which catalogues the various things she needs to know about different tasks and activities. However, her husband is very critical of this system and tries to remove its presence from the house ⁴²⁶ .
	Searching for a sense of self	More often than not, individuals struggle to participate in their daily lives, in an attempt to reach their pre-stroke level of participation ⁴⁴⁷ .
	Developing acceptance	One prominent theme among those women who had apparently lost hope was acceptance. Although the loss of hope is often associated with depression, these women described an acceptance of their limitations [89].

	Enduring a plateau in recovery	During rehabilitation some patients experience a status quo (levelling out in their rate or degree of progress) regarding the dimension self-care ³⁹⁸ .
	Changing expectations and examining priorities over the recovery period	Gradually, they learned that their initial timeframe was too optimistic. The `horizon of time' shifted from a few days to a few weeks, to half a year, to within a year, and so forth. This change occurred as the patients gained experience with their bodies and the slowness of improvement ³⁹⁵ .
4) Reflecting on management	Decision making about treatments	Discontinuing medication, both prescribed and non-prescription analgesics, was reported by participants in all groups because of insufficient pain relief and side effects or fear of side effects ⁴⁰⁶ .
	Shared decision-making about treatments	Although decision-making about their own treatment is difficult for most patients, they valued shared decision-making, e.g. about destination and moment of discharge, recreation, meals, therapy schedules, care routines, and aids ⁴⁵¹ .
	Monitoring progress in recovery	Mr Neville an 80 year old man set himself the target of walking unaided by the time he left hospital....He kept a diary of is progress which he made available to the research team...Stroke survivors presented their goals as an aspiration or a challenge. By definitions they were activities that were important or valued and they could not perform. The goals were often related to the recovery of specific skills that were part of personal competence and identity ³⁹² .
	Gauging recovery by comparing self to others	Comparisons with other patients - one patient took the example of a stroke patient who recovered well as a source of confidence in her own recovery. Other patients, however, reported feeling depressed at the fact they were not rehabilitating as well as other patients ³⁹⁶ .
	Self-monitoring for further signs of stroke	Several survivors reported that they were more sensitive to their body and were vigilant in seeking to identify any body signs or changes that could be an early warning of another stroke. Mrs Dean and Mrs Garrett were both sensitive to changes close to their brain, but they reacted in different ways to episodes of facial numbness ³⁹² .
	Maintaining confidence in care plan	Whenever participants were transitioning to a new goal, for example from gaining physical function while in rehabilitation to establishing independence within the community, the experience was marked by a decrease in confidence. This decreased confidence was the result of being faced with challenges not experienced since their stroke ⁴⁰¹ .
	Keeping up to date with new treatments	One man told a story about when he had asked the doctor for more protective treatment against new strokes ⁴¹⁰ .

The four areas of treatment burden identified in the literature will now be discussed.

5.3.2.1 Making sense of stroke management and planning care.

The cognitive processing of information involved in stroke management was frequently mentioned in the literature. During management of their stroke, it is necessary for patients to find and comprehend a large amount of information about their healthcare^{402;410;413;421;424;436;447}. Even before diagnosis, patients assess symptoms and make decisions about seeking help^{413;434;435}.

Poor knowledge of stroke was evidenced by the failure of the majority of participants to respond to their stroke symptoms as an emergency. Many participants continued to conduct their daily activities and postponed seeking medical attention because they perceived it was inconvenient or unnecessary and they thought their symptoms would resolve themselves⁴³⁵.

Once the decision to seek help has been made by a patient, they attend a health professional for assessment, yet some described difficulty in obtaining a correct diagnosis⁴²².

Several participants reported having multiple contacts with primary care services prior to diagnosis of stroke and hospital admission⁴²².

Following diagnosis, patients learn about their diagnosis of stroke from a health professional, and are given information on necessary investigations, acute interventions, medications, and risk factor modification^{402;410;436;447}.

Participants who took on an active role would initiate health information exchanges by spontaneously requesting information, clarifying information, and requesting further information if the initial information was insufficient⁴³⁶.

The information received is not always easy to come to terms with, such as information about long-term physical disabilities, or information that is unexpected^{404;411}.

When he described the encounter with the physician at the Department of Rehabilitation Medicine, he seemed to have been

surprised when the doctor told him that he might not recuperate and the doctor instead talked about retirement⁴⁰⁴.

Patients described difficulty in obtaining information, frequently encountering barriers from health services. Information provision was either lacking, poorly timed or in a form that is incomprehensible^{37;396;400;410;434;436;437;439-441;456}. Patients depicted a lack of time being given for the provision of information from doctors, nurses and allied health professionals and similarly inadequate time for patients to ask questions in return⁴³⁶. One study reported that women complain about poor information provision from medical staff more strongly than men⁴¹⁰.

Following the consultation, access to information was described as insufficient, with a lack of resources available to patients in the community. This can result in extensive information seeking^{394;413;436;437;440} by patients as they attempt to make sense of the array of changes that have occurred in their lives^{395;398;402;420;423;430;436;447;451}.

As a result they spend significant time seeking information from elsewhere, making personal sense of their circumstances and feeling unprepared and unequipped to deal with the array of changes that are occurring in their lives³⁹⁴.

Education for family members was also described as lacking, resulting in the need for patients to research information on behalf of their caregivers⁴⁴⁷. One paper suggested that poor information provision is a particular issue for patients with certain characteristics that may make them more vulnerable and less able to communicate with health professionals⁴³⁶.

In most instances where no health information was exchanged... negative participant characteristics were observed... such as disinterest, fatigue, limited responsiveness or unresponsiveness, and uncooperativeness⁴³⁶.

Along with making sense of stroke and its management, much effort is allocated to planning and organising care during stroke rehabilitation. Patients make calculated decisions about their contribution to the management of their stroke such as prioritising therapies and setting goals^{392;393;395-397;401;404;405;415;418;422;424;426;433;434;436-439;441;450}. They make decisions about risk

factor management, altering health-related behaviours and planning lifestyle changes to prevent a further stroke⁴⁰⁸.

The respondents felt a motivation to make changes to promote their health in order to avoid a new stroke. Strategies used for this purpose were different and related to the problems perceived. Retirement from work or a change in work intensity, changes in responsibility taking in life, making priorities that were believed to promote health, exercise, dietary changes and regular control of risk factors were ways the respondents believed they would gain better health and avoid a new stroke⁴⁰⁸.

Goals for recovery often focus on reaching a former social status or role within the family^{393 392;397;404;437;442}. One study reported that goal setting varies between men and women, with women focussing on resuming tasks within the home and men concentrating on the accomplishment of tasks out with the home environment⁴⁰⁷.

Patients develop expectations of themselves as well as their health service providers and work at maintaining motivation during the long recovery process^{394;396;423;433;440;445;455}. Many patients unfortunately described a lack of support from health services for this motivational and planning stage, and reported taking responsibility and initiative for their own care, for example by drawing on former life skills to organise their recovery^{397;414;426;433;451}.

When the informants experienced that the rehabilitation professionals did not take action, they took control of the situation themselves. The informants expressed pride in their own capacity to take the initiative and in their ability to take action³⁹⁷.

As they adjust to their new circumstances, patients solve problems as they arise^{424;434} and develop strategies to cope with uncertainty during their recovery^{392;394;401}. Some patients described experiencing strong emotions associated with stroke management such as frustration at time taken up by management strategies⁴¹⁶ and guilt at decisions made, for example planning for extended periods of rest during the day^{418;422;447}.

All this planning and increased time were perceived as a source of frustration for participants⁴¹⁶.

Patients reported developing coping strategies such as the use of relaxation techniques, humour, hope, reasoning, positivity, waiting, altruism and engaging in meaningful activities that give pleasure^{394;404-406;414;416;420;423;423;437;443;444;448;453;455;456}. Some described using spirituality and faith as a method of coping^{414;426;430;431;444;455;456}.

5.3.2.1 Interacting with others

During rehabilitation patients engage with a range of health professionals both in secondary care and in the community for emotional support and practical help^{37;394;400;405;410;413;422;431;434;443;447;455}. One study reported that women are more likely to describe the formation of an alliance with health care assistants on the ward, whilst men form alliances with nurses and therapists or other patients⁴¹⁰. Some patients described relying on the expertise of health professionals, seeking validation of treatments as appropriate and worthwhile, and preferring health professionals to take a paternalistic attitude towards them^{395;398;402;402;451}. Others prefer a more equal relationship with health professionals so complained about paternalistic care, reporting that they spend significant time negotiating with health professionals to achieve shared decision-making, particularly in the nursing home setting^{402;424;434;451}.

We have found that the older stroke patients used various ways of negotiating with the health care staff in their subordinate position to influence their situation on the ward. The negotiations can be seen as expressions of resistance or adjustment, whereby resistance could result in increased power for the participants⁴¹⁰.

One study reported that men frequently try to exert influence over their care, with women taking a more passive role⁴¹⁰.

Patients described setting goals for recovery in discussion with health professionals, and some reported a mismatch in ideas between themselves and therapists with regard to priorities for rehabilitation^{393;405;433;434;437;443;456}.

For them recovery involved dimensions that were not included in the health care professionals' concept....The goal for them was either to recapture their former social position or to adapt to another life situation³⁹³.

Patients reported that a lack of adequate information as described earlier can make goal setting for recovery very difficult ⁴³⁹.

The majority of participants reported that they didn't know enough about stroke recovery to be able to actively set goals ⁴³⁹.

Interaction with a high number of health professionals can be confusing for patients; some reported receiving conflicting information from different parties, with a lack of continuity of care within each service as well as poor communication between services. This can result in fragmented care ^{37;396;400;402;415;436}.

Some patients described a lack of time, empathy and understanding from health professionals ^{392;398;400;404;405;414;424;440;443;444;455;456}. Poor interactions between patients and health professionals can interfere with the development of trusting relationships, which in turn worsens communication and prevents patients gaining the knowledge they need for the recovery process ^{410 37;400;406;434}.

Lack of understanding had also to do with attitudes, with what they experienced as unreasonable demands on the part of both the professionals and their next of kin. They described incidents where the professionals had been annoyed with them when they had been in a bad mood or very tired during their physical exercises, or when encountering over-strained professionals. There were also experiences of a feeling of superiority on the part of the professionals, expressed in a comment or a glare ⁴⁰⁰.

Communication difficulties with health professionals are a particular issue for aphasic patients ^{404;437;453}.

However, he described with contempt how he initially after the stroke had been observed by his therapists. He demanded to be met through dialogues that gave him relevant conversation, support and stimulation. Certainly, he understood the professionals' way of working, but he found it could be done in a more conversational and descriptive way that involved him as a person. The dialogues with professionals should involve him in what was going to happen in spite of his incapability to understand all that was said ⁴⁰⁴.

As well as interacting with health professionals, patients described relying heavily on family members for emotional and practical support when managing their stroke ^{37;65;394;398;400;401;407;417;418;425;426;434;441-443;448;450;451;453;455;456}, with one

study suggesting that this is particularly the case for women. Aphasic patients described using carers to help them with their communication ^{417;443}.

Negative interactions with family members were described by some, either in the form of a lack of empathy or overprotection and paternalism, and some patients reported feeling guilty about their dependency ^{392;411;414;416-419;423;425;432;433;444;450;453}.

Negative supports hindered strategies designed to adapt to disabilities. For example, one woman's efforts to adapt to her cognitive disabilities and enhance her sense of mastery and control were repeatedly foiled by her husband's negative attitudes and attempts to remove her adaptive aids ⁴²⁶.

Patients described an adjustment to changes in personal relationships and family roles ^{392;394;419;423;424;444;447;453}, and an attempt to protect family members from any negative impacts or burdens that they may face as a consequence of their stroke and its management, for example by arranging respite care ^{65;404}.

He appreciated all contacts with other people, found them valuable to his rehabilitation, and frequently used the expression that he “had to be open”. However, daily intercourse meant embarrassing misunderstandings, especially in relation to those who were closest to him. He found that he had an obligation not to be embarrassing to them and to see to it that embarrassing situations would not dominate everyday life ⁴⁰⁴.

Patients additionally reported developing relationships with fellow patients and support groups who provide them with moral support ^{394;398;410;425;432;443;443;445;451;453}, and whom they may compare themselves with in order to gauge recovery or validate treatments ^{395;396;406;412;414;415;423;430-432;444}.

Other stroke survivors have a prominent influence on an individual's level of hope post stroke. Participants who were having difficulties coping post stroke relied on other survivors for motivation and a symbol of hope. Interactions with other stroke survivors was a reality check for those individuals who were recovering quickly, as they provided a comparison for their own rate of recovery ⁴³¹.

Younger, less disabled stroke patients reported feeling uncomfortable attending therapies and support groups alongside older, more disabled patients whom they struggle to relate to ^{399;442}. Unfortunately, enduring stigmatization from others

was reported by patients. This seemed a particular issue in relation to the management of physical disabilities such as the use of a wheelchair or adapted cutlery^{402;406;411;419;422;425;430;440}.

One positive outcome from the experience of stroke described by patients was the ability to help others in similar circumstances. Although this means expending time and energy, patients reported feeling rewarded for such efforts with the general consensus that altruism aids their own recovery^{432;437}.

A few people spoke of goals related to improving the lives of others, including other people with aphasia. Some participants devoted time to helping speech pathology students by being available for clinical placements, some volunteered in groups, and some wanted to increase people's awareness of aphasia⁴³⁷.

5.3.2.2 Enacting management strategies

Enacting work includes the work of enduring institutional admissions, managing stroke in the community, reintegrating into society, and adjusting to life after stroke.

Institutional admissions

Stroke patients initially undergo admission to hospital for acute care^{395;422}, which is often followed by extensive inpatient rehabilitation, attending therapists, taking medications and working arduously to regain lost functions^{65;393;395;397;400;401;405;443;444}.

During initial rehabilitation, the major focus is put on regaining the lost functions. The days are structured around training sessions, be they physical therapy, occupational therapy, speech therapy or ADL training³⁹⁵.

They adjust to their new physical abilities and practice self-care in preparation for discharge^{398;405;418;434}. Patients may then be admitted to a care home if discharge to their own home is not feasible^{398;451}. During their time as inpatients, they are required to fit into the daily routines set by institutions^{395;410;436}.

During the few days the participants were in the ward, there were a lot of new things to consider. Apart from facing the fact that they had

had a stroke, they had to become aware of the daily routines in the ward and try to understand and follow them. This concerned, for example, hours when meals were served, what time the doctors' rounds took place, what nurse and nurse assistant were responsible for their specific care, how and when it was appropriate to call for help, when the therapists were present at the ward and the staff's expectations of their rehabilitation and outcome⁴¹⁰.

Many described enduring negative environmental circumstances such as inadequate time allocated for rehabilitative activities, long waiting times for personal care, unfamiliarity with a range of gadgets, lack of stimulation, poor quality of meals, inadequate support from staff during mealtimes, and a lack of autonomy, dignity and privacy^{394;396;398;405;419;420}.

Both women and men felt that the days in the ward were quite long and that the therapist helped them in their rehabilitation only for a very short time each day. The daily time for rehabilitation was, in most cases, no longer than 1 or 2 hours. During weekends, no rehabilitation was organized for the participants⁴¹⁰.

Complaints were similar in the hospital and nursing home setting, with a particular complaint in nursing homes being a lack of autonomy, with care that was regarded as too paternalistic^{398;451}. Patients often receive personal care from hospital staff whilst on the ward, and men reported feeling more vulnerable than women, finding this harder to endure. They described the development of strategies to cope with the situation⁴⁰⁷:

Men showed vulnerability. They wished to manage by themselves and felt vulnerable when they had to rely on nursing care that involved bodily care. They seemed to have various strategies for dealing with this situation: to accept it or to take command and say how they wanted to be treated. Men described embarrassment at being naked in front of nurses, and also that nurses were sometimes shy of their nude bodies. By conforming to the role of patient the tension could be eased⁴⁰⁷.

Managing stroke in the community

Once at an appropriate stage of recovery, patients are discharged home. This transition is a significant and often challenging time for patients^{398;418;451}.

Unfortunately many patients reported discharge services as poorly co-ordinated, badly managed, and inadequate for preparing for life back in the community

^{394;398;401;402;418;419;422;433}.

They described a sense of abandonment by the medical system, associated with concern that they had exhausted the limits of available help but were not ‘back to normal’³⁹⁴.

Once discharged from therapy, patients described difficulties in gaining advice and support in the community, and appeared to be confused about who to contact if they have concerns^{394;402;419;433;434;436;454}.

Not being given accessibility and continuity pertained to the difficulty of getting in contact with the professionals by telephone and making appointments, delayed appointments with the doctors and physiotherapists, and delays and uncertainties about promised treatments⁴⁰⁰.

This appears to resonate across various countries with varying healthcare systems. One study carried out in Nigeria reported that even those physiotherapy services privately paid for have inadequate equipment available⁴⁵⁵. Another paper from Canada stated that level of disability affects the availability of certain services⁴³³.

In the community, patients follow routines and integrate management strategies into their everyday lives, for example changing their diet, incorporating physical exercise and managing risk factors^{165;394;406;411;415;419;421;425;445;447}.

Since the stroke, three survivors had adopted cholesterol-lowering diets, one had excluded wheat products and another had espoused a ‘healthy’ diet (reduced fat, increased fruit and vegetable intake). One now drank less alcohol and had lost weight⁴¹⁹.

Medication regimes are established, with patients adopting strategies to promote adherence such as using cues and aids or relying on the colours of tablets³⁷. They also endure side effects of medications^{37;405}. Patients are required to learn self-care through their own practice, using their own initiative and managing their time appropriately³⁹⁸. They follow advice and strive to achieve the goals that have been set for their recovery through hard work and determination^{392;397;401;431;433;434;443;450}.

Participants described that the process of community reintegration up to one year post stroke, rehabilitation involved transitioning between a series of goals: gaining physical function, establishing independence and adjusting expectations to get back to real living⁴⁰¹.

Patients with physical disability are frequently required to make adaptations to their home to accommodate new equipment ^{65;416;418;419;425;429;430;432}.

Despite the challenges stroke survivors reported, many of them had made accommodations to their home. Some had renovated the kitchen and bathrooms, but mostly people had installed grab bars and railings on staircases. Bath mats, raised toilet seats and large button phones were used frequently ⁴³².

Patients experience a range of environmental risks due to their disabilities and are required to deal with these on a daily basis ^{56;440}. Some patients are even required to move house to accommodate new disabilities, and waiting times can be long ^{165;425}.

As a proactive strategy, one participant moved to a bungalow prior to his stroke to accommodate his difficulty with stairs. Other participants, poststroke, rearranged their living and sleeping spaces to avoid stairs. Although some considered these changes prior to their stroke, the stroke caused them to take action sooner than expected ¹⁶⁵.

Home care services such as personal care and meal delivery services may be utilised by patients who are less physically able. These were often described as inadequate, with complaints over both the availability and standard of services, for example, poor continuity of personal care and a lack of choice regarding meal deliveries ^{400;419;425;432}.

Following discharge from inpatient care, patients are required to attend numerous health care appointments ^{394;395;433} and negotiate numerous therapists ^{65;395;422;433}. As described above in the hospital environment, inadequate information about available services, poor access to care, poor continuity of care and poor communication between therapists were described as frequent and problematic issues ^{396;400;402;415;433;434;436}.

Not being given accessibility and continuity pertained to the difficulty of getting in contact with the professionals by telephone and making appointments, delayed appointments with the doctors and physiotherapists, and delays and uncertainties about promised treatments ⁴⁰⁰.

Only one paper explored the difficulties of managing co-morbidities alongside stroke, with reports that treatments conflict with one another and that predisposing disabilities interfere with rehabilitation ¹⁶⁵.

Reintegrating into society

As time progresses, patients attempt to integrate stroke management into their social circumstances and aspire to return to previous ways of living

394;395;397;415;416;432;453 .

Once home, life goes on, one way or the other. The patient is faced with completing a range of different personal and practical tasks both necessary and voluntary. In addition, the patient continues training sessions in order to continue the recovery process ³⁹⁵.

Patients may be prohibited from driving either for life or for a set period of time before taking a competency test, and some described this process as frustrating. Those who can no longer drive are required to negotiate other methods of transport, which can be difficult due to disabilities ^{425;441}. Patients strive to regain this skill, and some struggle to understand the logic behind the ban on driving. They report feeling unsupported by services, and find the assessment process unfair, which can lead to possible rebellion against medical and legal advice ^{401;409;441}.

Although being evaluated, the participants described that the evaluation was felt as a violation of the right of self-determination, a situation that they had not chosen, but that had struck them on top of the onset of stroke. The driving evaluation was a dramatic event in their rehabilitation and made them feel powerless ⁴⁰⁹.

Many patients aspire to return to work and regain their former social position, but described a lack of support from health services as well as friends, family and work colleagues with regard to this goal ^{397;442;448}.

When the informants experienced that the rehabilitation professionals did not take action, they took control of the situation themselves. The informants expressed pride in their own capacity to take the initiative and in their ability to take action ³⁹⁷.

Personal mobility aids are acquired to help with mobility both inside and outside the home. However, access to appropriate items can sometimes be an issue for

patients^{65;429;430;432}. Some described having to either purchase these themselves or use inappropriate or unsafe aids, putting them at risk of falls^{425;441}. The use of wheelchairs can be made difficult by environmental factors such as steps and narrow doorways, particularly for manual wheelchair users^{429;430;432;433}.

Financial issues are likely to vary from country to country depending on the health care system and welfare provision². Patients in Nigeria and Iran, which are both developing countries, described poor access to care for those who do not have the means to pay for private services⁴⁵⁴.

They suffered from having no access to the few existing rehabilitation centres and suffered from low incomes, which made it impossible for them to get such services at their homes. They felt that the government should help them in providing these services as they would then enjoy a better quality-of-life and escape from physical, emotional and social limitations⁴⁵⁴.

However, patients in developed countries with partially funded government healthcare systems or universal access to healthcare also reported suffering financially. They reported a frequent need to purchase special equipment such as mobility aids and adapted cutlery themselves^{425;432}. Patients in these countries described the organizations that assist with the arrangement of financial benefits from government agencies as obstructive, poorly co-ordinated, and confusing to navigate^{425;433;442;448}.

Mr. D...can walk only 100 yards, but he wants to shop independently for groceries. He asked his doctor to prescribe a battery operated scooter. At the state/provincial level, the health system would pay 80% toward an electric wheelchair, but not for a scooter. Mr. D withdrew the funds from his federal level retirement plan. This money was considered income at the federal government revenue level, and the state/provincial level income supports program for the severely handicapped. He lost income supports until he depletes his retirement funds⁴³³.

One paper described how less disabled patients can be denied government benefits, yet struggle to gain employment due to disabilities⁴⁴². A fear of losing financial benefits upon return to work due to the inflexibility of government policies can in fact deter patients from returning to employment^{433;448}.

Adjusting to life after stroke

Following a stroke, patients create a new daily structure to accommodate their new disabilities and treatments ^{395;402;416;437;440;445;450}.

If major limitations persist, developing a new daily structure, which can allow as much as possible of the activities that the patient wants to continue, is a major task during this phase. Also, adjusting valued activities or developing new ones to substitute for the ones no longer possible also must occur. This is not necessarily an easy task, especially if the applied criterion for acceptable performance is the level of performance before the stroke ³⁹⁵.

They spend time and effort relearning how to carry out tasks that were familiar to them pre stroke and some described a level of rumination over how to carry out these tasks appropriately ^{394;409;412;441}. Patients reported the need for a high level of planning and organisation in their lives that had not previously been required. They reported spending significant time planning activities ahead of time to accommodate disabilities, as well as adopting strategies to deal with physical and cognitive difficulties such as learning how to manage a fall, resting, or creating lists or filing systems ^{394;404;406;416-418;426;430;440;440;443;450;453}.

The study data suggest that problems with performance of habits after stroke, previously used to accomplish daily occupations had been disrupted. The participants had to plan ahead, think, and reflect when carrying out a daily occupation simply to manage their everyday lives. Despite living in a familiar home environment, many of the daily occupations that participants had previously done no longer seemed to be easy to perform and even if repeated often they didn't become habitual. Participants felt that, no matter what they did, they had to think about and plan their daily occupations in advance ⁴¹⁶.

Aphasic patients described using strategies to aid communication with others such as carrying communication cards, repeating words, gesturing, and using drawings or technical devices. Some patients, however, reported finding the use of such strategies either inappropriate for their needs or too laborious to use ⁴¹⁷.

Those with physical disabilities described negotiating potential environmental dangers both inside and outside the home that were not a consideration prior to their stroke ³⁹².

Being able to get about independently, whether on foot, in a car or wheelchair was an activity which respondents valued highly but

presented them with risks and challenges that they had to manage and negotiate. Outside the home there were a variety of risks, not only was there the risk of falling but also the potential embarrassment of doing this in public as well as the difficulties created by fatigue and inability to walk far enough³⁹².

Alongside all these adjustments, patients reflect on life and on their new situation. They strive to recapture their sense of self as they cope with their altered ways of living^{412;414;418;423;429;432-434;442;447;450}.

They also re-examine their priorities in life with regard to their health and their social circumstances^{395;428}.

Through reflection, participants were able to gain insight into what recovery and life with stroke meant and to re-examine priorities. Participants re-examined their priorities in the areas of illness/health, work and family role⁴²⁸.

Acceptance plays a huge part in the recovery process, with patients spending significant time and effort working towards and achieving acceptance of their new life^{394;416;429;430;440;453}. These psychological adaptations to the consequences of stroke appear to be a key aspect of adjustment. However, patients described feeling unprepared for the slow pace of recovery, resulting in great disappointment as they meet with unexpected setbacks^{165;398;401;404;434;455}. As time goes by, patients experience what their bodies are capable of and therefore change their expectations over the rehabilitation period^{395;401;404;412;416;418;432-434;440;441;448;450}.

During the next stage of the process of community reintegration, participants adjusted their expectations of themselves relative to their capacities.... The participants' expectations of their abilities to perform activities such as shovelling snow or engaging in roles such as earning money for the family or caring for children were based on previous experience prior to the stroke and their interactions with others. It took many participants several months post rehabilitation to master this stage, and others still had not mastered it one year after inpatient rehabilitation⁴⁰¹.

5.3.2.3 Reflecting on management

During management of their stroke, patients are required to make decisions about their health care, which requires an appraisal of their treatments, either

with the help of others such as health care providers^{398;422}, or based on their own judgements^{37;404-406;413;440}.

Although decision-making about their own treatment is difficult for most patients, they valued shared decision-making, e.g. about destination and moment of discharge, recreation, meals, therapy schedules, care routines, and aids³⁹⁸.

They described a need to maintain confidence in the care plan set by health professionals^{37;401;414;418;424;431} and to keep up to date with newly available treatments by asking health professionals for information⁴¹⁰.

One man told a story about when he had asked the doctor for more protective treatment against new strokes⁴¹⁰.

Patients may make decisions that deliberately contradict advice given by health professionals, such as driving against medical advice, or refusing medications or therapies. It appears that this can result as the consequence of a breakdown in communication between patient and health professional, or alternatively due to a lack of understanding on behalf of the patient^{37;397;398;404;419;440;455}.

Patients reflect on their achievements during the rehabilitation process, self-monitoring progress to make judgements about their success

^{392;395;401;412;418;419;423;424;431;434;445;453;455}.

Mr Neville an 80 year old man set himself the target of walking unaided by the time he left hospital....He kept a diary of is progress which he made available to the research team...Stroke survivors presented their goals as an aspiration or a challenge. By definitions they were activities that were important or valued and they could not perform. The goals were often related to the recovery of specific skills that were part of personal competence and identity³⁹².

Many patients described fear of another stroke; some reported an exhausting, constant rumination over avoidance of risk factors and a vigilant monitoring of signs of further disease^{392;418;435}.

Participants within the cohorts remained fearful that they would experience a subsequent stroke and this was “always in the back of my mind” (Participant 11, female, age 79). Though essentially a realistic concern, fear resulted in dysfunctional responses by some participants with close monitoring or avoidance of perceived risk

factors—often to the point of impairing quality-of-life or social interaction. Such responses appeared to correlate with their experiences of, and interpretations of, their acute strokes⁴³⁵.

5.4 Discussion

5.4.1 Studies included

Each included study explored in depth a particular aspect of the patient experience in a specific context, rather than comprehensively covering the entire patient experience of treatment burden. Studies were from many different countries across the world with the majority of data gathered in the community, although several inpatient settings were also studied, such as the acute rehabilitation ward and the nursing home. The availability of information about participant characteristics proved to be very variable and sometimes limited. A variety of methods of data analysis were detailed, although most had similarities in that they sought to identify common themes discussed by participants through identifying individual themes emerging from the data and then grouping these into broader categories.

During screening, many studies explored the patient experience of stroke but did not meet the inclusion criteria due to a lack of information about treatment burden. These studies tended to focus on the experience of illness as a burden rather than management itself, for example the experience of symptoms and the effects of this on everyday living. Other studies examined burden from the carer's perspective rather than the person who had suffered the stroke, or involved mixed groups of participants such as patients and health care providers in focus groups, with no clear distinction in the reporting of findings. These studies were excluded to ensure that treatment burden specifically from the patient perspective was examined.

As discussed in Chapter 4, the quality appraisal instrument was intended as a series of reflective questions to inform discussion and not as a scoring system to exclude papers (See Table 8). Aims and methods were generally clear and studies provided a rich picture of the patient experience of stroke and its management. Although details on participant characteristics were variable, most gave adequate information to allow the reader to understand the sample and to

make judgements about the generalizability of results. Qualitative studies do not necessarily aim to provide results that are generalizable to a large population, and most papers acknowledged this, placing results in context. One marker of quality infrequently addressed was the possible influence of authors and researchers on the research process itself, for example information on their professional roles or their epistemological and ontological stances. Details of conflicts of interest were also generally lacking. However, these omissions could be explained by restrictions set by publishers due to word limits or formatting.

5.4.2 Treatment Burden

Treatment burden is defined as the impact of healthcare practices on well-being. To the best of my knowledge, this is the first qualitative systematic review to explore treatment burden in stroke. For the first time this review has been able to create a comprehensive taxonomy of treatment burden in stroke, shown in Table 11. There were four main areas of treatment burden identified, each representing a process of stroke care: 1) making sense of stroke management and planning care; 2) interacting with others including health professionals, family and other stroke patients; 3) enacting management strategies, which includes (a) enduring institutional admissions, (b) managing stroke in the community, (c) reintegrating into society, and (d) adjusting to life after stroke; and 4) reflecting on management.

In Chapter 7, the treatment burden taxonomy is verified, expanded upon and explored through analysis of interviews with individuals who have had a stroke. Additionally, aspects that influence the capacity of each individual to cope with their treatments are explored.

5.4.2.1 Update to search

The search update to February 2013 revealed a limited amount of new information, including more detail on the hospital stay, medication taking and financial burdens. One new paper was found from a developing country which was also useful as there had been a paucity in the original search. No pertinent papers were found in the search up to Feb 2016.

5.4.2.2 Aspects of Treatment Burden missing from the literature

Certain aspects of stroke management were mentioned less than expected, for example the process of acute care, medications, and the use of new technologies. Only one study explored comorbidity¹⁶⁵, despite evidence that those with chronic disease report comorbidity as having an important influence on treatment burden⁹², and despite co-morbidity being common in stroke, as shown in Chapter 6. Missing burdens are likely to reflect a lack of conceptualisation of treatment burden in the literature. Two studies made gender comparisons with regard to the patient experience of managing stroke^{407;410} but little information was provided to allow comparisons based on other patient characteristics such as age, ethnicity, and socio-economic deprivation.

5.4.3 Limitations/strengths

The search was limited to publications from the year 2000 and onwards. As the aim was to understand the current patient experience, it was most pertinent to review the literature over the past decade, reflecting patient experiences of treatment burden based on current health service practices rather than historical ones. Global management of these conditions have changed over time, for example, stroke management has changed greatly in recent years with the introduction of stroke units and community rehabilitation programmes^{2;457} and hence this was judged to be a reasonable approach, but could be viewed as a limitation. Also, the search was restricted to English language papers as there were no resources available for translation. There was no geographical restriction set; however, the language restriction may have imposed a degree of geographical restriction and there was a paucity of data from low income countries. An important strength is that an exhaustive search was conducted and this search proved to be both sensitive and specific to the research question.

The tight inclusion criteria avoided collecting too broad a spectrum of methodologies, beneficial as high numbers of studies using extremely varied methods makes in-depth analysis of the data and applicability of findings extremely challenging. This approach helped to maintain focus whilst producing a rich picture of stroke management. As a result, the number of studies included was considerable yet still feasible for the application of qualitative analysis.

However, the exclusion of methodologies such as telephone and postal questionnaires could be regarded as a limitation, as it is possible that some studies exploring treatment burden may have used these methods.

As detailed above, the search was updated to February 2013 for the purpose of publication in a peer reviewed journal at the request of reviewers. There had been a delay of around 18 months between the search being carried out and submission for publication, for the following reasons 1) the review had uncovered a significant number of papers for analysis 2) the need for a second reviewer at all stages caused some time delays as second reviewers tended to have less time to work on the project 3) a period of maternity leave was taken. A subsequent search was undertaken to look for pertinent papers that either stated the exploration of treatment workload or treatment burden in stroke as an objective, or that added new information, and none were found.

Studying a phenomenon that had not previously been well conceptualised well in the literature was a challenge, although during the course of the review several conceptual papers on treatment burden in chronic disease were published^{8;94 14 13 93;112} which helped greatly with analysis. No papers were found that sought to understand treatment burden in stroke as an explicit aim, nor have any been found subsequently. However, information on treatment burden was discovered in the papers included from the descriptions of the patient experience of stroke management. This was therefore an attempt to apply a conceptual framework to a set of studies that have used alternative theories and methods to analyse the patient experience.

Another issue was the complexity of data extraction, as within each paper there was a significant amount of irrelevant qualitative data that was difficult to separate from that on treatment burden due to the difference in focus between the primary studies and the review. There was considerable data on illness burden such as the effect of symptoms on everyday living, and on lifework burden such as managing the home or maintaining employment, carried out in parallel to but not as a direct consequence of the illness. This is in keeping with the milestone work published by Corbin and Strauss on the three lines of work experienced by those with chronic illness as described in Chapter 2⁷². Such burdens all merit further exploration but were not the focus of this work.

A strength of this review was the robust theoretical underpinning to the data analysis. The use of framework synthesis³⁸² was appropriate as there were preconceived research objectives based on knowledge of the literature and clinical experience, yet this method ensured that results arose directly from the data. This approach was highly pragmatic and useful, as others have found^{295;342}, and it enhanced transparency of coding. While the suppression of interpretive creativity³⁴⁵ is a potential risk, this was minimised by paying close attention to any data that may have fallen outside the framework, and iteratively adapting the framework during analysis to ensure that analysis was somewhat inductive³⁸². This novel method of data analysis was very useful for identifying the components of treatment burden in stroke from the patient perspective, and no aspects of treatment burden were identified that fell outside this framework.

The large variation in research objectives of included studies means that a diverse range of treatment burdens are described. A huge advantage of this is that, for the first time, information about treatment burden has been pieced together from various sources to create a more comprehensive picture. However, one limitation is that the papers and therefore participants studied are heterogeneous in nature, which makes comparisons between papers difficult, for example to compare papers arising from different countries. It is likely that there is significant variation in health system delivery between countries, including availability of services through state-sponsored insurance, and this will influence the burdens experienced.

Both severity of stroke and level of disability are likely to influence treatment burden, yet both were generally poorly described in the included papers, and those that did describe them used varying measures and terminology. It could be argued that the most physically and mentally impaired may be the most burdened and the least likely to participate in research, a common problem in the research arena. For example, the papers that studied aphasic patients described a particular difficulty for these patients in communicating with therapists and carers, a perhaps unsurprising but important finding^{404;437;453}. The inclusion of papers that study aphasic patients and wheelchair users is almost certainly a strength of this review^{404;437;453 429;430}, but there is likely to be an over representation of able bodied patients. Time since diagnosis is also likely to influence treatment burden, as patients adjust to their condition and the

process of rehabilitation. Interestingly, the quality appraisal instrument used did not judge quality based on the detailed provision of patient characteristics. During appraisal, judgements were made about whether the sample was appropriate for the research objectives of that individual study, and if authors were honest about generalizability. In the qualitative research arena, these factors tend to be more pertinent than producing work that is generalizable to other populations, one argument made by those against qualitative syntheses²⁷³. However, with transparency in reporting about generalizability, qualitative synthesis is invaluable for informing clinical practice and health policy.

5.5 Conclusion

In this chapter, the creation of a comprehensive taxonomy of treatment burden underpinned by international research has been described. The taxonomy is not universally generalizable, but intended to give insight into the scope of burdens experienced by those with stroke. The taxonomy is broadly categorised into: 1) making sense of stroke management and planning care; 2) interacting with others; 3) enacting management strategies and 4) reflecting on management. Patients described care as fragmented and lacking in continuity, with poor communication between patient and clinician as well as between healthcare providers. Information provision is described as generally poor, and patients would like clinicians to spend more time with them. There is considerable room for improvement with regard to both inpatient and community services.

In Chapter 7, the taxonomy of treatment burden created here is extended by adding findings from a qualitative analysis of interviews with stroke patients from the Greater Glasgow and Clyde area. An exploration of factors that influence the capacity of individuals to cope with their treatments is also undertaken. Treatment burden appears to be significantly affected by the micro and macro organisation of health services, which are likely to vary considerably between localities. This is discussed further in Chapter 8. Published papers from the systematic review described here are shown in Appendix 8. In the next chapter, prescribing and comorbidity in stroke are examined through analysis of primary care data.

Chapter 6 – Multimorbidity and prescribing in people with stroke

6.1 Introduction

6.1.1 Aims of this chapter

To examine the prevalence of multimorbidity and prescribing in people with stroke, making comparison to those who are stroke-free.

6.1.2 Rationale

In this thesis, treatment burden has been defined as a series of cognitive and physical tasks that must be accomplished by those with chronic illness in order to manage their disease, and the effect of these tasks on health and well-being. In Chapter 5, treatment burden in stroke was explored through a qualitative lens, giving insight into disease management from the patient perspective. In this chapter, quantitative techniques are used to explore multimorbidity and prescribing in stroke. As discussed in Chapter 4, the term multimorbidity is the presence of two or more long-term conditions without any being cited as the index ¹⁵⁴, while comorbidity refers to the presence of one or more morbidities in addition to an index condition such as stroke ¹⁵³. In this chapter, the term multimorbidity is used because the analyses described involve comparison of those with stroke to those who are stroke free and those in the latter group do not have an index condition. Quantitative measures are important in our exploration of treatment burden as this provides governing bodies with objective measures that can be used to compare patient groups and inform choices when planning care.

In Chapter 3, it was highlighted that only a small number of studies have examined co-morbidity and prescribing in stroke and that large, generalizable studies are lacking. No patient-reported measures of treatment workload or burden in stroke were found, with only very narrow aspects of care having been quantified in the medical literature. In Chapter 2, several patient-reported measures of treatment burden were discussed that have been created for those with chronic disease, although not specifically for those with stroke. The burden

of taking medications features consistently in these measures, as does the influence of multimorbidity on the encumbrances of healthcare.

As more people survive acute events such as stroke and as the population ages, multimorbidity is becoming a global challenge for policy-makers, clinicians, and patients^{9;153;154}. There is a known association between the number of morbidities suffered by those with chronic disease and the prescribing of polypharmacy (multiple medications), as well as other aspects of healthcare utilisation such as hospital admissions^{159-161;248;249}. This supports the premise that those with higher numbers of conditions to manage are likely to experience higher levels of treatment workload⁹. These individuals are also likely to have lower capacity to cope with their treatments, for example it has been shown that number of morbidities is positively associated with increased age, deprivation¹⁵⁴ and poor quality-of-life⁴⁵⁸, all of which reduce patient capacity¹³. As well as causing inconvenience to patients, polypharmacy can contribute to other treatment burdens such as adverse drug events and admission to hospital^{82;88;89}. Multimorbidity and prescribing are therefore extremely relevant in the exploration of treatment burden.

6.1.3 Research question

What is the prevalence of multimorbidity and prescribing in people with stroke in Scotland, compared to those who are stroke-free?

6.2 Methods

6.2.1 Study design and Participants

To meet the study aims, a cross-sectional study based on a nationally-representative dataset managed by the Primary Care Clinical Informatics Unit (PCCIU) at the University of Aberdeen in Scotland was undertaken. This fully anonymised dataset contains clinical data on all people that were alive and permanently registered with 314 primary care practices in Scotland on March 31st 2007. Comprising approximately one third of Scottish adults, this sample has been shown to be representative of this population⁴⁵⁹. In the UK, registration with a medical practice is required for an individual to access National Health Service (NHS) healthcare in the community. It is estimated that

over 98% of the population are registered with a medical practice⁴⁶⁰, which systematically records information on each patient in an electronic medical record, for the purposes of registration and subsequent everyday medical care. Data were examined that had been extracted from medical records and collated for a previous study of multimorbidity which had examined the presence of 40 conditions¹⁵⁴, including stroke. The NHS National Research Ethics Service had approved the use of these data for research purposes (Appendix 9).

6.2.2 Data collected and disease definition

Data consisted of the following variables: gender, age, socioeconomic deprivation (measured from patients' postcodes using the Carstairs score⁴⁶¹), counts of regularly prescribed medications and the presence of 40 long-term conditions, including stroke.

As discussed in Chapter 4, there is no 'gold standard' method for the measurement of multimorbidity. Therefore, the 40 long-term conditions included in a previous study¹⁵⁴ had been chosen and defined based on a recent systematic review²⁵⁰ and expert consensus¹⁵⁴. Existing definitions for each long-term condition had been used if possible, mainly those used in the Quality and Outcomes Framework (QOF) or by NHS Scotland^{154;373;374}. If no standard definition was available, or there was concern about under-recording, then conditions had been defined by the clinical members of the research team. For example, depression was defined as the presence of a QOF Read Code in the last year or receipt of 4 or more prescriptions for antidepressant drugs (excluding low dose tricyclics which are usually used for chronic pain) in the past year¹⁵⁴. This was discussed in detail in Chapter 4. A table taken directly from publication of the original study¹⁵⁴ is shown in Appendix 2, detailing the full definitions of each condition. This original study had included measurement of the presence of a combined group of stroke or transient ischaemic attack (TIA)¹⁵⁴, but for the purposes of the analyses described here, the presence of stroke alone was defined using the QOF Business Rules codeset³⁷³ and TIA ignored. These codes are shown in Appendix 10. For the measurement of multimorbidity, a count of long-term conditions was taken, with morbidities being noted as either mental health or physical.

As there are no standard definitions of regularly prescribed treatments or measure of polypharmacy, I utilized a count of current regular prescriptions, including tablets, inhalers, stoma care and topical therapies^{379;380}. Regular prescriptions ('repeat') are clearly distinguished in UK general practice electronic medical records from one-off ('acute') prescriptions such as those for most antibiotics. For the purposes of these analyses, any regular prescription that was still active (i.e. available for issue on request) on the date of extraction and had been prescribed in the last 84 days was counted as current medication.

6.2.3 Statistical analyses

Descriptive statistics comprised cross-tabulations, frequencies, percentages and graphical illustrations. Analyses were predicated on a comparison of the characteristics of people with stroke (cases) and without stroke (controls). First, the numbers of morbidities and prescribed medications in stroke cases and controls were calculated and proportions within each group computed. Second, logistic regression, which produces odds ratios, was used to summarise the relationship between stroke and the presence of comorbidities and prescribed medications. The odds ratios represent the odds that a characteristic will occur given a particular outcome (stroke cases), compared to the odds of a characteristic occurring in the absence of a particular outcome (controls). In these analyses, having zero comorbidities, or zero prescribed medications, was the referent category, and stroke was the outcome. Taking the analyses of comorbidity and stroke as an illustration, a higher proportion of comorbidity in people with stroke versus those without would result in an odds ratio greater than 1.0. Conversely, a lower prevalence of comorbidity in people with stroke would result in an odds ratio lower than 1.0. Thus, if in examining the prevalence of one to three comorbidities in people with stroke versus controls, the odds ratio was 4, this means that there is a 4 fold increased odds (risk) of having one to three comorbidities (as opposed to none) in people with stroke.

Odds ratios were initially unadjusted - for the purposes of comparison - then adjusted for the key confounding factors of age, gender and socioeconomic deprivation. Further adjustment for number of morbidities was made when polypharmacy was the characteristic of interest. GP practices could potentially vary in their tendency to prescribe medications and this could confound

associations between stroke and number of prescriptions. A sensitivity analysis was therefore carried out with practice identification number added into the fully adjusted model. Odds ratios (for a unit change in category) were compared before and after addition of practice number. For the purposes of these analyses, a p value < 0.05 was deemed statistically significant. All analyses were carried out using Statistical Package for the Social Sciences (SPSS) software (Version 21).

6.3 Results

Analyses were based on 1,424,378 individuals (724,949 women) aged 18 years and over who were registered with a general practitioner. A total of 35,690 people (2.5%) had a diagnosis of stroke. As anticipated, the mean age of people in the stroke group (72.68 (SD 12.21)) was higher than that in the controls (47.36 (SD 17.93)). Demographic characteristics for each group are shown in Table 12.

Table 12 - Stroke status and demographic characteristics (N=1,424,378)³⁸³

	Stroke N (%) 35690 (100)	No stroke N (%) 1388688(100)	Unadjusted OR (95% CI) ^a	Adjusted OR (95% CI) ^{a,b}
Men	18071 (50.6)	681358 (49.1)	1.07 (1.04 to 1.09) ^c	1.49 (1.46 to 1.53) ^c
Age group				
18-24	50 (0.1)	151643 (10.9)	1	1
25-34	157 (0.4)	229239 (16.5)	2.08 (1.51 to 2.86)	2.08 (1.52 to 2.86)
35-44	592 (1.7)	278401 (20.0)	6.45 (4.83 to 8.61)	6.53 (4.89 to 8.71)
45-54	2019 (5.7)	251775 (18.1)	24.32 (18.37 to 32.20)	24.80 (18.73 to 32.83)
55-64	5650 (15.8)	213683 (15.4)	80.19 (60.70 to 105.94)	82.58 (62.51 to 109.10)
65-74	9847 (27.6)	145433 (10.5)	205.35 (155.51 to 271.16)	212.61 (161.01 to 280.74)
75+	17375 (48.7)	118514 (8.5)	444.64 (336.83 to 586.95)	476.65 (361.07 to 629.23)
Deprivation quintile				
1	5993 (16.8)	266036 (19.2)	1	1
2	7724 (21.6)	296430 (21.3)	1.16 (1.12 to 1.20)	1.09 (1.05 to 1.12)
3	8251 (23.1)	313996 (22.6)	1.17 (1.13 to 1.21)	1.20 (1.16 to 1.24)
4	7008 (19.6)	264376 (19.0)	1.18 (1.14 to 1.22)	1.28 (1.24 to 1.33)
5 most deprived	6714 (18.8)	247850 (17.8)	1.20 (1.16 to 1.25)	1.42 (1.37 to 1.47)
a all p values <0.001				
b adjustments were made for all other demographic variables e.g. age and deprivation when examining gender.				
c reference category is women				

Comorbidities

Table 13 shows the number (percent) of total morbidities, physical morbidities and mental health morbidities in the stroke and control groups along with odds ratios for stroke in relation to these variables. Comorbidity was common in stroke: of the study members with stroke, the percentage that had one or more additional morbidities present (94.2%) was almost twice that apparent in the control group (48%) (OR adjusted for age, gender and deprivation; 95% CI: 5.18; 4.95 to 5.43). Disaggregating the data into type of morbidity revealed that physical morbidity was markedly more common in people with stroke (adjusted OR 4.50; 95% CI 4.31 to 4.68) and mental health morbidity was also more common but the relationship was less strong (adjusted OR 2.10; 95% CI 2.05 to 2.15).

Table 13 - Stroke status according to number of morbidities (N=1,424,378)³⁸³

	Stroke N (%) 35690 (100)	No stroke N (%) 1388688 (100)	Unadjusted OR (95% CI)^a	Age, gender and deprivation adjusted OR (95% CI)^a
Total number of morbidities^b				
None	2053 (5.8)	721430 (52.0)	1 (referent)	1
One-three	17750 (49.7)	551295 (39.7)	11.31 (10.81 to 11.85)	4.35 (4.15 to 4.56)
Four-six	12300 (34.5)	100500 (7.2)	43.01 (41.03 to 45.09)	8.59 (8.17 to 9.04)
Seven or more	3587 (10.1)	15463 (1.1)	81.52 (77.04 to 86.26)	12.81 (12.05 to 13.61)
Number of physical morbidities^b				
None	2769 (7.8)	800202 (57.6)	1	1
One-three	20716 (58.0)	510846 (36.8)	11.72 (11.26 to 12.20)	4.03 (3.86 to 4.20)
Four-six	10414 (29.2)	70709 (5.1)	42.56 (40.79 to 44.41)	7.32 (6.99 to 7.67)
Seven or more	1791 (5.0)	6931 (0.5)	74.68 (70.05 to 79.61)	10.33 (9.64 to 11.05)
Number of mental morbidities				
None	21961 (61.5)	1163095 (83.8)	1	1
One-three	13533 (37.9)	223739 (16.1)	3.20 (3.13 to 3.27)	2.08 (2.04 to 2.13)
Four or more	196 (0.5)	1854 (0.1)	5.60 (4.83 to 6.49)	3.56 (3.03 to 4.20)
^a all p<0.001				
^b excluding stroke				

The ten most frequent co-morbidities present in people with a diagnosis of stroke were: hypertension (60.9%), coronary heart disease (29.5%), painful condition (21.9%), depression (20.7%), diabetes (18.8%), chronic kidney disease (14.3%), constipation (13.8%), atrial fibrillation (13.0%), thyroid disorders (11.9%), and chronic obstructive pulmonary disease (11.9%).

Figure 2 displays the odds ratios (adjusted for age, gender and deprivation) for stroke in relation to the 31 physical morbidities examined. Table 14 elaborates on this by showing both unadjusted and adjusted odds ratios along with the crude prevalence of all physical morbidities in the stroke and control groups. In all, 28 out of the 31 physical morbidities examined were significantly more common in the stroke group; this was 27 after adjustment for potential confounding factors. For instance, epilepsy (adjusted OR 4.43; 95% CI 4.14 to 4.74), hypertension (adjusted OR 2.67; 95% CI 2.61 to 2.73), peripheral vascular disease (adjusted OR 2.47; 95% CI 2.37 to 2.58), atrial fibrillation (adjusted OR 2.44; 95% CI 2.36 to 2.53), and coronary heart disease (adjusted OR 2.06; 95% CI 2.01 to 2.11) were all more common in people experiencing a cerebrovascular disease event. By contrast, dyspepsia was markedly less common in the stroke group (adjusted OR 0.63; 95% CI 0.60 to 0.66).

Figure 2 - Odds ratios and 95% confidence intervals (adjusted for age, gender and deprivation) for stroke in relation to the 31 physical morbidities examined

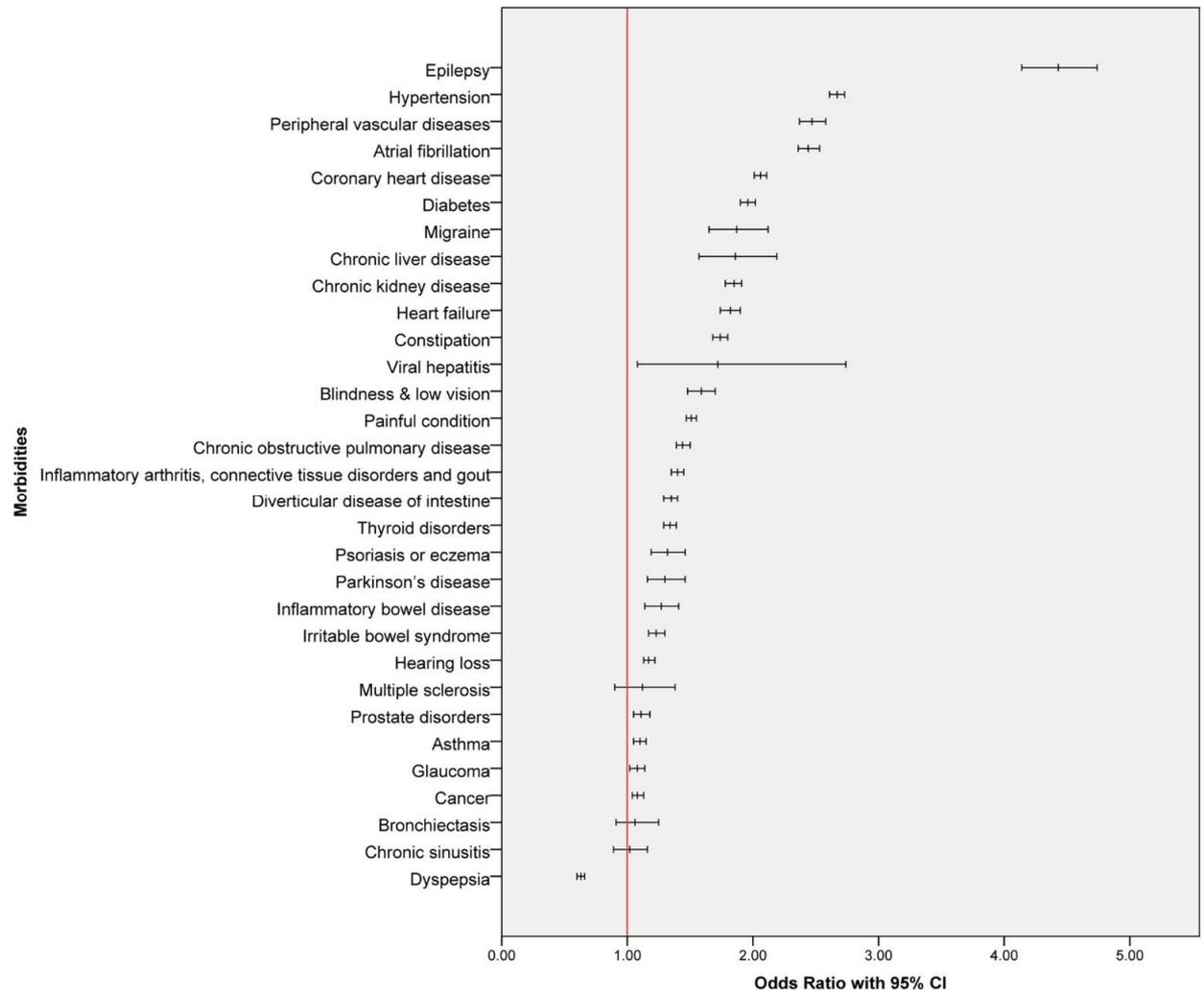


Table 14 - Stroke status and prevalence of physical morbidities (N=1,424,378)³⁸³

	Stroke N (%) 35690 (100)	No stroke N (%) 1388688 (100)	Unadjusted OR (95% CI) ^{a,b}	Age, gender and deprivation adjusted OR (95% CI) ^{a,b}
Epilepsy	1186 (3.3)	11198 (0.8)	4.23 (3.98 to 4.49)	4.43 (4.14 to 4.74)
Hypertension	21742 (60.9)	212572 (15.3)	8.62 (8.44 to 8.81)	2.67 (2.61 to 2.73)
Peripheral vascular diseases	3286 (9.2)	19954 (1.4)	6.96 (6.69 to 7.23)	2.47 (2.37 to 2.58)
Atrial fibrillation	4652 (13.0)	19324 (1.4)	10.62 (10.27 to 10.99)	2.44 (2.36 to 2.53)
Coronary heart disease	10518 (29.5)	70949 (5.1)	7.76 (7.58 to 7.95)	2.06 (2.01 to 2.11)
Diabetes	6697 (18.8)	68134 (4.9)	4.48 (4.36 to 4.60)	1.96 (1.90 to 2.02)
Migraine	273 (0.8)	8978 (0.6)	1.19 (1.05 to 1.34) p=0.006	1.87 (1.65 to 2.12)
Chronic liver disease	159 (0.4)	2455 (0.2)	2.53 (2.15 to 2.97)	1.86 (1.57 to 2.19)
Chronic kidney disease	5100 (14.3)	28466 (2.0)	7.97 (7.72 to 8.23)	1.85 (1.78 to 1.91)
Heart failure	2977 (8.3)	15922 (1.1)	7.85 (7.53 to 8.17)	1.82 (1.74 to 1.90)
Constipation	4934 (13.8)	31482 (2.3)	6.92 (6.70 to 7.14)	1.74 (1.68 to 1.80)
Viral Hepatitis	19 (0.1)	1156 (0.1)	0.64 (0.41 to 1.01) p=0.053	1.72 (1.08 to 2.74) p=0.023
Blindness & low vision	1124 (3.1)	7254 (0.5)	6.19 (5.81 to 6.60)	1.59 (1.48 to 1.70)
Painful condition	7810 (21.9)	118321 (8.5)	3.01 (2.93 to 3.09)	1.51 (1.47 to 1.55)
Chronic obstructive pulmonary disease	4235 (11.9)	48872 (3.5)	3.69 (3.57 to 3.82)	1.44 (1.39 to 1.50)

Inflammatory arthritis, connective tissue disorders and gout	4198 (11.8)	53810 (3.9)	3.31 (3.20 to 3.42)	1.40 (1.35 to 1.45)
Diverticular disease of intestine	3472 (9.7)	30341 (2.2)	4.83 (4.65 to 5.01)	1.35 (1.29 to 1.40)
Thyroid disorders	4244 (11.9)	67699 (4.9)	2.63 (2.55 to 2.72)	1.34 (1.29 to 1.39)
Psoriasis or eczema	446 (1.2)	9923 (0.7)	1.76 (1.60 to 1.93)	1.32 (1.19 to 1.46)
Parkinson's disease	361 (1.0)	2380 (0.2)	5.95 (5.33 to 6.65)	1.30 (1.16 to 1.46)
Inflammatory bowel disease	382 (1.1)	9369 (0.7)	1.59 (1.44 to 1.77)	1.27 (1.14 to 1.41)
Irritable bowel syndrome	1539 (4.3)	50598 (3.6)	1.19 (1.13 to 1.26)	1.23 (1.17 to 1.30)
Hearing loss	3968 (11.1)	50766 (3.7)	3.30 (3.19 to 3.41)	1.17 (1.13 to 1.22)
Multiple sclerosis	92 (0.3)	3755 (0.3)	0.95 (0.78 to 1.17) p=0.650	1.12 (0.90 to 1.38) p=0.309
Prostate disorders	1424 (4.0)	13809 (1.0)	4.14 (3.91 to 4.37)	1.11 (1.05 to 1.18) p=0.001
Asthma	2285 (6.4)	82220 (5.9)	1.09 (1.04 to 1.14)	1.10 (1.05 to 1.15)
Glaucoma	1544 (4.3)	14375 (1.0)	4.32 (4.10 to 4.5610)	1.08 (1.02 to 1.14)
Cancer	2937 (8.2)	40727 (2.9)	2.97 (2.85 to 3.09)	1.08 (1.04 to 1.13)
Bronchiectasis	173 (0.5)	2641 (0.2)	2.56 (2.19 to 2.98)	1.06 (0.91 to 1.25) p=0.454
Chronic sinusitis	248 (0.7)	8917 (0.6)	1.08 (0.95 to 1.23) p=0.219	1.02 (0.89 to 1.16) p=0.820
Dyspepsia	2571 (7.2)	76633 (5.5)	1.33 (1.28 to 1.38)	0.63 (0.60 to 0.66)
^a reference category is absence of each condition				
^b all p values <0.001 unless otherwise stated				

In Figure 3 we show the odds ratios (adjusted for age, gender and deprivation) for stroke in relation to 8 mental health morbidities.

Table 15 shows unadjusted and adjusted odds ratios along with the crude prevalence of all mental health morbidities in the stroke and stroke-free groups. In all, 6 out of the 8 mental health morbidities examined were significantly more common in the stroke group, and following adjustments all 8 mental health morbidities were significantly more common. This includes drug and medication use problems (adjusted OR 2.34; 95% CI 2.25 to 2.43), depression (adjusted OR 2.09; 95% CI 2.03 to 2.15), alcohol problems (adjusted OR 2.05; 95% CI 1.96 to 2.15) and anxiety & stress (adjusted OR 1.61; 95% CI 1.55 to 1.66).

Figure 3 - Odds ratios and 95% confidence intervals (adjusted for age, gender and deprivation) for stroke in relation to the 8 mental morbidities examined

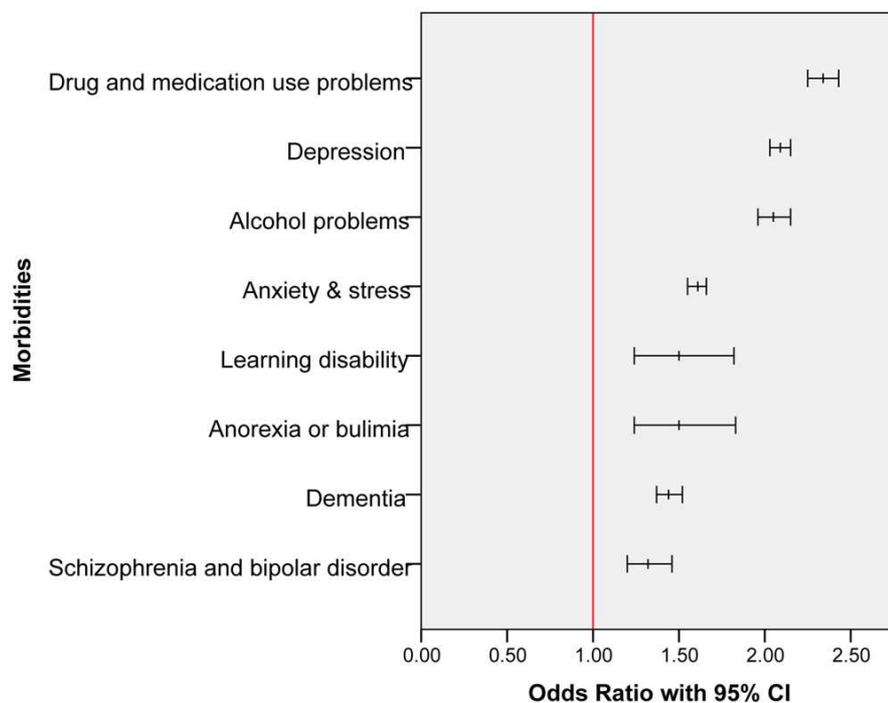


Table 15 - Stroke status and prevalence of mental health morbidities (N=1,424,378)³⁸³

	Stroke N (%) 35690 (100)	Non stroke N (%) 1388688 (100)	Unadjusted OR (95% CI) ^{a,b}	Age, gender and deprivation adjusted OR (95% CI) ^{a,b}
Drug and medication use problems	3831 (10.7)	38629 (2.8)	4.20 (4.06 to 4.35)	2.34 (2.25 to 2.43)
Depression	7394 (20.7)	136549 (9.8)	2.40 (2.33 to 2.46)	2.09 (2.03 to 2.15)
Alcohol problems	2062 (5.8)	40301 (2.9)	2.05 (1.96 to 2.15)	2.05 (1.96 to 2.15)
Anxiety & stress	4026 (11.3)	51700 (3.7)	3.29 (3.18 to 3.40)	1.61 (1.55 to 1.66)
Learning disability	115 (0.3)	4899 (0.4)	0.91 (0.76 to 1.10) p=0.336	1.50 (1.24 to 1.82)
Anorexia or bulimia	118 (0.3)	5188 (0.4)	0.89 (0.74 to 1.06) p=0.189	1.50 (1.24 to 1.83)
Dementia	2075 (5.8)	9621 (0.7)	8.85 (8.43 to 9.29)	1.44 (1.37 to 1.52)
Schizophrenia and bipolar disorder	452 (1.3)	12041 (0.9)	1.47 (1.33 to 1.61)	1.32 (1.20 to 1.46)
^a reference category is absence of each condition				
^b all p values <0.001 unless otherwise stated				

6.3.1 Regular prescriptions

As anticipated, the number of regular prescriptions was significantly correlated with number of morbidities in the stroke (spearman rho = 0.58 p<0.001) and control (spearman rho = 0.75 p<0.001) groups. Table 16 shows the number of repeat prescriptions in the stroke and control groups accompanied by odds ratios. Those with stroke were more likely to be on a repeat prescription than the control group (adjusted OR 4.53; 95% CI 4.33 to 4.74). In the stroke group, 12.6% had 11 or more repeat prescriptions compared to only 1.5% of the control group (OR adjusted for age, gender, deprivation and morbidity count 15.84; 95% CI 14.86 to 16.88). The sensitivity analysis showed no evidence of a practice effect (OR without practice ID 1.55; 95% CI 1.54 to 1.56 and OR with practice ID 1.52; 95% CI 1.50 to 1.53).

Table 16 - Stroke status and number of repeat medications (N=1,424,378)³⁸³

	Stroke N (%) 35690 (100)	No stroke N (%) 1388688 (100)	Unadjusted OR (95% CI)^a	Age, gender and deprivation adjusted OR (95% CI)^a	Age, gender, deprivation and morbidity count adjusted OR (95% CI)^a
Number of medications					
None	2447 (6.9%)	863688 (62.2%)	1 (referent)	1	1
One-two	3038 (8.5%)	240721 (17.3%)	4.45 (4.22 to 4.70)	2.38 (2.26 to 2.52)	2.29 (2.17 to 2.42)
Three-four	6566 (18.4%)	122518 (8.8%)	18.92 (18.05 to 19.82)	6.25 (5.95 to 6.57)	5.78 (5.49 to 6.08)
Five-six	8185 (22.9%)	75512 (5.4%)	38.26 (36.55 to 40.05)	10.50 (9.99 to 11.03)	9.36 (8.89 to 9.86)
Seven-eight	6721 (18.8%)	43344 (3.1%)	54.73 (52.20 to 57.38)	13.90 (13.20 to 14.63)	11.94 (11.29 to 12.62)
Nine-ten	4219 (11.8%)	22536 (1.6%)	66.08 (62.76 to 69.57)	16.22 (15.34 to 17.15)	13.44 (12.65 to 14.29)
Eleven or more	4514 (12.6%)	20369 (1.5%)	78.22 (74.32 to 82.32)	20.13 (19.05 to 21.27)	15.84 (14.86 to 16.88)
^a all p<0.001					

6.4 Discussion

6.4.1 Summary of findings and implications

Analyses of this large, demographically representative sample of people in Scotland showed that multimorbidity and polypharmacy were much more common in people with a diagnosis of stroke. More than a third of those with stroke (34.5%) had 4-6 comorbidities compared to just 7.2% of controls and 12.6% were being prescribed eleven or more different medications, thus suggesting that a large number of those with stroke endure a significant burden of illness with a concomitant demanding burden of treatment. The number of conditions an individual has is likely to increase treatment burden in several ways, and this was discussed in detail in Chapter 2. These findings are consistent with current knowledge that those with stroke are an elderly population with considerable cardiovascular disease risk⁴⁶², for whom effective treatments are increasingly available to alleviate symptoms and address underlying causal factors³⁴.

Diagnoses of most chronic conditions were more common in the stroke group and this remained the case after adjustment for age, gender and deprivation.

Dyspepsia was the only condition that was significantly more common in the stroke-free group. This is likely to be due to how dyspepsia was defined i.e. those with 4 or more prescriptions for dyspepsia medication were counted but this excluded those on NSAIDs, aspirin or clopidogrel, and the latter two are commonly prescribed for those with stroke.

Stroke patients were considerably more likely to be on higher numbers of medications than controls after adjustment for age, gender, deprivation and morbidity count. Number of medications is known to be associated with an increased risk of prescribing errors and adverse drug events^{85 379;380} and can therefore be considered a directly measurable proxy measure of wider aspects of treatment burden. In this study, 21.9% of people with stroke had a painful condition, 20.7% had depression and 13.0% had atrial fibrillation, increasing the risk of being prescribed NSAIDs, antidepressants and anticoagulants concomitantly, a combination known to increase the risk of adverse events such as bleeding. However as discussed in Chapter 2, the optimal number of drugs for an individual is likely to be variable⁸⁹; therefore, caution should be exerted in

the interpretation of results as the measurement of treatment burden is undoubtedly more complex than a simple count of medications.

The number of medications prescribed was correlated with number of morbidities recorded in both stroke and control groups, but more so in the control group. This should be interpreted with caution as stroke patients are likely to already be on significant numbers of preventative medications before other morbidities are added, and many of these medications, such as statins for reducing cholesterol levels, are prescribed for multiple concordant morbidities that require similar drugs such as stroke, coronary heart disease and peripheral vascular disease ¹⁶¹. This reduces the likelihood of additional morbidities increasing the number of medications prescribed in the stroke group compared to controls.

Stroke was considerably more common in older age groups, an unsurprising finding, but one which has important implications for the impact of treatment burden, as elderly individuals are likely to be at higher risk for having poor financial and social resources, reducing their capacity to cope with high levels of treatment burden ¹³. Factors that influence patient capacity to cope with treatments are explored in the next chapter.

6.4.2 Strengths and limitations

These analyses were undertaken using data from a large, nationally-representative, primary care sample and as far as I am aware this is the first study of such scale that examines comorbidity and polypharmacy in stroke. This sample is representative of the Scottish adult population ⁴⁵⁹; however, it may not reflect experience in other countries and healthcare systems.

The prevalence of stroke in this sample was similar to that shown in other studies ^{23;462}, further validating the data; however, data were collected for clinical rather than research purposes. PCCIU data is reliant on data entry systems and completeness within contributing practices. Some practices may have been 'paper light' meaning they no longer use paper notes at all, resulting in more complete data entry relating to consultations. The majority will have used a mixed system of computer and paper recording at the time of data

extraction. However, the data used in this study such as prescription data and diagnosis coding is expected to be quite complete in all practices, and additionally, any items relating to QOF, and therefore payment to practices, are likely to have been well recorded. As recruitment was at the practice level, the most likely bias that could arise in this type of study is a selection bias due to unknown differences in practices who agreed to take part versus those who did not. However, the large numbers in the sample and the knowledge that the sample is representative of the Scottish population are both reassuring.

No standard methods for measuring comorbidity or prescribing exist and therefore a pragmatic approach was taken. There are limitations of the definitions used for some morbidities. For example, because dyspepsia is thought to be poorly recorded in primary care records, patients who were on therapies for dyspepsia were counted as having that condition even if a read code was absent. However, those on aspirin and clopidogrel were excluded as patients on these medications are often given dyspepsia medication prophylactically. This will have precluded most stroke patients from a diagnosis of dyspepsia and therefore the finding that dyspepsia was more common in the control group should be interpreted with caution. Thirty nine comorbidities were examined which is substantially more than in previous studies. The rationale for including the conditions examined and the rules for identifying the presence of each are described in detail by the team who previously collated the data¹⁵⁴ and discussed in Chapter 4. Medications bought over the counter or given from secondary care are not included, although at the time of the analyses prescriptions to over-65s and to many people with chronic conditions were all free, with others being able to cap their out-of-pocket costs, thus suggesting a financial incentive to get medication via the primary care practice.

As this is a cross sectional study, the data is taken from one particular point in time, and therefore no conclusions about temporality or causation can be made. The measure of comorbidity was unweighted, as the aim was to be descriptive rather than to assess outcomes. This was deemed to be the most appropriate method and is similar to that used by others investigating the prevalence of multimorbidity^{154;375;376} but could be viewed as a limitation. It should also be

noted that due to the nature of the study, multiple analyses were carried out. It was decided to report significant results as $p < 0.05$, but results should be interpreted with caution as some results could have arisen by chance. Additionally, the large sample size will have increased the likelihood of finding significant results, and for these reasons, odds ratios were reported to enhance clarity.

Lastly, this study examined comorbidity and prescribing in order to explore treatment burden in stroke. However, there are many other aspects of treatment burden still to be examined, for example clinic visits, co-ordination of care, and financial burden of therapies. Additionally, the development of a patient-reported measure would enable a more detailed examination of treatment burden in stroke from the patient perspective. This will be discussed further in Chapter 8.

6.5 Conclusion

In this large, nationally-representative study, multimorbidity and polypharmacy were shown to be strikingly more common in those with stroke than those without. Diagnoses of most of the 39 long-term conditions were significantly more common in the stroke group. Polypharmacy can be thought of as a direct measure of one aspect of treatment burden and this and multimorbidity are also likely to be proxy markers for other aspects of treatment burden, as patients face the demands of managing multiple medications and conditions simultaneously. The published paper from the work described in this chapter is shown in Appendix 11.

Chapter 7 - Treatment Burden as Experienced by the Stroke Patient

7.1 Introduction

7.1.1 Aims of this chapter

This chapter has two aims: 1) to verify and expand the taxonomy of treatment burden already created; and 2) to explore factors that influence an individual's capacity to manage their health.

7.1.2 Rationale

Two major findings have been described in this thesis so far: 1) A taxonomy of treatment burden in stroke created from a systematic review of the qualitative literature (Chapter 5)^{382;384} and quantification of multimorbidity and prescribing in a large, nationally-representative sample of stroke patients (Chapter 6)³⁸³. In this Chapter, qualitative analyses of interviews with those who have had a stroke are used to expand the taxonomy of treatment burden described in Chapter 5 and to additionally explore what factors influence patient capacity to manage health problems and respond to the requirements of healthcare providers^{13;131}. As discussed in Chapters 2 and 4, the decision to include an exploration of patient capacity in this study was informed by emerging theories in the literature that suggest that investigation of capacity alongside treatment burden is important in order to provide a rich picture of the patient experience^{13;14}. As described in Chapter 3, comprehensive exploration of patient capacity in stroke is currently lacking.

A novel aspect of this work is that the interviews were carried out and analysed in two parts: a first set of fifteen analysed using the same framework used in the systematic review in Chapter 5; and a second set of fourteen analysed using thematic analysis. Methods were influenced by results from the systematic review, Normalization Process Theory (NPT) and theories of treatment burden and patient capacity that were emerging in the literature^{13;14}.

7.1.3 Research question

What treatment burdens do those with stroke describe and what factors affect their capacity to cope with treatments?

7.2 Methods

Ethical approval was granted by the local Medical Research Ethics Committee. Documents are shown in Appendix 12.

7.2.1 Recruitment of participants

A total of 29 participants who had previously had a stroke were recruited from the Greater Glasgow and Clyde area, through both primary and secondary care, including general practices, outpatient clinics and inpatient wards (Stobhill Hospital and Glasgow Royal Infirmary). Those in primary care received information about the study through the post from their GP, along with a letter inviting them to take part. Those in secondary care were approached by a research nurse and given both verbal and written information. Interested participants then sent a reply slip with their contact details, and all were given my contact details in case they required any further information. Times for interview were arranged over the phone. Correspondence sent to primary care practices and secondary care clinics during recruitment are shown in Appendix 13. The information pack given to potential participants is shown in Appendix 14.

Recruitment was purposive to include a range of patient characteristics including gender, age, deprivation, time since diagnosis and severity of disability. Inclusion criteria were: patients aged 18 years and over; diagnosis of haemorrhagic or ischaemic stroke. Exclusion criteria were: a history of mental impairment that would suggest that they would be unable to give informed consent to participate in the study; unable to communicate in English (there was no funding for translators); a history of violence towards members of the primary health care team or other health professionals; a terminal illness, other than stroke, with life expectancy less than 6 months. Thus individuals were excluded without clear evidence of stroke, or who would be unable to provide informed consent, or who present a risk to the research team, or for whom life

expectancy is particularly limited. Patients with aphasia were included, during the interviews alternative methods of communication were used as necessary and carers often spoke with non-verbal verification from the patient.

Importantly, patients with co-morbidities were not excluded.

Recruitment was iterative in that analyses of initial interviews informed recruitment for subsequent ones. For example, after fifteen interviews a gender imbalance was noted and therefore more females were recruited for the last fourteen. Additionally, it was noted that those who had been diagnosed with stroke a long time ago found it hard to recall much about their experiences and therefore those diagnosed in the last five years were purposively sought. It is important to note that although a different method of data analysis was used for the second set of interviews, the same phenomenon was explored (treatment burden) and therefore addressing an imbalance in participant characteristics was still relevant.

7.2.2 Data collection

Each participant was interviewed once in their own home. All gave informed consent prior to the interview starting. The consent form is shown in Appendix 15. One man tired during the interview and asked for it to be completed on a subsequent day. Interviews were semi-structured, however questions were open-ended and participants were encouraged to discuss aspects of treatment burden they felt had been omitted from the schedule. Interview schedules for the first fifteen were theory driven (NPT) and also informed by findings from the systematic review and my clinical experience. Participants were asked to describe the care they had received for their stroke and any burdens they had encountered. Data saturation appeared to have been reached after analyses of data from this first set of interviews; therefore, during the second set, burdens already identified were presented to the patient for verification and comment, and any new burdens sought. Participants were also asked to order the four categories of treatment burden found in the systematic review (making sense of stroke management and planning care; interacting with others including health professionals, family and other stroke patients; enacting management strategies; and reflecting on management) from 'most burdensome' to 'least burdensome'. Additionally, due to an emphasis on patient capacity in the

emergent theories on treatment burden in the literature [1,2], participants were asked to explain factors that had increased or decreased their abilities to cope with their treatments, such as their own personal attributes or support received from others. Field notes were taken during the interviews. Both interview schedules are shown in Appendix 16.

At the end of each interview, an assessment of disability was made using the Modified Rankin Scale (shown in Appendix 17) and this assessment was verified by the patient. Interviews were digitally recorded and then transcribed verbatim by another party. Following the interviews, SIMD decile was calculated from the participant's postcode using an online tool (<http://www.sns.gov.uk/>) and the following data were gathered from primary care records: time since last stroke; number of strokes; number of TIAs; number of co-morbidities; number of regular medications. Medications included all tablets, topical treatments, inhalers and sprays on repeats. Repeat medications were included if filled in the last three months, and acute medications included if obtained three months or more in a row. On examination of the records, it transpired that two patients had in fact had a TIA rather than a CVA (participants 13 and 24), in these cases time since last TIA was noted. Another participant (participant 12) had TIA documented as her first 'stroke' in the medical notes but soon after had left arm weakness documented so this was assumed to be a CVA not TIA.

7.2.3 Data analysis

7.2.3.1 First fifteen interviews

Data from the first fifteen interviews were analysed to explore treatment burden using the same coding framework as was used for the systematic review described in Chapter 5, underpinned by NPT (shown in Chapter 5, Table 9). This allowed direct comparison of results with the review and therefore verification and expansion of the taxonomy of treatment burden. As discussed in Chapter 4, NPT is a sociological theory that seeks to explain how a set of practices such as those involved in stroke management are implemented, embedded and integrated into everyday life^{117;118}. This theory has been widely used in research exploring the implementation of health technologies and complex interventions^{119;121;463}, and more recently it has been utilised in research that explores

treatment burden experienced by those with chronic disease^{11;12;122;384}. NPT is built on four constructs that organize the patient workload of chronic disease management into the following broad categories: sense-making; interacting with others; enacting management strategies; and appraisal work¹¹⁸.

Data were analysed using Nvivo 10 software. The five stages of framework analysis were followed: familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation^{346;347;349 348}.

Familiarisation

This involved reading and rereading the transcripts as well as listening to an audio version of the interviews to familiarise with the content and become 'immersed' in the data.

Identifying a thematic framework

The coding framework was based on the one adapted and refined during data analysis in the systematic review described in Chapter 5. During analysis the framework was scrutinised for any further necessary modifications, but none were necessary and therefore the framework remained unchanged (shown in Chapter 5, Table 9).

Indexing, charting, mapping and interpretation

Data were coded under the four NPT domains (coherence, cognitive participation, collective action, reflexive monitoring) and their subconstructs. Several codes were created within each subconstruct which pertained to aspects of treatment burden. A careful note was made of any treatment burdens that fell outside the coding frame, in order to assess if the framework was 'fit for purpose' and to minimise the risk of 'shoe horning' findings into the framework, as discussed in Chapter 4. No such treatment burdens were found.

To enhance reliability of coding, four transcripts were coded separately by one of my supervisors with experience in qualitative research, and any differences were discussed (interviews with participants 2,6,8, and 15). This was deemed

appropriate as the coding frame had already been developed during coding of data in the systematic review³⁸². No formal assessment was made of inter-rater reliability as the benefits of this in qualitative research are limited³⁵⁶, however no major conflicts arose. Additionally, during the coding process, my supervisor and I were involved in another project that required us to rate complex interventions with regard to their impact on treatment burden and patient capacity¹³², and it was felt that this enhanced our agreement on how to code the interviews in this study.

Following this first stage of coding, themes were created by examining data to look for regularities, irregularities and relationships between components. Data were examined to look for codes that had captured very little data to establish if this data had been coded in error and in fact belonged under a different code with similar meaning (i.e. two codes were aggregated) or if it was a stand-alone item. Data were also examined to look for any data that contradicted other items to explore deviant cases.

A pragmatic approach was taken to subsequently analyse, reorganise and merge themes into a taxonomy of treatment burden using the same four NPT derived headings as in the systematic review, to allow later comparison of findings. At this stage, it was noted that treatment burdens fell into one of two categories: healthcare tasks or care deficiencies. Burdens were therefore further organised into these two groups within each NPT-based heading. This allowed results to be compared to findings from the review whilst adding conceptual depth to results.

7.2.3.2 Second fourteen interviews

Thematic analysis was used to code data from the second fourteen interviews. This was to confirm data saturation following analysis of the first fifteen interviews, and to allow additional exploration of factors that influence an individual's capacity to cope with their treatments. As discussed above, participants had been asked to grade the categories of treatment burden from 'least burdensome' to 'most burdensome' but most found this very difficult and data was not deemed reliable enough for analysis. This is discussed further below.

During data analysis the six stages of thematic analysis were followed: familiarization with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report³⁸⁶.

Familiarization with data

Transcripts were read through and interview recordings listened to. Field notes were examined. Possible codes were noted.

Generating initial codes

Treatment burdens and factors that influence capacity were coded. Interviews were listened to during coding of transcripts as it was helpful to hear the tone of the participants' voices and any pauses in the flow of conversation. Previous codes and transcripts were revisited during the coding process resulting in codes being split or deleted, and therefore the process was iterative. By the end of this stage, data had been reduced into a set of codes.

Searching for themes among codes

Codes were examined to look for patterns, relationships and conflicting ideas, then broader themes created. Some codes were noted to contradict one another, so the data were revisited to check that codes were true to the data and to theorize any apparent reasons why participants reported contradictory experiences, e.g. poor access to a general practitioner could be due to the patient's own mobility difficulties or due to the practice system being substandard, or both.

Reviewing themes

Themes were examined to look for patterns, relationships and conflicting ideas, resulting in splitting or condensing of themes. The data was then revisited to check that themes were true to the data.

Defining and naming themes

Themes were sorted into those that described treatment burden and those that described factors that influence capacity. Themes were examined and notes made about why they were interesting. A few sentences were written to describe each theme and final names given to them.

Producing the final report

Reflections were made on how themes relate to the research question and a thick description of the data given with exemplar quotes.

7.2.3.3 Overall integrative analysis

Components of treatment burden found in the second set of interviews were compared to and merged with the taxonomy created in the first. This taxonomy was then compared to and merged with the original one created in the systematic review described in Chapter 5. A taxonomy of factors that affect patient capacity was created separately.

7.3 Results

7.3.1 Participants

29 participants were recruited, 18 from primary care and 11 from secondary care. 16 were male and 13 female, Table 17 gives detail on age, gender, deprivation (SIMD decile) and disability (Modified Rankin score).

Table 17 – Participant details

Person	Sex	Age group	Number of co-morbidities	Number of medications	Number of strokes	Number of TIAs	Rankin score	SIMD decile	Time since diagnosis in months
1	Male	70-79	2	6	2	2	4	1	241
2	Male	70-79	2	4	1	0	2	8	241
3	Male	60-69	5	9	1	0	2	2	150
4	Male	70-79	4	9	1	1	2	9	58
5	Male	70-79	4	6	1	0	2	4	99
6	Female	70-79	2	8	1	0	0	2	145
7	Female	70-79	7	15	1	1	2	1	85
8	Male	70-79	1	6	1	0	2	9	2
9	Male	60-69	1	3	1	0	2	1	9
10	Male	40-49	2	4	1	0	2	2	217
11	Male	50-59	0	3	2	0	4	1	6
12	Female	60-69	1	8	3	0	4	2	88
13	Male	50-59	5	9	0	1	2	3	66
14	Male	40-49	0	3	1	0	3	1	7
15	Male	70-79	5	8	1	0	0	5	14
16	Female	70-79	3	12	1	0	3	5	28
17	Female	70-79	5	10	1	0	1	8	4
18	Female	60-69	3	7	1	0	3	8	64
19	Female	50-59	3	7	1	0	2	7	28
20	Female	60-69	5	11	1	1	1	7	51

Person	Sex	Age group	Number of co-morbidities	Number of medications	Number of strokes	Number of TIAs	Rankin score	SIMD decile	Time since diagnosis in months
21	Female	80-89	6	9	1	0	3	4	67
22	Female	60-69	0	0	1	0	0	7	25
23	Male	60-69	3	9	3	0	4	2	73
24	Male	80-89	2	11	0	3	1	9	13
25	Female	80-89	4	7	2	0	3	4	12
26	Female	70-79	1	11	1	0	2	9	131
27	Female	60-69	10	11	1	0	2	1	44
28	Male	50-59	3	8	1	0	3	1	8
29	Male	80-89	12	8	1	1	2	1	4

7.3.2 Treatment Burden

Treatment burdens were identified as arising from either: 1) the workload of healthcare; or 2) the endurance of care deficiencies. Healthcare workload encompassed the acts of thinking, organising, doing and reflecting that occur during the management of stroke. Care deficiencies were aspects of health or social care that did not meet perceived needs or expectations. These two components of treatment burden are reported below under the same four phases of stroke management as described in Chapter 5: Making sense of stroke and planning care; interacting with others; enacting management strategies; and reflecting on management. A summary is shown Table 18.

Some new aspects of treatment burden were identified in the interviews that had been missing from the systematic review described in Chapter 5. These are shown in Table 19. No new treatment burdens were uncovered in the second set of interviews when compared to the first. Similarities and discrepancies between findings from the interviews and the systematic review are reported alongside the results.

Table 18 – A summary of treatment burdens uncovered

	Healthcare Workload	Care Deficiencies
Making sense of stroke management and planning care	<ul style="list-style-type: none"> • Understanding symptoms, investigations, treatments, risk factors • Information gathering • Taking responsibility • Goal setting & prioritising • Problem solving • Managing uncertainty & maintaining motivation • Developing coping strategies • Coping with negative emotions 	<ul style="list-style-type: none"> • Lack of information provision & poor signposting • Information hard to understand • Poorly timed information • Not enough verbal information • Not tailored to individual • Lack of support with care planning
Interacting with others	<ul style="list-style-type: none"> • Seeking advice or help from health and social care professionals • Gaining support from friends, family, fellow patients • Strained relationships • Protecting carers • Stigma 	<ul style="list-style-type: none"> • Misdiagnosis • Paternalism • Lack of understanding • Mismatch in ideas • Poor access to GP • Poorly co-ordinated care • Poor continuity • Poor communication from GP
Enacting management strategies	<ul style="list-style-type: none"> • Acute care • Inpatient rehabilitation • Discharge home or to care home • Community rehabilitation • Outpatient appointments • Medications • Risk factor modification • Co-morbidities • Adaptations to home • Home care • Return to driving and employment • Mobility aids • Finances • Enacting coping strategies • Psychological adjustment • Alternative therapies 	<ul style="list-style-type: none"> • Waiting times as inpatient • Unpleasant ward • Poorly supported discharge • Poor GP follow up • Poor follow up for milder cases • Lack of help with transport to appointments • Complicated medication regimes • Poor access to home adaptations and walking aids • Substandard home care • Poor access to driving assessment • Complicated benefits system • Lack of psychological support and support groups
Reflecting on management	<ul style="list-style-type: none"> • Routine appointments for review • Joint healthcare decisions • Reflecting on progress • Non-adherence • Keeping up to date • Worry about another stroke 	<ul style="list-style-type: none"> • Lack of review for milder cases • Poor long term follow up for all

Table 19 – New aspects of treatment burden found from analysis of the patient interviews (not found in the systematic review in Chapter 5).

Treatment burden category from Table 11	New treatment burden	Exemplar Quote
2) Interacting with others	Accessing appointments in primary care	I mean I remember like if I came out and Dr X says I've to make an appointment for two weeks time and she would say oh right well just phone up on the morning of the appointment...You know and I would say well why would the doctor say make an appointment for two weeks time and you are telling me that I've to phone in the morning. (Participant 22)
	Poor communication from primary care about changes to treatments	But they advised me to come off the amiodarone but that was all they said, they said they would write to my doctor. So the next thing I knew there was two items on my prescriptions. But I had, I had never heard of them you see and I thought I don't think these are mine you know. (Participant 6)
3)a) Enacting management strategies: institutional admissions.	Undergoing difficult or frightening therapies	Ah, I was, I was shaking, I was shaking I mean say it's about six stairs but I was shaking because a walking stick that was what they gave me, a walking stick and I went and then this leg was going everywhere oh I couldn't but I done it and when you could do that you get out. (Participant 26)
	Waiting as an inpatient for specialist care	And then they put me down to another ward, general and I spent a week in the general with this dizziness. And then eventually they took me for the tunnel. And they brought me out and they said you've had a mini stroke. (Participant 17)
	Admission to a hospital far from home	And then well they took her, once they got her sort of stabilised blah blah blah because well my daughter spoke to that wee nurse, she knew her and she says it will be easier for cabbing to the Mansion House than it is from the Southern. Especially it was the winter and the snow was about that thingy. So she says we've got facilities, your wife is stabilised we've got facilities in Mansion House with speech therapists, physiotherapists and nurses and that so she went there. (Husband of Participant 16)
3)b) Enacting management strategies: managing stroke in the community	Strategies to remember and organise appointments	That calendar. Every time I go to the doctors I write it down. And I leave a note in the car on my wee kind of box and I'm always in and out there putting my phone in or my fleece or whatever so I always look at it to see if

		there is anything in it and if I see it I say right what's this about. (Participant 13)
	Undergoing alternative therapies	I went to the Alexander Technique for a while and I think he helped me but I haven't been for a wee while have I? He helped my balance they manipulate you, you know your shoulder and when you go in he looks at you and he says I can see you are not standing properly or you are not walking properly and he tries to get you doing things right, you know looking into a mirror and things like that and that definitely did help. (Participant 2)
	Organising and collecting prescriptions	I go and pick them up myself. I phone it up or else I just drop, I was in this morning, I dropped it in and you know I ticked all the things I need and I'll get them on Wednesday when I'm down to get my blood checked. I can't, sometimes I've seen me forgetting to mark things down and getting home and saying oh jees I've missed that and missed this. And after a couple of days down at the doctors again. Instead of doing it all the one it's always in bits and pieces. I do try to do everything at once and I get everything, it's like monthly packs. (Participant 13)
	Complicated medication regimes (varying instructions between tablet, frequent changes to dose, medication or manufacturer)	Well they've just changed one of them, it's the same stuff only... it's got no days on, most of them have Monday, Tuesday, Wednesday so if I go today and I see Monday's there I know I've forgotten one you know...they've changed one of them and its got no bloody days on it at all. No days on it. But I checked the other ones which have the days on so I know whether I've taken them or not because they all get taken together. (Participant 5)
	Warfarin therapy	It's under control this is quite good, well that's eight weeks from when she first went it was maybe two weeks, three weeks because it was going up and down like a yo-yo but just recently it's went down. (Husband, Participant 16).
	Travelling to appointments in primary and secondary care	I did go by the ambulance service a couple of times; you know the wee mini bus. But it was, I had to wait five hours for a lift coming back from hospital you know. And I never had any money or food or anything, you know I felt as if I was going to pass out. (Participant 10)
	Poor follow up from primary care after discharge	Now I don't know because of the illness is that all I require mainly trying to keep me more independent I don't know but

		should've I had back up, I don't know. I thought maybe a couple of days somebody just to look in. (Participant 8)
3)d) Enacting management strategies: adjusting to life after stroke	Accessing psychological therapies	Yes I was able to go to Dr Bloomfield who is a psychotherapist. And he's based at the Western and I went to him for 18 months and he gave me strategies to work on...Like focus on good, focus on, focus on your caravan, you feel good doing that you know on a scale of 1 to 10 how happy does that make you? These kinds of things. (Participant 20)
4) Reflecting on management	Formulating an emergency plan for another stroke	They show you how to get down on the floor and to let yourself go and to try and crawl and if you can't crawl just lie for a minute or two, move your head to see your head is all right, move your arms try and wiggle your toes and then you bring yourself to the nearest object that is solid...That you can get to, that's if you've not got this thing round your neck. (Participant 7)
	Enduring poor follow up to monitor progress, particularly for those who are less severely disable	But I just feel as if they think well we are maintaining, I'm on a lot of medication you know and as long as nobody ever says we'll review that or anything and I've been doing that I've been taken all that for four years, I might not need it. (Participant 20)

7.3.2.1 Making sense of stroke and planning care

Healthcare workload

Similar to findings in the review, participants described making sense of stroke symptoms before they sought medical help. Those who had experienced very obvious signs of illness such as paralysis down one side or inability to speak had contacted either their GP or the ambulance service promptly. One participant was alone at the time of his stroke so had to lie on the floor until symptoms had resolved enough for him to reach a telephone.

And everything suddenly went down there, no speech, nothing. After what, a couple of hours I thought I'll try and move, somebody I can't talk, couldn't get on the phone, that was it, but it eventually cleared about three o'clock, that was about ten o'clock. It cleared about three o'clock in the afternoon. I phoned the doctor and he came up and he said ok come and see me next week, then they thought no we'll send you to hospital and that started in the Royal, accident and emergency. (Participant 8)

Those who had vague symptoms such as mild visual problems, dizziness or abnormal sensations had often delayed seeking help as they were unaware that these could be signs of stroke.

I had come down from the golf. I'd been feeling pins and needles for a few days if not weeks. And they were progressively getting a wee bit worse. I went to the golf and it was so bad I came home and said to my wife I'm going up to A & E I'm not happy about this and they just put me in right away. (Participant 15)

Participants reported that after receiving their diagnosis in secondary care they were given a mixture of written and verbal information, and some had received bad news about their prognosis. Again, these results are similar to findings from the review. All participants had been issued with a 'stroke book' from the local health board, consisting of details about their condition, contact details and information about stroke charities. One dysphasic male patient also received a DVD about recovery from stroke.

See I was under the impression before this happened to me that a stroke meant something to do with the heart or something like that. I didn't know exactly what it was. And when I started to get information I realised what had happened to me medically. This is just, I'd say for the first day, twenty four hours it was hard to take it all in. Because I thought I was a fit person. (Participant 9)

Another finding similar to the review was that participants described making sense of different types of stroke, investigations, treatments, and the roles of different health professionals.

In hospital you get to know the doctors and who is who after like a couple of days or something. You see them. (Participant 14)

Again, similar to the review, participants described self-directed research as a common method of collecting information. Some described reading books and leaflets obtained from the hospital, library or charities, others used the media. Two participants described looking up information on the internet.

We did (look up information) because with the stroke thing we were up there, they send you quite a bit of information. The one that we are affiliated to...chest, heart and stroke. I'll show the book I've got one in there, the magazine things. (Participant 7)

Some displayed poor knowledge because they had used unreliable sources.

Well it's always on my mind that I could because they say you take three strokes, a lot of people have told me that and I knew that myself you take three strokes. Years and years ago when I was younger when my family took them away back but it's different now because a lot of medication now, when my family took it I used to hear them saying if they take a third stroke that's you you know and that was on my mind you know, if I take a third stroke but touch wood I've been fine so far. (Participant 16)

Similar to findings from the review, many participants described spending time planning their recovery during rehabilitation that included setting and prioritising goals. Goals between participants varied depending on the level of disability, but they were commonly related to tasks in the house, employment or hobbies. One paper in the review had suggested that goals differed between men and women, but this was not the case for participants in this study.

Also similar to findings in the review, participants described the cognitive processing required during rehabilitation, including problem solving, dealing with uncertainties of how well they would recover, and maintaining motivation.

I think it was will power with me that brought me back to life. Will power I think it was to get me back you know so I got up and I done it even though I didn't feel you know I still done it you know. (Participant 16)

Enduring care deficiencies

Information provision at the time of stroke was very variable. Some felt they and their families had been kept well informed, but most felt they had not received adequate information about investigations, treatments, risk factor modification, follow up, services available to them on discharge, and signs of another stroke. This resonates with findings from the review. However unlike one of the studies included in the review, no differences between men and women were apparent.

No I don't think they spoke enough. They never let you know what was, exactly what was happening. And you didn't get much feedback off them... they just don't give you any information on how its, how to avoid it, how it's happening, stress things like that. They just don't tell you anything. It's just a case of take these tablets. And you'll be all right. They don't discuss it in any great detail so what happens. (Participant 13)

Some participants that had received information felt that it was difficult to understand. Others could not remember the information they were given at the time of their stroke because they had been too unwell, and it was felt that this had not been an appropriate time to receive information.

And when it hits you it's hard to take in, you need time to assimilate all the information. (Participant 9)

Many found the 'stroke book' helpful that they received, but some felt that it was not accompanied by enough support or verbal information from health professionals.

They came up and says there's a booklet and it's all there, whereas if they said there is a sheet of paper that gives you some information, take that in and then see, read a booklet well I think it was twelve pages, yeah, you start reading it, say you read a page, two pages and you put it down by the time you pick it back up again you've got to go back and read the two pages whereas if they gave you two pages to read there and then and you went through them, you would take them in easier because you know that's all there is to take in and then the next time they give you another couple. (Participant 9)

Some participants appeared confused about where to find information, suggesting that signposting to reliable sources of information by health services is inadequate. Interestingly, several participants said they preferred to not be given information about their stroke in case this caused anxiety. This was more common in women than men.

I don't, I don't look into anything because I think in my mind what I don't know I can't think about. (Interview 22)

Findings from the review had suggested that patients receive a lack of help with care planning and cognitive processing from health services. Participants in this study gave varied reports of this, with patients less severely affected by their stroke tending to feel the least supported.

Okay I was a very mild case; I'm not complaining bitterly that nobody was there to back me up. But I feel it would have been good for someone to say hey we've got a couple of wee tests here just, let's see how you do this. And say yeah you are doing it better than you did three months ago or two months ago and there was nothing. (Participant 15)

7.3.2.2 Interacting with others

Healthcare workload

Participants were asked to give detailed accounts of their contacts with health professionals. On the ward, participants described interactions with medical staff, nursing staff, auxiliaries, and a wide range of therapists. One study in the review had reported that men and women tended to form alliances with healthcare assistants and men with nurses and therapists; however, no such differences were found in this study.

The lady bless her who came round to wash the floors every morning, the whole blooming, she would go morning, morning, happy as Larry and smiling, how are you today, how are you doing, communication all the time. The man that comes round at half past ten in the morning and brings everybody cups of tea and the same man comes back in the afternoon gives us a cup of tea... (Participant 24)

In the community some had been referred onto the community stroke team, which included a range of therapists who continued treatment for a fixed time following discharge. The GP and practice nurse were the main points of contact thereafter. Most participants reported contacting their GP regularly for advice. The majority contacted the surgery by telephone and then either took advice over the phone, organised an appointment at the surgery or made arrangements for a home visit. Some reported turning up at the surgery in person to make an appointment. Practices varied in their systems for allocating appointments, some required patients to contact them on the day they needed to see the doctor, and others made appointments in advance. Several patients had contacted out-of-hours primary care services at some point.

See I don't phone the surgery I go down there for half past eight. Because if I phoned looking for an appointment for that day, I've no car now so if she said I'll give you an appointment for quarter to nine I would never make it down for quarter to nine so I go down there and wait for them opening and... I get an early appointment. (Participant 6)

Again similar to the review, some reported negative interactions with family members due to the strain of managing their stroke, which was often related to a change in family dynamic due to new disabilities post stroke. Participants did

not always like to feel reliant on others, and many did not like the stigma attached to needing care.

Enduring care deficiencies

In the review, many negative interactions between patients and health care professionals had been reported, such as misdiagnosis, mismatch in ideas, and poor continuity of care. Participants in this study were therefore asked about any negative interactions in more detail, and positive interactions were also recorded.

As reported in the review, some participants reported misdiagnosis at initial presentation of stroke. Some had sought help from a medical professional on more than one occasion before stroke was diagnosed, with unsatisfactory outcomes.

I felt the right side going...I found it hard to talk...so I went up to the hospital and I told the doctor I spoke to, this was the Royal what the symptoms were and he said it was viral. And he sent me home so on the Saturday things just gradually got worse and I went back up to the hospital and I spoke to another doctor, a different doctor and the same information again as the first one. He says it sounds as if you've had a brain, a stroke, she says I'm going to need some tests and things like that, she says we are keeping you in. (Participant 9)

During the hospital stay, nursing treatment on the acute stroke ward was described by most as excellent. However, experiences of nursing care varied between hospitals and also between wards, with some describing care that did not meet their expectations. For example one participant had been offered lunch before she had been given a swallowing assessment leaving her at risk of choking on her food, and another complained that one of the nurses had made several mistakes when checking blood pressure and administering medications.

And then in the morning when she came round to give us the medication I was...say for instance I get six there was only four and I said to her there is only four there I think I should get six and she went oh well what one's is it that's not there, that's missing and I went I don't know I don't know and she went away and I had to wait for the staff nurse to come in and I went look I never took them I said that's what I've, that's my medication there I went but there is two missing. (Participant 20)

Several participants reported a lack of time with doctors, allied health professionals and nursing staff during their hospital admission, leaving them feeling isolated on the ward, particularly at weekends. This was similar to findings in the review.

It was the weekend I never got any physio to the Monday but after that I seemed to come on quite well and I was out of hospital within two weeks so...I never realised how you know at the weekends in hospital they don't have the same staff and you don't get the same treatment so literally I had to wait until the Monday but once I got it...it was regular. (Participant 18)

Findings from the review had suggested that stroke patients can experience unsatisfactory interactions with their therapists such as paternalistic care or a mismatch in goals for recovery. However, in this study most participants spoke highly of their therapists on the ward and in the community, with very rare reports of unsatisfactory encounters.

With regard to primary care, many participants spoke highly of their GP, but similar to findings in the review, some reported unsatisfactory interactions, usually in the form of receiving treatment or advice they felt was inappropriate, lacking in empathy, or too paternalistic.

Well the one doctor I felt she was, I've never seen her before and she was new and I felt she was, she wasn't listening to me because I was actually scared to take them and I did take, I never, I've got, I took the prescription and I got them but I never took them. I put up with the pain because I thought you know I was scared to take them because it said that on the so I never took them. (Participant 18)

One participant also complained about poor communication from her GP, describing how she had not been informed about a change in her medications. This burden had not been found in the review.

But they advised me to come off the amiodarone but that was all they said, they said they would write to my doctor. So the next thing I knew there was two items on my prescriptions. But I had, I had never heard of them you see and I thought I don't think these are mine you know. So I spoke to the, she is not there now but the practice manager and she said are you sure you didn't get a letter, we wrote to you I said well I never got the letter I mean I never have any problems with Neil here but I didn't get that letter but they had ticked the boxes that said patient has been advised. (Participant 6)

Several participants reported incidents involving poor communication between their GP and other health or social care professionals which jeopardised their care. This resonated with findings from the review. One man was nearly prescribed harmful medication due to poor information exchange between his GP practice and local pharmacy.

There was only one thing that came up which I just could not understand there was a chemist I had to go down and see at the health centre one day and he wanted to discuss my medication. And he said you are needing to be on, they took me off aspirin when I had the stroke and he said you need to be on aspirin, I said no I think from what they said that caused me the problem, oh no you definitely need to be on aspirin and I said well I'm not going to take any I said you better go and check up on that so he went and I don't know who he spoke to and he came back and he said you are right you shouldn't be on aspirin because I had a bleed. (Participant 2)

The review had lacked detail on accessing appointments in primary care, so participants were asked to elaborate on this. Most were happy with the access available, describing the appointment system as satisfactory. Those who were satisfied reported being able to see their own GP within a few days or any GP on the same day if they needed urgent attention. However, there were some participants who described unsatisfactory waiting times of two weeks or more, and some complained that they were required to phone up the surgery in the morning of the day they wanted an appointment.

Well it's the same as everything else know what I mean, the standing joke is you get an appointment but you might be dead before your appointment. Well they are not too bad because it's usually about two days, something like that...speaking to my daughter and she makes my appointment, for her it could be a week but that's just something we have got to put up with with the national health service. (Participant 9)

Of those who had requested their GP to visit them at home, most did not report difficulties, although a few did. One man had not had an annual review of his medications in several years as he could not attend the surgery and had struggled to arrange a home visit for this.

If you can get him to come out to the house you know, a lot of them don't come to the house you know. Yes to get there you know. (Participant 12)

Access to the out of hours health care service were also described as difficult by some. This was generally considered worse than access to services during working hours.

Participants were asked about continuity of care, as this had been an issue highlighted in the review. Not all patients felt that seeing the same doctor was important, but some described continuity in primary care as lacking.

Yes I would say if it's in cases you know there is something wrong with you then it's important it's the same person who is not looking up a bit of paper or looking at a screen to see what he's, they know what's wrong with you, they know what's going on with you and for someone else just to come in and go oh I'm only a locum I don't know.
(Participant 22)

With regard to outpatient appointments, a few mentioned that they had often seen doctors in training rather than the consultant, meaning that continuity had been lacking. Most were not concerned about this, but one lady blamed inexperienced staff as the cause of her being misdiagnosed with visual defects that prevented her from driving. She remedied this by asking to see senior doctors in all subsequent appointments.

This wee nurse well this wee doctor that I saw first who to me didn't know what she was doing and just said right tokay I'll send you to an opticians then and when I went, it's the thing where you've to, you've to press the button when you se the wee lights, I don't think it was explained to me very well because when I went to do it at the opticians they took a great deal of time with me and I passed with flying colours because there is nothing wrong with my eyesight.
(Participant 19)

Similar to findings in the review, some participants described receiving conflicting information from different health professionals.

Yeah now the chemist said that it was all right to take the statin in the morning as well, my other doctor said he thought it was better at night. (Participant 20)

7.3.2.3 Enacting management strategies

Institutional admissions

Healthcare workload

Participants gave a more detailed description of their time in hospital than was gained from the review. None had spent any time in a nursing home. They described admission through the emergency department for assessment and initial treatment. They described this process as unfamiliar and prolonged, with numerous investigations being carried out to establish a diagnosis.

The doctor took him into the cubicle and we were in there a few hours and obviously they took his bloods and things and the nurse was in checking his blood pressure and checking his heart. (Wife of Participant 14)

Participants reported being admitted to hospital for varying lengths of time, ranging from several days to several months. Most described receiving initial care on an acute ward for several days, followed by transfer to a rehabilitation ward for subsequent therapies, often in another hospital. One man was transferred from a different city during the acute phase of treatment as his family had moved house during his hospital stay.

Soon after admission, patients had generally undergone assessment by a physiotherapist, occupational therapist, speech and language therapist, and dietician. Appropriate therapies were then provided according to patient needs, and patients described working hard to achieve goals.

But I made my mind up that I was going to get up and walk again and I just pushed myself and pushed myself. (Participant 2)

One new and interesting finding in this study was that many participants described their therapies in hospital as frightening, for example climbing stairs unaided for the first time.

Enduring care deficiencies

Participants that had required an ambulance at the time of their stroke all reported it had arrived quickly, and most felt that their emergency care in hospital had been good. However, three participants had been kept waiting for a long period of time in the Emergency Department (ED).

When they took her there we waited well, that took about four or five hours because the doctor, there was only one doctor on and he was rushed off his feet, he apologised, he said, they came and gave us tea

we waited that long then they came back and they said he asked me what you're asking me, start from the beginning. (Participant 16)

Similar to findings in the review, some felt the ward had been unpleasant due to very unwell patients being mixed with those who were more able bodied, noise at night, poor food and a lack of stimulation. One lady talked about how this had motivated her to get better.

Yes I was determined to get out, I wasn't well with staying there because you were in the ward I mean I wasn't young young but I wasn't old either and quite a few of the people that were in the ward were really old and they'd been in it for months. And I thought there is no way I'm going to be here for months. So I ate all the food that I didn't like, I did everything I was told to do and I did more, I would get up and walk about and just make sure I did what I had, I knew I had to do it to get out of hospital and get well again and that's what I did and I was out the thing two weeks, in fact the day the doctor said to me how do you feel about going home I says can I go just now. (Participant 18)

Some patients had received personal care such as help with toileting from nursing staff during their stay. Others were able to manage these tasks themselves. In contrast to findings from the review, participants who required personal care did not report a loss of dignity or long waiting times for care. Fitting into ward routines were also not described as a problem. In fact, most participants in this study reported the standard of nursing care as very high.

One new finding was that several participants reported waiting a long time for investigations or specialist care whilst in hospital. One lady had been admitted to a general medical ward with dizziness and waited for a week before an MRI was done and her stroke diagnosed. During this time she felt that her symptoms were not taken seriously and that her care was substandard until she was transferred to the stroke ward.

And then eventually the stroke nurse found me. She was raging. I'd been in there seven days; she said I've been looking all over for you I said well don't blame me you know... I think they were just moving me for convenience because there was a bed in these wards and there was no room in the stroke ward. (Participant 5)

Another man waited so long for an investigation of his heart (ambulatory electrocardiogram monitor) as an inpatient that he was discharged during the

time he was waiting and had to return several weeks later as an outpatient for the test.

And I left and came back home and then five weeks later went back in to the Western out patients to get fitted for, to get a tape and then take it back 24 hours later so it could be de-counted etc. (Participant 24)

Two participants had been admitted to a hospital far away from their homes which made it hard for their relatives to visit, one because of a bed shortage and the other because they needed specific care only available at that hospital. In the latter case the staff had made arrangements for a transfer back to the participant's local hospital as promptly as was possible, and this had been greatly appreciated by the participant and her family.

Managing stroke in the community

Healthcare workload

To augment findings from the review, therapies undertaken in the community were described in more detail by participants. They reported that they had seen a variety of therapists in the community following discharge, including a physiotherapist, occupational therapist, speech and language therapist, dietician, and psychologist. Therapists often worked as part of a community stroke team, but some participants were unsure if this was the case, and as found in the review, some found it difficult to differentiate between therapists and their different roles. Most described that following discharge they underwent an intense period of outpatient appointments or home visits that lasted several weeks, followed by a quieter period. Most had required therapy for limb weakness or speech difficulties. Unlike in the review, none had required treatment in the community for difficulties in eating.

Oh aye, physios came. Aye they come out to the house with us, occupation therapy, they were great aye, they were great. They were coming out weekly. (Carer: three times a week.) Physio and occupational therapist, you know they done, they were a wee tag team. Aye I did, I had a busy time (Participant 10)

Similar to in the review, patients described working hard to achieve goals set during therapy sessions by practising exercises on their own in between appointments, and they also described making lifestyle modifications. Several

participants had stopped smoking; others had cut down but not stopped. A few had made modifications to their diet, started taking more exercise and reduced their alcohol intake. Participants described how they had learned new self-management strategies, for example one male patient described learning to manage his catheter at home.

A nuisance but otherwise no no I change it every six days and stuff no problem...But the nurse will come in and change the first bit about once a month I would say they are in due in now sometime but no, it's fine, it's a nuisance and annoying. (Participant 8)

Another new finding was the work that participants described when organising and collecting prescriptions. They reported varying arrangements with their GP and chemist, depending on their personal circumstances. Those with poor mobility and a regular prescription tended to get this delivered weekly or monthly to their door without having to leave the house. Others relied on friends and family to pick it up for them. Most did not report difficulties, but a few struggled, for example those who were elderly or on numerous medications.

I go and pick them up myself. I phone it up or else I just drop, I was in this morning, I dropped it in and you know I ticked all the things I need and I'll get them on Wednesday when I'm down to get my blood checked. I can't, sometimes I've seen me forgetting to mark things down and getting home and saying oh jees I've missed that and missed this. And after a couple of days down at the doctors again. Instead of doing it all the one it's always in bits and pieces. I do try to do everything at once and I get everything, it's like monthly packs. (Participant 13)

Similar to findings in the review, patients described taking numerous medications, often in addition to treatments for co-morbidities. Some mentioned drug interactions or side effects, but these had generally been dealt with by the doctor and were no longer an issue. Most said they adhered to their medication regimes, regarding these as important. Some had pill boxes that organised the tablets into daily doses to aid adherence. When discussing medication, participants often minimised the complexity of the regime until they were questioned further.

Well maybe it's not a lot by some standards but the warfarin I've got to take 3mg, well it's in two different lots. Monday, sorry, Sunday to Tuesday I take 4mgs. Wednesday to Saturday I take 3 mgs. Once, I

take that once a day at 6 o'clock at night so the other ones the atenolol I take twice a day, one in the morning and one at night. I take four tablets in the morning, two at teatime or depending what dosage I'm taking and three at bedtime so I don't really take an awful lot...Sometimes I forget taking the warfarin but you can take that up to about 10 o'clock I think but if I miss it I don't take it double the next day I just take, start from scratch again. (Participant 18)

Those on warfarin described having a card with information on it that they could show to health and allied health professionals such as the chiroprapist or dentist, and they found this useful.

Although in the review only one paper mentioned co-morbidities, most participants talked about managing other illnesses alongside their stroke. They described symptoms, medications, therapies, surgical procedures, and appointments. As well as chronic diseases such as diabetes, asthma and hypertension, patients talked about acute illnesses they had suffered such as gallstones or influenza, and musculoskeletal injuries they had acquired.

I've got a yearly check up in the hospital and one down in the surgery, the diabetic clinic, you know how I'm doing with diabetes, they take a blood test and all that, you know, then I go back up to the nurse to find out how it was and the results. (Participant 1)

In the review, appointment volume for those with stroke was reported as high. Reports were variable between participants in this study; however, volume was reported as highest in the year following diagnosis, for those more severely affected by disability and for those with multimorbidity.

I was there in, let me see, I had two appointments there on the 10th and the 19th March and the 25th and I'm not counting you as an appointment...you know my next appointment is in 27th May. And then I've an appointment to see (the doctor) in...June (Participant 29)

Participants valued their health care practitioners attempting to minimise number of appointments by dealing with multiple issues simultaneously. Participants on warfarin tended to describe more burdensome appointment schedules. This was a new finding that had not been reported in the review.

It's under control this is quite good, well that's eight weeks from when she first went it was maybe two weeks, three weeks because it was

going up and down like a yo-yo but just recently it's went down.
(Husband, Participant 16).

The review had included information on nursing home care, but following discharge from hospital all patients in this study returned home. Some had to gain new, more suitable accommodation due to disabilities; others made adaptations to their home.

He's got his lift for your bed, you've got your two lifts for his bed...to get him on his chair or the one to put him into his bed. We've got all the things in the bathroom, we've got that trolley, we've got the other trolley in a room, we've got our wheelchairs, what else have we, well the ramp was there when we came in, we got the ramp put in at the other house. We've got, well it was our own, we bought the beds ourselves, you know like the hospital bed, it rises top and bottom. (Wife, Participant 1)

Two patients had sourced alternative therapies using their own initiative, one had researched and then started practising tai chi and the other had paid to see a practitioner who taught him the Alexander technique. Use of such therapies had not been found in the review.

I went to the Alexander Technique for a while and I think he helped me but I haven't been for a wee while have I? He helped my balance, they manipulate you, you know your shoulder and when you go in he looks at you and he says I can see you are not standing properly or you are not walking properly and he tries to get you doing things right, you know looking into a mirror and things like that and that definitely did help. (Participant 2)

Enduring care deficiencies

Many participants described the period following discharge from hospital as a very difficult time. Some complained that they were discharged abruptly with a lack of follow up or support from secondary care. This resonates with findings from the review.

Carer: I mean they didn't, they told us what we would need to do but they basically threw her out and that was it, that's it, you are in charge of her....and they said oh there is this available and that available and I had to organise it all. I had to organise her physiotherapy, young person's place over in Shettleston. (Participant 12)

Several blamed poor communication between care providers as the reason for poor follow up, resulting in patients having to chase up appointments or results. Many with milder disabilities felt that there was a lack of community therapies available. This resonates with one study included in the review that reported that patients described their level of disability as affecting access to services.

The physiotherapist put me walking, toilet...and you can walk and get into the bath, you don't need help. You can reach yourself, that was a bit disappointing, you are sent home with that, apart from the district nurse coming in every four weeks. That was it, no back up, no nothing. None at all. (Participant 8)

However, those with more severe disabilities tended to describe more comprehensive follow up that involved either home visits from the community stroke team or visits to the outpatient department for several weeks after discharge. Services such as cardiac rehabilitation and the day hospital were reported as helpful, and the community stroke team was often described as an excellent, well-co-ordinated service.

Yeah I think it was Goodryn the occupational therapist, I think she is the one that co-ordinates it. And they all had a diary and Terry had a timetable. And they all communicated and they all knew where each and every one would be at any time you know. So like if we had to change plans at the last minute they could automatically say oh Jen's due out that day and we'll let her know and they would appoint. So there was great, great service, great I cannot fault it anyway. (Wife, Participant 11)

One lady described the number of home visits from the community stroke team as too frequent. However, this finding was unusual, as most reported that they enjoyed these visits and found them important for recovery.

One new and important finding was that many participants complained about a lack of support with regard to travelling to appointments in primary and secondary care. Patient transport systems were universally described as substandard with long waiting times and therefore tiring, extended journeys. Appointments were occasionally missed due to patient transport delays. Those who arranged their own transport found public transport systems difficult to navigate and taxis expensive. Many patients felt they should receive more

financial support from government systems. The centralisation of certain services had made travel times longer and journeys more difficult.

I did go by the ambulance service a couple of times; you know the wee mini bus. But it was, I had to wait five hours for a lift coming back from hospital you know. And I never had any money or food or anything, you know I felt as if I was going to pass out. That's it, that was quite a, if I knew it was going to be like that I would have taken provisions with me you know. So I wasn't too happy about that but what can you do it's just the state, of the care status quo.
(Participant 10)

In the review, several studies had reported that patients found it difficult to gain advice and help in the community as they were confused about whom to approach. A new finding from this study was that many participants felt that GP support was lacking following discharge from hospital.

Now I don't know because of the illness is that all I require mainly trying to keep me more independent I don't know but should've I had back up, I don't know. I thought maybe a couple of days somebody just to look in. Because as you said beginning even moving, making your tea, making your dinner, I'm awful tired after that, nobody came in. Now whether general practice, I don't know. (Participant 8)

Only two participants reported good support from their GP immediately following discharge, which appeared to have been arranged ad hoc by the GP rather than formally requested by the hospital. Both of these participants lived in fairly affluent areas (SIMD 7).

No Dr X came to the house obviously because he's the family doctor and we've known him for years because I mean once I was discharged I phoned to say that I was to make an appointment to come and see him and I remember the girl in the surgery phoned back, he wants to come and see you...no Dr X says you've not to come out...He'll come and see you...Because I couldn't drive (Participant 22)

Several participants had been given a telephone number for a contact in secondary care that they could call if they needed advice or help, avoiding the need for them to see their GP first and be referred on. This appeared to make patients feel empowered and reduced waiting times for expert advice.

And even with the Southern General as I say when I came out and he said any problems if you want to talk to anybody we are only a phone call away. So it really was, it was and it was the doctor's secretary

that you got through to...So you could make an appointment or whatever, it wasn't as though you were getting passed from pillar to post. (Participant 22)

Regarding medications, many participants said they were happy with the regime advised by their healthcare provider. These satisfied patients were on 7-9 medications, with the exception of one who was on none. Satisfaction did not therefore appear to be related to number of tablets, although those on higher numbers did complain about having to take tablets at different times of the day, and warfarin appeared to add particular difficulties as the dose often varied from day to day and was altered frequently depending on the result of a blood test. These findings were all new as they had not been uncovered in the review.

The warfarin is a slightly adhoc thing because I don't know what I'm taking tonight because I haven't been told. But I will be in due course but I've got threes and ones and fives, I'll probably never need them and then I record on here. (Participant 24)

Another new finding was that participants reported frequent changes to medication type or dosage as problematic because this made it harder to follow a regime. Such changes had been made, for example, due to side effects or a change in clinical guidelines.

Like everything else the new tablets came in, they are cheaper, this was a dear tablet and they got rid of it you know so I took that for years right and every time I went to the chemist she says oh that's not in, we don't get that in now it's went out of production you know and I says well I need that you know so I went to Dr X and she wrote a wee letter to take to the doctor and Dr X said it's done away with now that wee tablet so I'm on a white tablet and it's a cheaper tablet, we know it's a cheaper tablet. (Participant 16)

A few participants also reported that changes in drug manufacturer had resulted in their medications changing in size, shape or colour. This made it harder for them to remember to take them. One patient changed chemists as he didn't like the new tablet on offer; others adjusted to the change.

Well they've just changed one of them, it's the same stuff only... it's got no days on, most of them have Monday, Tuesday, Wednesday so if I go today and I see Monday's there I know I've forgotten one you know...they've changed one of them and its got no bloody days on it at all. No days on it. But I checked the other ones which have the days

on so I know whether I've taken them or not because they all get taken together. (Participant 5)

Participants were generally very happy with the pharmacy delivery services they were receiving; however, two did not like that they lost control of which tablets they could request each month, fearing that mistakes may be made.

Several studies in the review had reported that patients often make adaptations to their home following stroke, so participants were asked about this process. Most described the assistance they had received from health and social care as good; however, some reported that adaptations to the house had been difficult to organise.

I did try and get a shower cabinet in for him...because it's awkward for him getting in and out the bath. I've got the shower above the bath...but it's very awkward for him getting in and out the bath. No we will not get it we've been told, there is not much, there is no money for it to do, for anything like that you know...she more or less told us she said we'll get somebody down to assess it but we never heard anymore. She said it's more or less you won't get it. (Wife, Participant 10)

Once adaptations had been made, some participants had found them unsatisfactory so had decided to remove them, for example one lady had been advised to replace steps outside her house with a ramp, but the ramp was not flat so she could not use her quad stick on it. Another lady had disliked an adaptation of her toilet and had taken it back out. Those who had to move house into alternative accommodation due to disabilities following their stroke gave mixed reports. Some had found this an easy process and others felt that waiting times were long.

I had a house, all the stairs. So I put in for a back and front door you know so I managed to get this because it had the shower you know the walk in shower. Aye when you come into it yes. Well four years it took me to get this house. (Participant 12)

Several studies in the review had reported home care as substandard. In this study, several participants had home carers who visited them once or twice a day. Level of care depended on the individual's own abilities, some helped with personal care, and others simply helped to prepare food. The amount that this was subsidised by the government varied depending on each participant's

financial situation. Most described home carers as helpful for making simple meals and helping with tablets but many would have appreciated more help. Those who had little support from friends and family and could not afford private help did not feel that the state funded home care was adequate for their needs.

No because they don't, they can't do the things that you need. Well see like if you are, say for instance sake, windows, can't do that.
(Participant 7)

Reintegrating into society

Healthcare workload

Similar to findings in the review, many participants described obtaining walking aids or braces to aid mobility, although some chose not to use them.

Participants were asked about returning to work and driving, as these were two aspects of reintegration into society that arose from the review. No participants were working at the time of interview. Two were hoping to get back to work but were awaiting assessment, and four had returned after their stroke but then subsequently retired. Depending on level of disability, some were no longer able to drive, some had been banned for a short time, and others had regained permissions though taking a driving test.

I had to go for it; it was about two hours in Paisley. Oh jings it was really strict...It was, it wasn't actually written but I had things down in front of me and I had to identify which things. Read out a passage of words and then after about twenty minutes she said I'll come back to that and ask you questions on it and everything to do with the highway code, there was simulator you know for driving...with the red lights you know you had put your foot on the break when the lights went on and then they took me through Paisley for about half an hour driving. (Participant 2)

Similar to in the review, participants described organising their finances post stroke. This included organising sick pay through their employer or applying for benefits from the government.

The only problem was with my own what do you call them personnel department because you would send in the sick lines and they would get lost in the work and then my benefits would get stopped, now that's nothing to do with the doctor that's to do with the interior

workings of our departments. So I just had to keep on top of them and then I had phoned the DHSS for something and I got a very nice man, he was very helpful and he said to me you are the first person I've dealt with this week that has actually worked so just leave it with me and he went out his way to sort things out for me. (Participant 19)

Enduring care deficiencies

Regarding mobility aids, most participants reported that they had obtained walking sticks, zimmers, and wheelchairs with relative ease. Participants that required splints all described the process of obtaining their splint as extremely arduous and the follow up as poor. Some described the wheelchairs provided by the NHS as difficult to use, as these required someone else to push the wheelchair from behind. Those who had tried to obtain electric ones had run into great difficulties and ended up buying these themselves. These findings resonated with the review.

Uh huh yeah because the wheelchair that we you know gladly got from the NHS which is a godsend but to get an electric pack on the back because it's really difficult, I find it difficult to push Terry because I've got problems with my wrists. And it would help for a wee bit of independence as well. (Wife, Participant 11)

Practical advice from health professionals about coping strategies to aid mobility was appreciated by participants.

In the review, taking a driving test post stroke was described as an arduous and over complicated process. In this study, those who had to retake their driving test gave mixed reports. Although the process was universally described as challenging, many accepted this was necessary; however, one lady complained that the wait to take a driving test was too long and the driving test centre too far away.

See from now you need to go to Edinburgh, they've shut it all down by the way...Aye you've to go to Edinburgh but what I was just going to do was get a train to Edinburgh...Then just a taxi, you just need to swallow it you know what I mean...I don't know how much it would cost me about £30 likely in a taxi. And then sitting your test and then coming back and by the way see if you fail it it's another year before you can sit it again. (Participant 19)

Several studies in the review had reported government benefit systems as complicated and hard to negotiate. In this study, participants' experiences of applying for benefits were variable. Some reported good assistance from health services, but many had struggled to gain help, and they described the process as complicated, poorly co-ordinated and difficult to understand. Some had to wait a long time for any money which caused financial difficulties.

But I had to wait months, I had to wait months to get the right money if you know what I mean, the DLA and that. I had to wait months for that...see the home help I pay that every month, £161.40 a month right and they were sending the bills in when I wasn't getting money to cover it right. (Participant 28)

Some participants had turned to charities for help as they had received no help from health services.

It was fortunate really we went to, there is one, where stroke patients, it's got nothing to do with the hospital it's a charity I think. So we went in there and I went in with her and we were talking to this woman who was very convinced she knew everything and she did. So she said I'll fill the form in for you, so she filled the form in for me. (Participant 5)

Adjusting to life after stroke

Healthcare workload

Participants reported adopting coping strategies to compensate for physical disabilities and communication difficulties. Examples of coping strategies include planning activities ahead of time, carrying out activities more slowly, resting periodically, and communicating through friends and family. These findings resonate with the review.

I don't make it obvious that I've got bad balance. I tend to just touch things when I'm passing. When I go out down the steps... I put my hand on the privet hedge there, find a good strong branch that I know about as I'm going down those extra steps. (Participant 5)

Similar to findings in the review, participants reported spending time gauging their physical and mental limitations and adjusting to these. They also described the difficulties of coping with progress that was slow. Some talked about changing their expectations of recovery as they realised their limitations.

See there was a point in my treatment and while I was there I was wondering what's happening and am I going to get back to what I was. See and that's the frightening part because you start to realise that the things you done, what happens if you can't do them? (Participant 9)

Enduring care deficiencies

Findings from the review had suggested that patients are not adequately prepared psychologically for the consequences of stroke and the hardships of recovery. In this study, a few participants had been offered psychological therapy following their stroke and most had accepted this and found it useful; however, one man had declined this service. Many had not been offered any psychological therapies and although most said they would not have been interested, a few felt that this would have helped them.

Yes I was able to go to Dr X who is a psychotherapist. And he's based at the Western and I went to him for 18 months and he gave me strategies to work on...Like focus on good, focus on, focus on your caravan, you feel good doing that you know on a scale of 1 to 10 how happy does that make you? These kinds of things. (Participant 20)

Availability of stroke groups was often reported as poor, particularly for younger people. This finding resonates with the review.

You know they were people maybe in their late seventies, eighties, some people ninety and they didn't want me because I was only just turned sixty and they, in their eyes there was nothing wrong with me and I didn't look to be anything wrong with me but it was all in my head, it was psychological. (Participant 20)

Due to a lack of availability of appropriate support groups, some participants described funding their own groups.

We get, actually we get taxis (to the stroke club), or Jimmy is in his eighties, Jimmy takes so many, well he took me yesterday and Anna and he brings us home but it's not right because if he had an accident it's not fair to him, it's not fair to his family that he's got to be helping us to get here so a taxi, we've decided we are not doing that. Aye, and we pay for that hall up there, we pay by the hour. So the hall I think is £12.50, I think its £12.50, is it £11.50 an hour something like that. And we pay that, the boy puts the, he's got one of these big tea maker things for hot water. (Participant 7)

7.3.2.4 Reflecting on management

Healthcare workload

Similar to findings in the review, participants described attending routine appointments with both specialists and their general practitioner or practice nurse to review their progress in the longer term. They reviewed medications, made joint healthcare decisions, and had changes made to medications. They also reported using these consultations to ask about new or alternative treatments.

I think realistically its every six months. They call me in; they call me in to do it because I've had a stroke for example. They call me in and say it's time for your checks yeah, they maybe take four blood tests. They maybe take a cholesterol check, test; yeah I think it would be every six months actually. (Participant 15)

The review had highlighted that patients report a desire to keep up to date with newly available treatments. In this study, a few participants expressed an interest in this; however, most appeared uninterested and many said they would rather leave it in the hands of health professionals to tell them if any new treatments became available.

Patients talked about reflecting on their treatments, progress and general health. As found in the review, some compared their progress to others. Many felt that they were 'lucky' as they had not been as badly affected as other people they knew. Some participants monitored their abilities to carry out simple tasks.

I was watching the cup of tea (shaking) and I was seeing the cup of tea not quite so violent for example. And calming down a wee bit and I thought yeah that's better. I was watching the foot. And I was seeing that that was improving progressively. (Participant 15)

Similar to findings from the review, some participants described worrying about the possibility of another stroke and spending time considering how they could modify their risk.

A new finding was that several reported planning how they would respond should another stroke or similar emergency occur.

They show you how to get down on the floor and to let yourself go and to try and crawl and if you can't crawl just lie for a minute or two, move your head to see your head is all right, move your arms try and wiggle your toes and then you bring yourself to the nearest object that is solid...That you can get to, that's if you've not got this thing round your neck. (Participant 7)

Enduring care deficiencies

One new finding was that those with less severe disabilities reported a lack of short term follow up and help monitoring progress, leaving them left to gauge recovery on their own.

No only I do keep coming back to the thought that I feel someone should have been there, someone should have been there to be able to, to be able to say to you are doing okay, just keep going the way you are. (Participant 15)

Many patients also described longer term follow up as poor, and this appeared to be independent of stroke severity or whether initial follow up had been poor. Poor long-term follow up resulted in medications and treatments not being reviewed for long periods of time and confidence in longer term treatments being low. These were new findings not demonstrated in the review.

But I just feel as if they think well we are maintaining, I'm on a lot of medication you know and as long as nobody ever says we'll review that or anything and I've been doing that I've been taken all that for four years, I might not need it. (Participant 20)

In the review, it was uncovered that some patients deliberately contradict advice given by health professionals. A few participants in this study did report structurally induced non-compliance after reflection on their own wishes. Reasons given included side effects, over complicated treatment regimens that they wished to simplify and a mismatch in ideas with health professionals.

She took that pain and she told me all about it and she would give me the pills dah dah dah no you are not, stop giving me them, I'm not taking them. So she's going to give me pills that your granny would have taken. But only a small amount and the side effects I will be sick and they'll make me groggy. And I says right well you can write it out I'll take it for a month, aye okay and away she went...and later on I thought about it and I thought I'm not taking them for a month they are going to make me sick (Participant 26)

7.3.3 Patient Capacity

Six main themes were identified that describe the factors that influence patient capacity to manage health problems: personal attributes and skills; physical and cognitive abilities; support network; financial status; life workload; and environment. These are shown in Table 20 and described in detail below.

Table 20 – Factors that affect patient capacity to manage health and follow treatments

Patient capacity theme	Subtheme	Exemplar Quote
Personal attributes	Positive characteristics e.g. resilience, independence, patience, humour and determination.	I just kept saying I was dead positive, I just decided that you know okay I'm like this and I've got to do my best to get on as well as I can. (Participant 18)
	Negative characteristics e.g. disorganisation, poor engagement with health services, worry, frustration.	Well it's always on my mind that I could because they say you take three strokes, a lot of people have told me that and I knew that myself you take three strokes. (Participant 16)
	Knowledge and past experiences e.g. of stroke or other illnesses.	My past experience. I think that's what helped me. Because I know what to expect. And try, try hard. (Participant 23)
	Practical capabilities e.g. physical, visual, hearing.	I won't be stubborn I'll say to myself I'm needing a doctor I'm going to phone so but recently I've been phoning the wrong numbers. I know the numbers but my hands don't ... and I phone different people in fact some people now realise that it's this silly old woman. (Participant 21)
	Cognitive capabilities e.g. memory, problem solving.	Because sometimes we forget to take, she forgets to take her tablets. Now and again. Sometimes she remembers see she takes wee lapses of memory loss, she'll maybe remember and then she'll forget. (husband, participant 16)
	Skill set e.g. internet use.	I don't know how to use it anymore I've lost my skill for a computer. I've got a tablet there and that my son bought me at Christmas and I don't know how to use it. (Participant 20)
Support network	Friends and family give practical and emotional support such as information gathering, medications and transport to appointments	The warfarin one my daughter always makes sure I take it. (Participant 18)
	Volunteers / charity	So the woman from the chest, heart and stroke volunteer came every Wednesday to talk to me. And do quizzes with me and just generally ask about my family and all that sort of thing and that went on for the 13 weeks while I was still in hospital and that was great. (Participant 25)

	Support groups and other stroke patients	The doctor at one point sent me to a stroke society place to speak to people and it was very, very helpful because there are people there the same as you (Participant 22)
	Employment provides support network	But in, well it's taken me a year I'd say to come to terms because obviously the way my husband is, my work was my sanity you know like friends like just every day talk but it's taken me like a year now to think there is other things than this you know that you can do. (Participant 22)
Financial status	Financial struggles e.g. loss of income, delay in benefits	Well I'll tell you, see the home help I pay that every month, £161.40 a month right and they were sending the bills in when I wasn't getting money to cover it right. And I went like that I says listen nobody is getting paid, gas, electric, TV licence, nobody is getting paid, they are like what, I said nobody is getting paid, I'm not paying nobody so the supervisor comes down from the home care...(Participant 28)
	Ability to pay for own mobility aids, adaptations, private healthcare or home care.	I get Moira, I've got, now which I find frustrating I have to, I've got a little board up in the kitchen or in the hall and it tells me what days Moira is coming and how many hours...It's not through the home helps if you know what I mean. It's this is done privately. (Participant 21)
Life workload	Co-morbidities	Like from day to day well some days if I think I'm walking a bit better than what I do sometimes but then I've got problems with my legs, I've got lymphatic oedema in my legs so my legs are really heavy and I've got arthritis in my knees so some days it's really hard. (Participant 18)
	Stress at work	Now after two years I mean I would say that even my work, it was diabolical trying to get me back and eventually I was going back and I had like a phased return to work but going into phase return to work it lasted for two days and then I was back to where I was so and it was only a year past in January I actually gave my work up I thought it's not worth the stress. (Participant22)

	Dependants	My husband suffers from senile dementia so I had this to contend with and even in the hospital I'm trying to organise things that were going on you know. (Participant 22)
Environment	Geographical location e.g. distance from hospital and transport links	Is when somebody tells you we want you in every morning at 10 o'clock to take your blood sample so we know what warfarin you should take tonight? When you are getting up here at say 8 o'clock you get washed and dressed into the Western waiting there find a car park if you can etc etc which is impossible. Except I have a blue badge and so and I thought this is ridiculous we've got a medical nurse, health clinic in Milngavie...why am I going in there? (Participant 24)
	Home environment	Pauline she gave me a grid for my bed, for under the bed to hold onto to get up. It's a grid you put under your mattress. And I hold onto to it to get me up you know. (Participant 16)
	Availability of aids or gadgets	I had to get it (tablets) put into the (dosette) box. Yeah because I was getting it all mixed up and I was missing stuff at the beginning. So I've had it in that ever since and I still just keep it. (Participant 20)

7.3.3.1 Personal attributes and skills

Personality appeared to play a considerable role in how patients managed their health and perceived their care. Those who displayed characteristics such as resilience, self-efficacy, independence, patience, and humour reported an ability to cope with even the most difficult treatments.

You have to be able to have a bit of a laugh about it. (Participant 11)

Participants' experience of their interactions with health professionals varied depending on their personality and personal preferences. For example, some were happy for their doctor or therapist to take a paternalistic role, whilst others preferred shared decision-making. Interestingly, women tended to prefer a more passive role to men. Similar had been found in the review.

Have you felt sort of involved in decisions about your care or?

No...I just leave it to the doctors. (Participant 17)

Disorganisation appeared to decrease capacity, for example one lady with aphasia had lost all her communication cards but had made no effort to ask for more, making tasks such as travelling by bus difficult as she could not communicate with the driver. Participants who had distanced themselves from health services or showed a lack of interest in recovery communicated a sense of relief at avoiding being burdened by treatments, yet often felt more unwell as a consequence and therefore reported either an escalation in treatments by healthcare providers or a diminished capacity to cope with their everyday lives. For example, one woman who was diabetic confessed to only drinking sugary drinks despite having received advice not to. She was on eleven daily medications including five for her diabetes which was poorly controlled. Another man had refused to seek medical help after a fall despite a decrease in activities of daily living and an inability to carry out his usual exercises.

Negative thinking appeared to affect capacity. Some participants expressed that they were 'worriers' and described negative thoughts or worry about aspects of care such as drug interactions or further stroke. Such negative thinking appeared to consume time and energy. One man felt set back by having recurrent strokes, this had frustrated him and diminished his motivation for recovery.

I think it's been harder this time than it was with the big one...possibly because of the length of time that I'd spent with the big one and knowing I don't know is it knowing I'd got so far and then this happens you take another one and I don't know, it's hard to explain I'm sorry I just...I can't put it into words. (Participant 23)

However, at another point in the interview the same man expressed that he had been able to draw on his previous experiences of stroke to prepare for what to expect the second time. Similarly other participants expressed that being armed with knowledge or experience had helped them to manage their stroke.

Well I do well I read the wee papers but I've got, I've got different medical books which tells you different things, a lot of people don't like to know medical books but I like to read them. Well I look about when I'm in the bookshop I see if there is anything, anything that suits my eye then I buy it. Well the stroke, I read the stroke the symptoms of the stroke are how I took so I know that now. (Participant 16)

Those who had poor knowledge appeared less competent in their stroke management, for example they were less aware of symptoms that may require medical assistance.

Oh yes. I thought a stroke where did that come from because I never had any symptoms I don't suppose you do get symptoms with a stroke, more with a heart attack? (Participant 17)

Several patients described using project management skills, for example to develop reminder systems for medications or appointments.

That calendar. Every time I go to the doctors I write it down. And I leave a note in the car on my wee kind of box and I'm always in and out there putting my phone in or my fleece or whatever so I always look at it to see if there is anything in it and if I see it I say right what's this about. Aye right okay I remember. Aye that's my dictionary, that's my bible that is, everything is on that. (Participant 13)

Some participants reported that they lacked the necessary skill set to use the internet, and others displayed a lack of interest in this.

I don't know how to use it anymore I've lost my skill for a computer. I've got a tablet there and that my son bought me at Christmas and I don't know how to use it. (Participant 20)

7.3.3.2 Physical and cognitive abilities

Practical and cognitive capabilities were described as influential on an individual's capacity to cope with their stroke management. For example, those with physical disabilities who had lost the capability to carry out practical tasks such as washing and toileting found they had a diminished capacity for self-management, and those with visual, hearing or cognitive difficulties struggled with logistical work such as managing appointments on the phone or organising tablets.

I won't be stubborn I'll say to myself I'm needing a doctor I'm going to phone so but recently I've been phoning the wrong numbers. I know the numbers but my hands don't ... and I phone different people in fact some people now realise that it's this silly old woman.
(Participant 21)

7.3.3.3 Support Network

Participants who had close friends and family in their lives appeared to find treatment regimens much less burdensome than those who coped alone. They described gaining emotional support, reassurance and help with decision making. Some described utilising their support networks to gather information.

It probably could have been better because there was a lot of questions that we didn't know and if it wasn't for the fact Jean's daughter, you know going onto the internet and she's a bit, OCD when it comes to finding out things and she was telling all but what they did do was I mean, like how to lift her and things like that. (Husband, Participant 12)

Many participants had obtained help from friends or family when interacting with health professionals, for example when obtaining their diagnosis.

My daughter phoned and she'd phoned and she'd said my mum has been, has had an accident. But Audrey, she works in the Western, she's a nurse practitioner. All brains and no brawn! And anyway she had phoned and the next thing she was up here and then the doctor arrived. She phoned the surgery. And she got speaking to the duty doctor. At the time and told him what had happened. She said well I'll go right to your mother just now. (Participant 7)

Many relied heavily on family or neighbours following discharge from hospital for a range of activities such as housework, personal care and help with therapies, medications and lifestyle modifications.

She had to, there was in the corner and she had to go in the corner and this was to try and build up the bad side and she had to take her good leg off and see how, well there was a possibility she could have fell so somebody had to be there all the time while she was doing that. (Husband, Participant 12)

Those individuals who reported difficulty travelling to appointments tended to lack a support network to help them with transport, meaning they relied on patient transport systems or public transport. Findings from the review suggested that women rely more heavily on family members for support; however, these findings were not repeated in this study. It was, however, found that women more commonly relied on their family to help with transport, whereas men more commonly obtained help with medications. Some participants chose to not ask friends or family for help as they worried they may be a burden to them. Others simply had no support network available. Both of these groups described a feeling of isolation and increased treatment burden, for example a lack of help with transport meant relying on public transport, taxis or patient transport systems.

You know I can feel very lonely. I sit down here and I can't see anybody walking up and down the street you know I can see across the street. But you don't see a smiling face you know or somebody giving me a wave or something like that but I'm very fortunate I, as I say I've got nice neighbours. (Participant 21)

When in hospital, many participants had highly valued the company of other patients and visitors, as they felt this had helped to improve their mood and maintain motivation for recovery.

Three days before I left, different people on each side and they were fine, they were only in for the tunnel, they weren't in for anything you know really and they all went home but I had company and the two ladies that, I couldn't talk to them because they were out of them most of the time, I felt that boring, obviously. But because I had this company and one of them actually comes from down the road there...That was a wee bit, I didn't know her and you know that really made my day...And you know before I left I had another lady next to

me and we blethered away and by then I was feeling better you know.
(Participant 17)

One man suggested that it would have helped him to speak to someone who had previously had a stroke before, and one lady who had been visited by a volunteer working for a charity said she had highly valued the time she spent with her.

So the woman from the chest, heart and stroke volunteer came every Wednesday to talk to me. And do quizzes with me and just generally ask about my family and all that sort of thing and that went on for the 13 weeks while I was still in hospital and that was great because my speech, I couldn't, my speech wasn't very, my speech was all right but I couldn't remember the right words to say if I was trying to describe something and she was helping me. And you know I was beginning to concentrate more when she was in with me, talking with me so that helped. (Participant 25)

In the community, many participants described finding support groups helpful.

The doctor at one point sent me to a stroke society place to speak to people and it was very, very helpful because there are people there the same as you and I remember one girls words saying you've got to think of it as not happening and start living your life. Or you go back the way and it was true because you thought you know you could walk out the door and anything could happen and that's the way you've got to look at it, go back to the way you were, you know no what ifs or buts. (Participant 22)

Those who were employed described their employers and colleagues as a source of support and mourned the loss of this if their employment had terminated.

7.3.3.4 Financial status

All patients in this study were receiving treatments under the NHS therefore most care was free at the point of contact. However, as described earlier, certain services such as home care did require payment, and some participants also chose to pay for services or treatments privately due to long NHS waiting times or poor availability. Financial status varied between participants, some of those who were employed had been able to claim sick pay through their employers but others had lost employment and therefore had suffered a reduction in their income. Many were entitled to financial benefits funded by the UK government and a few who had received such payments reported a

higher disposable income than before their stroke. Some found their financial difficulties a great source of stress.

Well I'll tell you, see the home help I pay that every month, £161.40 a month right and they were sending the bills in when I wasn't getting money to cover it right. And I went like that I says listen nobody is getting paid, gas, electric, TV licence, nobody is getting paid, they are like what, I said nobody is getting paid, I'm not paying nobody. (Participant 28)

One participant had received money from a charity to buy a suitable chair, but had been forced to spend this on food and utility bills because of delays in receiving benefits.

We had no money because of the, you don't get any money for the first three month of having a stroke or something to do with, you don't get any money anyway for X for the first three months of his illness. And we were in the process of applying for benefits so we had absolutely zilch and we got £400 from the chest, heart and stroke. Yeah it was for a chair but ...It's gone. (Wife, Participant 11)

Those with more financial resources were able to lessen their burden by paying for assistance such as cleaners. For example, one lady paid privately for a retired nurse to carry out daily chores for her. Others paid for home adaptations or walking aids.

We asked for a seat as well when we came out of hospital. You know and we didn't give us that we had to go and buy a seat, we had to buy a recline and tilt but she has actually improved since then to get up off the seat herself ...but when she first came out of hospital she didn't have the power or that and I had to go and buy one of these seats. Yeah that was £600 and they told me I had to have that before they would let her out of hospital. (Husband, Participant 12)

Almost all of those who needed a new walk in shower installed had opted to pay for this themselves as waiting times for installation by the local authority were very long and the quality of the showers provided poor. Those who required personal alarm systems also paid for these themselves, but the charge was small and no participants found this cost unreasonable.

It's, that's the wee home alert alarm...It's not dear, but that goes with me, it stays in here when I'm up but when I'm going into bed at night time I hook it onto my zimmer and put it on my bedside table. (Participant 25)

Some participants reported that they had been given financial aid by relatives to make adaptations to the house or gain mobility aids.

After I had the wee mini strokes my daughter said to me you need a shower because I had a bathroom. And you had to step into the bath. To have the shower and wasn't very good at stepping into the bath. And my daughter said to me you need a shower and I said well that's true I know we need a shower but they are very expensive. So she gave us an anniversary present. (Participant 25)

7.3.3.5 Life workload

Some participants described areas of their life outside stroke management that consumed time and energy and therefore impinged on their abilities to manage their stroke. For example, many patients mentioned co-morbidities that they managed alongside their stroke. This added to their workload and could also result in drug-drug and disease-drug interactions.

That's good, but obviously that medication, she did tell her one time to cut down one... paracetamol, try and cut down on the paracetamol, you can take paracetamol but try and cut, don't take too many because it can upset your warfarin when you take two, so she's trying to cut down she only takes them when you are really, when you've got a pain. (Husband, Participant 16)

One lady mentioned stress at work as particularly energy consuming and four participants described being a carer to someone else, which could interfere with the management of their own conditions.

My husband suffers from senile dementia so I had this to contend with and even in the hospital I'm trying to organise things that were going on you know. (Participant 22)

For those with dependents, availability of respite care increased capacity by freeing up time to fulfil other roles or follow management plans.

7.3.3.6 Environment

Those who lived further away from their GP surgery or hospital found it harder to travel to appointments, particularly if they were unable to use public transport. One man who lived in a semi-rural location had found daily attendance at the warfarin clinic over ten miles away particularly difficult.

Because of this he had made arrangements for his GP take over INR monitoring in the local clinic, and this had decreased his treatment burden considerably.

Is when somebody tells you we want you in every morning at 10 o'clock to take your blood sample so we know what warfarin you should take tonight? When you are getting up here at say 8 o'clock you get washed and dressed into the Western waiting there find a car park if you can etc etc which is impossible. Except I have a blue badge and so and I thought this is ridiculous we've got a medical nurse, health clinic in Milngavie...why am I going in there? (Participant 24)

With regard to the home environment, those who had been given access to aids such as mobility aids, aphasia cards and adaptations to their homes were able to self-manage more successfully than those who had not.

It's just an aphasia card. It does say that you've had a stroke...Cause when I went to the shops, I couldn't find what I wanted, and its hard to ask, and the security guy helped me and said ' there its there'. (Participant 14)

Although technology was not commonly used, one man described using an aphasia app on his tablet device to practice word recognition, and another kept an electronic diary in which he kept a note of all his medications and appointments.

7.4 Discussion

7.4.1 Overview of findings

The results described in this chapter have provided several important additions to the knowledge gained from the systematic review and cross-sectional study. First, many of the treatment burdens described in the previous chapters have been confirmed in the real world setting by those who have suffered a stroke, and the taxonomy created in the review has been expanded, with new treatment burdens shown in Table 19. Second, a deeper exploration of treatment burden in the interviews has resulted in two subcategories of treatment burden being identified: 1) the workload of healthcare 2) the endurance of care deficiencies. These two types of treatment burden have been presented under the same four process of stroke care described in Chapter 5: making sense of stroke and planning care; interacting with others; enacting

management strategies; and reflecting on management. A summary of results is shown in Table 18. This method of categorisation not only allows comparison of results with the systematic review, but is also a helpful way of organising and presenting a large and unwieldy list of burdens and furthermore allows examination of causal pathways (discussed in Chapter 8). Lastly, information on the factors that influence patient capacity to follow treatments has been gained.

Due to the small number of participants and nature of analysis in this study, comparisons between groups based on patient characteristics are difficult to make. However, broadly looking at the results and making comparisons based on gender, age, deprivation and level of disability score, few differences were noted between groups and those that were observed were subtle and in need of further investigation. For example, women were more likely to report gaining help with transport from friends and family, and more disabled patients were more likely to talk about obtaining walking aids, gaining suitable accommodation, and hiring carers. More affluent participants were more likely to report paying for their own equipment; they also discussed returning to driving more often, as did those whose employment depended upon this. Younger patients more often discussed cognitive work such as knowing limitations and setting goals. Access to a GP did not seem related to deprivation score, but those who were physically disabled or suffered from aphasia unsurprisingly appeared to struggle more with this. Some participants were generally more negative about their experiences than others, but all gave a mixture of positive and negative comments.

7.4.2 How do treatment burdens found compare to those in the systematic review?

Several differences were found between the treatment burdens uncovered in the systematic review and patient interviews. First, analysis of the interview data resulted in treatment burdens being categorised as either 'healthcare workload' or 'care deficiencies', yet in the systematic review there was no such division. Second, during the participant interviews, many treatment burdens were elaborated on. For example, more detail was gained on how participants gathered information about their treatments. There was also more detail on

which health professionals the participants had interacted with in hospital and in the community, and the quality and outcomes of these interactions. There was considerable more detail on how patients access primary care, their emergency admission, time spent in hospital, medication regimes, lifestyle modifications, adaptations made to the home, home care services and mobility aids.

Participants were able to provide an in-depth account of their experiences with the UK benefits system. The management of co-morbidities was described by most patients, despite the fact that only one paper in the review had mentioned this.

Third, there were some new burdens found from analysis of the interviews, and these were added to the taxonomy. These are given in Table 19. Fourth, a few aspects of treatment burden that had been found in the review were not uncovered during participant interviews. Difficult interactions with therapists were not reported by participants; in fact participants were more likely to describe difficult interactions with their GP, although this was still not common. Participants did not describe a loss of dignity on the hospital ward; instead standard of nursing care was reported as high. No participants were in a nursing home so treatment burdens in this setting were unable to be explored.

Differences between the two studies could have several explanations. There could be a true difference in treatment burdens between populations. This study examined a small sample from the Greater Glasgow and Clyde area whereas the review involved a broader exploration of papers from around the world. For example, nursing care may be better in this geographical area than in the areas covered by the review. Missing treatment burdens in the interviews could also be explained by the small sample size, for example less common burdens may have been missed. Additionally, due to a lack of conceptualisation of treatment burden in the literature, none of the papers in the review explored treatment burden in its entirety. This, along with the iterative nature of data collection and analysis, could explain why new treatment burdens were found in the interviews. Lastly, differences in methods of data collection could have influenced results, for example, speaking to patients directly is likely to have allowed deeper insight into the burdens experienced and therefore led to the subcategorization of treatment burdens into 'healthcare tasks' and 'care deficiencies'.

7.4.3 Patient Capacity

In addition to an expanded knowledge of treatment burden, the factors that affect the capacity of an individual to cope with their treatments have been explored in this study. This exploration was informed by two emerging theories in the literature - Burden of Treatment Theory (BoTT) ¹⁴ and the Cumulative Complexity Model (CuCoM) ¹³, both of which highlight the impact of an individual's own abilities and circumstances on their experience of healthcare. Results are summarised in Table 20. Participants described six factors that affect capacity: personal attributes and skills; physical and cognitive abilities; support network; financial status; life workload; and environment. Capacity was not found to be a static entity but rather one that is ever changing depending on circumstances at any one point in time. For example, relatives who usually care for an individual may go on holiday which would diminish capacity temporarily. Additionally, similar to treatment burden, many aspects of capacity are amenable to change depending on the availability of health and social care services, for example, availability of respite care could help in the above scenario when family are away.

7.4.4 Limitations / strengths

An important strength of this study was the limited exclusion criteria that allowed those with any level of disability or multimorbidity to take part. This, along with the recruitment methods used, resulted in a diverse group of individuals being included. However, as with all research studies, it is likely that the most unwell and deprived patients were 'harder to reach' and therefore the abler bodied and affluent over represented. Additionally, the small number of participants could be viewed as a limitation, particularly as only the second set of participants were asked about factors that affect their capacity. However, in the qualitative research arena this number of participants is generally accepted as sufficient, particularly when undertaking such exploratory work where generalizability of results to large populations is not intended. A detailed description of the sample to allow the reader to understand how results can be generalised is usually deemed adequate, and in this case comparison of results to the systematic review also helps. In this study, participants had a range of levels of disability and deprivation scores. Most were multimorbid and on six

medications or more. Time since diagnosis ranged from two months to twenty years, but around half had been diagnosed with stroke in the past five years. There were ten participants that also reported previous TIA or stroke. Recruiting women for the study proved to be harder than recruiting men therefore women were purposively sought for the second set of interviews. This could perhaps be explained by the prevalence of stroke being higher in men than women in lower age groups and women on average being left more unwell after stroke, resulting in a higher number of younger, more able bodied men who are more likely to participate in research than their older, frailer female counterparts⁴⁶⁴. Certainly the average age bracket of participants in this study was sixty to sixty nine years, younger than the average age of those with stroke in Scotland (seventy three years), suggesting that older patients are harder to recruit³⁸³.

Using two different methods of data analysis proved to be an arduous task, as comparisons between findings from each set of interviews had to be made as well as comparison of findings with the systematic review, which added to the overall workload. The use of two methods of analysis should however be regarded as a strength. As no new treatment burdens were found during analysis of the second set of interviews, this helps to confirm that data saturation had been reached. The use of two methods of data analysis in addition to the framework synthesis used in the systematic review served as a form of triangulation of methods, adding credibility to results. However, due to the limitations of qualitative work regarding generalizability, the taxonomies of treatment burden and patient capacity described here should be thought of as a frame of possible difficulties encountered by those with stroke that deserves further and more generalised exploration, rather than a definitive list. The investigation of capacity was limited to 14 participants from one health board area and this would benefit from further exploration in different patient groups. Additionally, no formal respondent validation was sought after data analysis due to ethical and funding restrictions; however, feedback was informally requested from participants throughout the interviews to clarify that the true meaning of what they had said had been understood.

One factor that could be viewed as a limitation is the use of one data analyst for the second set of interviews. During analysis of the first set, four interviews were also coded by my supervisor, but due to logistical reasons double coding

was not carried out during analysis of the second set. This was, however, deemed acceptable for two reasons: 1) my knowledge on the components of treatment burden and capacity were deemed to be comprehensive following extensive work on these topics ^{11;14;15;81;132;384}; and 2) evidence is lacking to support the use of multiple coders in qualitative research ³⁵⁶.

Lastly, my role as a GP could be viewed as a limitation, as discussed in Chapter 4. However, participants from the practice employing me gave a variety of opinions and comments on their experiences, including both positive and negative, therefore this did not appear to have a significant impact on results. A few participants became emotional during the interviews when talking about their stroke. In these cases, my training as a GP was useful as I was able to deal with their emotion during the interview and judge the extent of the upset, which in all cases was mild and fleeting.

7.5 Conclusion

This chapter has described analyses of face-to-face interviews with those who have suffered a stroke, which have enabled verification and expansion of the taxonomy of treatment burden created in Chapter 5 and a new exploration of patient capacity. The organisation of treatment burden into both processes of stroke care and types of treatment burden allows theorization of causal processes and the creation of a conceptual model of treatment burden and patient capacity in stroke. This is described in the next chapter.

Chapter 8 – Discussion

8.1 Introduction

8.1.1 Aims of this chapter

This chapter has five aims: 1) to integrate findings from the systematic review (Chapter 5), cross-sectional study (Chapter 6), and qualitative study (Chapter 7) to create a conceptual model of treatment burden and patient capacity in stroke; 2) to generate hypotheses about possible changes that could be made to healthcare practice and policy to lessen treatment burden; 3) to discuss strengths and limitations of this thesis; 4) to discuss how findings fit in with current knowledge; 5) to suggest future research requirements.

8.1.2 Rationale

This thesis aimed to explore the treatment burdens experienced by those who have had a stroke, and what factors influence patient capacity. Treatment burden is defined as the workload of healthcare and the influence of this on well-being. Patient capacity is the ability to follow treatments and manage health. The objectives set out at the start of this thesis were as follows:

1. To carry out a systematic review of the qualitative literature that explores how those who have had a stroke experience treatment burden.
2. To quantify comorbidity and prescribing in those who have had a stroke in Scotland.
3. To explore in depth the experience of treatment burden and factors that influence patient capacity by interviewing those who have suffered a stroke.
4. To integrate findings of the above to create a conceptual model of treatment burden and patient capacity in stroke.

Objectives 1-3 have been fulfilled in previous chapters through the use of a mixed methods approach that has provided a rich picture of the patient

experience of treatment burden and patient capacity in stroke. In Chapter 5, a taxonomy of treatment burden was created through systematic review of the qualitative literature (Table 11). Findings suggested four categories of treatment burden: 1) making sense of stroke and planning care; 2) interacting with others; 3) enacting management strategies; and 4) reflecting on management. In Chapter 6, a quantitative analysis of primary care records revealed that multimorbidity and polypharmacy are common in stroke, and that levels of these are high, for example one tenth (10.1%) of those with stroke have seven or more comorbidities and nearly a quarter (24.4%) are on nine or more medications. In Chapter 7, the taxonomy of treatment burden created in Chapter 5 was verified and expanded, and additionally treatment burdens were found to arise as a consequence of healthcare workload and /or care deficiencies (Table 18 and Table 19). A taxonomy of patient capacity was also created which suggested six factors that affect patient capacity: personal attributes and skills; physical and cognitive abilities; support network; financial status; life workload; and environment (Table 20).

In this chapter, a conceptual model of treatment burden and patient capacity in stroke is described, fulfilling the last objective of the thesis. This model was created following an examination of findings from Chapter 5, 6 and 7 in order to ascertain potential causal pathways. The model is described below, followed by a discussion of hypothetical changes that could be made to the design and provision of health and social care services in order to minimise treatment burden for those with stroke. These hypothetical changes were developed following scrutiny of the conceptual model. The rest of the chapter will focus on placing this thesis in context and suggesting future research requirements.

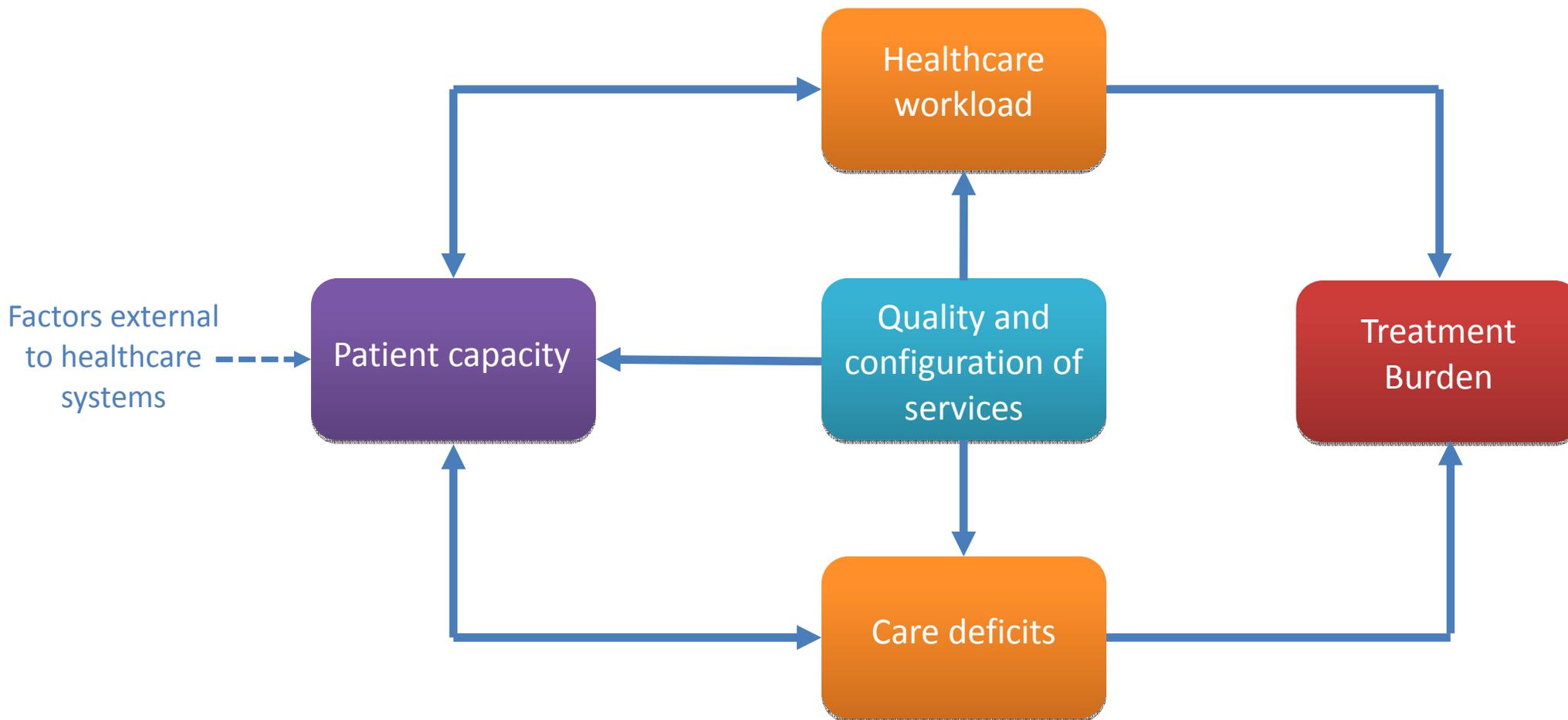
8.1.3 Conceptual model of treatment burden and patient capacity

Examination of the taxonomies of treatment burden and patient capacity provided in Chapters 5 and 7 along with findings from the cross-sectional study in Chapter 6 has highlighted several important causal pathways. The first is that treatment burden arises as a consequence of healthcare workload and/or care deficiencies. The second is that both healthcare workload and care deficiencies can influence and be influenced by patient capacity, for example a high healthcare workload may drain time and energy, and those with more financial

resources may pay for help with aspects of their care. The third is that the quality and configuration of health and social care can influence the presence of care deficiencies, the magnitude of healthcare workload and the capacity of patients to manage their health. For example, less clinical staff available on the ward may result in poor information provision from health services, which could increase workload as other sources of information are sought, and decrease capacity as those armed with less information may feel less confident to self-manage. Patient capacity can also be affected by factors independent of health services, for example those with dependents or time-demanding jobs may struggle to dedicate time to disease management. These relationships are demonstrated in the conceptual model shown in Figure 4. Scrutiny of this model allowed the suggestion of hypothetical changes that could be made to the design and provision of health and social care services in order to minimise treatment burden for those with stroke. This is discussed below.

Figure 4 - Conceptual model of treatment burden in stroke.

Treatment burden arises as a consequence of healthcare workload and/ or care deficiencies, which can both influence and be influenced by patient capacity. The quality and configuration of health and social care services can influence healthcare workload, care deficiencies and patient capacity (the latter is also influenced by factors external to healthcare systems such as the presence of dependents).



8.2 Potential changes to health service provision to minimise treatment burden

The insights into the experiences of those with stroke described in this thesis allow consideration of changes that could be made to clinical practice and policy in order to alleviate treatment burden. This could involve making changes from policy level down to the individual consultation^{9;156;465}. Some burdens may be directly modifiable, for example medication regimes may be simplified by taking several tablets at the same time of day. However, treatment burdens are also likely to influence each other, for example the burden of ‘self-directed research’ may be influenced by other burdens in the taxonomy such as ‘poor information provision’ i.e. those who have received poor information from health services are more likely to feel burdened by the task of self-directed research.

It is important to note that there are likely to be factors other than care provision that have a noteworthy influence on treatment burden. For example, healthcare workload is likely to be influenced by type and number of morbidities, and although improvements to health and social care can certainly modify burden, it may be inevitable that those with certain types or numbers of morbidities have a larger workload than others despite optimization of service provision. Similarly, although findings suggest that patient capacity is heavily influenced by the provision of health and social care, there are aspects of capacity that will also have influences elsewhere, for example social support will partly depend on the presence of family members living nearby, and some aspects of personality may be engrained therefore not amenable to change. With these caveats in mind, the following section discusses areas of burden for patients and makes suggestions as to how these may be lessened through changes in healthcare practice and policy.

8.2.1 Information provision

One important finding was that stroke patients spend significant time and effort seeking out, cognitively processing and reflecting on information about the management of stroke, and that the provision of this information by health services is currently inadequate. This resonates with previous work in stroke and

other chronic diseases^{11;12;93;122;223}. It is clearly demonstrated that 1) access to information is poor 2) adequate time is not given for the exchange of information 3) the information provided is not in a form that is easily understood by patients and not tailored to suit their needs and 4) information provision is often poorly timed. Those with stroke who were interviewed reported receiving written information in the form of a 'stroke book' as very useful, but they appeared to use this as a proxy for contact with health professionals, often perceived as deficient. Those participants who displayed a disinterest in their health appeared to have experienced poorer access to information, but it is difficult to ascertain if apathy was the cause or consequence of poor information provision. Those with stroke described expending much time and effort seeking information from other sources. However, there was a general disinterest in the use of the internet amongst the participants interviewed, and this may reflect the age of those with stroke, as two of the younger participants did report the use of such technology.

Enhanced communication between health professionals and patients along with improvement in the provision of information must be addressed by health services, as patients' understanding of the rationale behind therapies and their trust in management plans is pertinent to achieving optimum adherence³⁷. One participant suggested the implementation of a 'stroke buddy' system that would involve the use of volunteers who have had a stroke to support newly diagnosed patients on the ward as a potential solution. There is evidence of such interventions being effective in the community⁴⁶⁶ and this could be extended to the acute setting.

Participants interviewed displayed little interest in keeping up to date with new treatments by self-directed research after rehabilitation had finished, preferring to leave it up to health professionals to inform them of anything newly available. This is an interesting finding, as it demonstrates a confidence in health professionals with regard to information sharing, yet most patients had reported that information provision from their health care providers was poor at the time of diagnosis. The desire for information seemed to 'fade away' as time went on, and there appeared to be a lack of understanding that new options for therapies may become available. Additionally, those who did show an interest seemed to feel unsure about how to obtain up to date information. As the

‘stroke book’ given to patients in hospital had proved to be popular, a discussion of the benefits of keeping up to date could be included in this, and useful resources such as charity web pages or the practice nurse could be signposted.

Without being armed with appropriate information, patients are less equipped to plan and organise their care, to develop coping strategies and to set goals for recovery. Certainly patients who have limited access to information and therefore poor knowledge about their medications appear to be less likely to adhere to treatments³⁷. However, the clinical implications of poor information provision require further exploration. A recent Cochrane Review concluded that improved information provision to stroke patients showed no improvement in health-related behaviours, health service usage, or mortality⁴⁶⁷. However, the review did demonstrate an improvement in patient knowledge (which could arguably lead to more informed decision making), increased patient satisfaction and a small reduction in depression. It also suggested that interventions that actively involve the patient and carers with planned follow up for reinforcement of management plans had a more significant effect on mood. The best way to provide information is still unclear. It is possible that improved information provision as part of a more comprehensive intervention to decrease treatment burden may be more effective, and this should be explored through both quantitative and qualitative research.

8.2.2 Multimorbidity

One important finding from this work is that high levels of comorbidity are common in those with stroke. Those who were interviewed reported that comorbidities increased workload, resulted in drug-drug and disease-drug interactions, and decreased capacity for coping with treatments. There has been recent recognition of a lack of consideration of multimorbidity within clinical guidelines^{169;468}. This can result in a high volume of poorly co-ordinated investigations and treatments, as clinicians attempt to follow multiple guidelines simultaneously¹⁶⁸. Currently, stroke management guidelines typically fail to mention comorbidities or provide a lack of practical advice for clinicians^{31;34;469-471}. Only one stroke guideline was identified that acknowledged the issue of polypharmacy and again, detailed practical help was lacking⁴⁷⁰. Guidelines should be redesigned to take account of comorbidity and treatment burden, for

example by providing guidance on how to deal with potential drug interactions that may arise ¹⁶⁴.

8.2.3 Care co-ordination

The organisation of services at both macro and micro levels appears to significantly impact treatment burden. Stroke patients report interacting with a variety of professionals including hospital doctors, nurses, general practitioners, speech and language therapists, physiotherapists, occupational therapists, psychologists, and social workers. Poor continuity of care makes the development of trusting relationships difficult, and patients describe receiving ‘mixed messages’ from different carers who do not communicate with one another.

Attending and planning appointments was reported as taking up considerable time and effort, made all the more difficult by poorly organised, fragmented services. As well as increasing treatment burden through an increase in volume of appointments and medications, fragmentation can result in therapies contradicting or interfering with each other and causing difficulties for patients. This is particularly relevant for stroke patients with comorbidity who additionally have other treatment regimens to follow ⁴⁶⁵. Care pathways should be structured around the patient themselves rather than individual conditions, using a more generalist approach that considers issues such as comorbidity as well as the individual’s support network and financial resources ^{13;174;472}. For example, number of appointments could be reduced or better co-ordinated, generalist doctors utilized where appropriate, and reminder systems used. Communication between healthcare providers must also be enhanced, for example through better use of secure electronic email systems. To transfer policy into practice, it is important that quality measures include factors such as care co-ordination that will benefit those with multimorbidity ⁴⁷³. A restructuring of services as well as training pathways for clinicians will be required to enhance availability of more holistic, generalist healthcare for patients.

Issues such as poor continuity of care are likely to depend on the organisation and standard of health care systems which may vary substantially between

countries and localities². It would be useful for future research to examine differences in care co-ordination between geographical areas and any resultant effects on treatment burden. Research can then inform changes to practice and policy at a local level. Additionally, the use of certain technologies may be less available in low income countries and guidelines must take account of this.

8.2.4 The hospital stay

Those with stroke often describe the hospital stay as unpleasant, with a lack of autonomy over treatments, a loss of dignity and loss of control over daily routines. Stroke patients describe feeling abandoned on the hospital ward, describing long periods of time when they feel under stimulated and bored. Patients report that the time with nurses and therapists is too short; mirroring the lack of time spent imparting information as discussed above. This finding is echoed in a recent audit of stroke care in England⁴⁷⁴ and is of concern due to emerging evidence that functional recovery is associated with intensity and length of rehabilitative therapies⁴⁷⁵ as well as very early mobilisation following stroke^{7;476}.

Most of the participants interviewed blamed the healthcare system rather than the individual doctors, therapists or nurses, describing staff as overworked. In fact most talked highly of the staff despite reporting negative experiences of their hospital stay. These observations may have been accurate, or they may have been due to a reluctance to lay blame on staff that had become familiar whilst on the ward, or due to an influence of my role as a GP. The experience of stroke patients on the hospital ward deserves further exploration, and extreme cases of understaffing and negligent care previously uncovered in UK hospitals must make governing bodies vigilant for episodes of substandard care⁴⁷⁷.

Younger patients particularly felt that services available during their inpatient stay were inappropriate for their needs, and this should be addressed. Improved access to recreational activities or time off the ward would boost morale and maintain motivation.

8.2.5 The discharge process

Discharge from hospital is described by those with stroke as a particularly difficult time, with some reporting a sense of abandonment and lack of access to services. These findings tie in with previous research²³. Discharge to the community is a very important step in the recovery process, and this should be timed appropriately so that services are in place to support patients to continue with their stroke management at home.

There were contrasting stories from those who were interviewed, with some describing frequent visits and excellent support from the community stroke team. More disabled patients tended to report more adequate provision although there were exceptions to this. Longer term care following discharge from the community stroke team was a particular issue for many, and a point of continuous contact such as a stroke liaison nurse was not available, yet this can improve patient satisfaction and support the process of discharge and community rehabilitation⁴⁷⁸. Community stroke services have greatly evolved over the past decade, and in some areas an early supported discharge is now available for those who are mild to moderately affected by their stroke²³. Due to the constantly changing nature of stroke services, future research will be needed to address the success of newly available services with regard to community integration.

Many patients feel poorly supported when obtaining technical aids, making adaptations to the house and finding alternative accommodation. Obtaining help with housework and personal care is also difficult. In many areas of the UK some patients are eligible for free or discounted assistance with personal care, but help with housework is not routinely offered and this can be an expense for those who need to pay for help.

8.2.6 Access to services in the community

Those with stroke describe having difficulty accessing healthcare in the community, and this resonated across both developed and developing countries in the review. Several of the participants interviewed had struggled to receive a diagnosis of stroke, having attended a health professional on more than one

occasion before diagnosis was achieved. Stroke varies greatly in its presentation, and can mimic many other illnesses, therefore diagnosis can be difficult.

Improved education for the public as well as healthcare staff that are the first point of contact for patients is vital to improve speed of diagnosis and therefore access to time dependent therapies.

Those who were interviewed gave mixed reports about accessing their GP post-stroke. Most reported being able to see a doctor within a reasonable time period, but not a doctor who had seen them before. This was a particular issue with home visits. Attitudes to continuity of care were again mixed, with some complaining about seeing different doctors and others being happy to see any doctor at the practice. Some described difficulty using the telephone due to aphasia and felt that this was overlooked by both health and social care services. Level of deprivation did not appear to influence access to a GP, but those who were disabled or aphasic did describe access as more difficult, particularly if they had no friends or family to help them. Online systems for organising prescriptions and appointments are becoming more available in the UK and these have the potential to help those with aphasia to manage their health. However, physical and cognitive impairments may render this difficult, and a lack of interest in technology as displayed by the group of participants interviewed may be a further difficulty.

Transport to outpatient appointments was described as difficult by the participants interviewed, with public transport being challenging for elderly or disabled patients to use, taxis expensive and patient transport systems substandard. Those who had used patient transport systems reported long waiting times of several hours after their appointment to get home. In the UK, patients who are on low incomes can claim back money spent on transport to appointments in secondary care, but this does not cover taxi costs, often the only option for disabled patients. Some are entitled to a mobility car; however this relies on the patient being able to drive or having a family member who can drive them.

Findings suggest that access to psychological therapies for those with stroke is substandard and this finding resonates with that found by others^{384;479}. Patients describe the initial phase of rehabilitation as frightening, and report spending

significant time reflecting on their progress, adjusting to new circumstances and maintaining motivation. Better access to counselling or psychology services would be valuable.

8.2.7 Medications

Findings from the cross-sectional study suggest that polypharmacy is common in stroke. Those interviewed described complex medication regimes that they attempted to tie in with their daily routines. Some went to great lengths to sort out their tablets at the start of each day, others remembered to take them through the act of repetition or by using cues, dosette boxes, or family members to help them. Some had deviated from the prescribed routine in order to make it easier to remember them. Patients felt that changes in manufacturer and therefore size, shape and colour of tablet made it harder to follow their routine, as did complex regimes with tablets taken at different times of the day. Most found the system for obtaining their medications satisfactory and felt that help was available as needed. In Scotland, many pharmacies now offer services such as home delivery and shared care of repeat prescriptions to improve access to medications and maximise patient safety.

Adherence to therapies is thought to be substandard in those with stroke³⁵. Non adherence is defined as the failure to follow health behaviours and treatments recommended by a health care professional. Intentional nonadherence is associated with patient's beliefs and intentions, whereas unintentional is related to patient's skills or abilities⁴⁸⁰. It is likely that both of these are heavily influenced by treatment burden and patient capacity, for example, patients who have limited support from health professionals for stabilising their medication regimes have less confidence in their treatments and are less likely to adhere to medications³⁷ and those with cognitive difficulties who are on complex regimes may forget to take medications³⁷. May et al. propose the term structurally induced non-compliance⁹ meaning nonadherence to recommended therapies as a consequence of treatment burdens such as high workload and poor care co-ordination.

Increased time with health professionals would allow improved access to information for patients and a greater understanding of barriers to adherence

from health professionals, allowing joint decision making about treatments. Although this may cost health services money in the short term, any decrease in nonadherence would prevent wasted expenditure in the longer term ⁴⁸¹. Any effects of increased time with health professionals on adherence and health-related outcomes would require further investigation ⁴⁸².

8.2.8 Financial aid

Findings from the review suggested that financial status can affect access to healthcare across the globe. Only two papers involved research that had been carried out in low and middle income countries (Iran and Nigeria) and findings from these suggested that access greatly depended upon financial status. This was also the case in studies from high income countries with payment at the point of access systems such as the US. Interestingly, those in countries with universal healthcare access such as the UK also reported that financial status was influential on access to longer-term care due to complicated, difficult to negotiate systems and long waiting times that resulted in many self-funding. For example, those who were interviewed reported great difficulty in negotiating government systems for claiming benefits and obtaining certain walking aids or adaptations to their home. Additionally, although walking sticks and frames were described as readily available free of charge from the NHS, many chose to buy these or borrow from others due to the poor quality or aesthetic nature of the ones obtained from the NHS. More expensive items such as electrical wheelchairs and scooters were reported as very hard to come by, and most patients had obtained these themselves or received awards from charities. Those who had needed leg braces seemed to have experienced great difficulty obtaining ones that fitted.

However, although such difficulties were reported, all UK participants interviewed described good access to acute care following diagnosis with no barriers or financial difficulties. This contrasts with research done in countries that operate privatised systems, including the two studies from low income countries included in the review ^{92;454;455}.

8.2.9 Shared decision-making

Results suggest that inadequate communication from health professionals can result in poorly individualised care. As a result patients may feel unhappy with services and rebel against medical advice as relationships break down and they feel abandoned by their health care providers. A mismatch in ideas between patient and therapist can lead to great disappointment for the patient when unrealistic goals are not reached, a prerequisite for nonadherence to subsequent management plans, as confidence and motivation are negatively affected. It is important that health professionals spend time with patients to gauge their preferences with regard to their care and their involvement in the decision making process⁴⁸³. Previous research has shown that during the consultation patients are not always forthcoming with their own agendas and therefore eliciting their ideas, concerns and expectations is an important skill on the part of the health professional⁴⁸⁴.

The use of tools such as patient-reported measures of treatment burden and patient capacity could encourage a dialogue between healthcare provider and patient and allow shared decision-making, a technique that is thought to have many merits including improved adherence to treatments^{485;486}. For example, after a discussion about medication burden, a patient with a complicated regime who is struggling with adherence may benefit from the use of a pill box, delivery of medications from a local pharmacy directly to their home, or reducing medication schedules to once daily dosing^{485;487}. As discussed in Chapter 2, there have been recent advances towards the development of such measures, and the development of instruments for use in people who have suffered a stroke should be a priority in stroke research.

8.2.10 Supporting the social network

The physical, psychological and cognitive consequences of stroke can leave those affected socially isolated due to an inability to fulfil previous roles in the community. There is evidence that social isolation both pre and post stroke leads to worse health-related outcomes^{244;488} and that a good social network in those with chronic disease can influence attitudes to self-management⁴⁸⁹. Participants interviewed emphasised the importance of gaining help and support

from friends and family with their treatments as well as everyday chores and activities, although level of support varied and some reported negative interactions with family members. Good social support can increase patient capacity¹³, making the workload of healthcare easier to deal with. It is vital that governments invest money in the improvement of social support for those with stroke and their families. Findings from the review suggest that women ask friends and family for help more than men and further research should be carried out to identify those who are most vulnerable with regard to social isolation.

Social care systems such as home helps and meal delivery systems are frequently described by those with stroke as being of a very poor standard, for example providing a very narrow range of food at inconvenient times of the day. Some of the participants interviewed reported self-funding for these services from private companies. For those who are more able bodied access to services that aid a return to driving and employment is important, as those with stroke describe this as an important step in recovery. Only one interviewed participant described the return to work process as difficult, reporting a lack of support from government agencies and his employer; however, only four patients had returned to work following their stroke and two of these had been several years earlier (followed by retirement). Returning to driving was also not mentioned often. In the review, four papers focussed on the return to work process and two on return to driving (see Appendix 6 and Appendix 7). Results suggest that services to assist and support these processes are currently substandard.

Many interviewed participants reported a lack of availability of support groups, sometimes due to previously available services being closed due to a lack of funding. Younger participants felt that there was a particular lack of groups suitable for their use. Life outside stroke management has an effect on patient capacity and this should be considered by healthcare professionals, for example two participants mentioned that they were carers for their spouse.

8.2.11 Enhance self-efficacy

Those who displayed characteristics such as resilience, self-efficacy, independence, patience, and humour reported a heightened ability to cope with

their treatments. Although in some cases negative characteristics may be engrained and therefore difficult to modify, there will also be cases where attributes can be learned. There is evidence, for example, to support the use of self-management interventions to enhance self-efficacy in those with other chronic diseases and these have potential for use in those with stroke ¹⁴¹.

8.3 Strengths and limitations

Many strengths and limitations have been discussed throughout this thesis (Chapters 4-7); however, in this section an overall appraisal will be given in relation to the use of a mixed methods approach. As discussed in Chapter 4, the use of such an approach can be controversial, as some feel that qualitative and quantitative work are not compatible due to differences in epistemological and ontological assumptions. However, this thesis was approached from a modified realist stance, which allows the search for truth to be considered as a ‘regulative ideal’ while at the same time accepting that it is impossible to be absolutely certain that such truth has been attained. These beliefs lend themselves well to the collection of evidence from different sources that aid our understanding of treatment burden in stroke. This triangulation of methods has resulted in a broader and deeper understanding as well as increased credibility of results ²⁷².

The qualitative systematic review (Chapter 5) produced a taxonomy of treatment burden in stroke from a variety of settings, maximising the variation of treatment burdens found. The quantitative analyses of prescribing and multimorbidity (Chapter 6) provided some evidence of the scale of treatment burden encountered by those with stroke. Findings from these two chapters were then verified and explored deeply in a real life setting through interviews with those who had suffered a stroke in the local area, and factors that influence patient capacity were also explored (Chapter 7).

This thesis benefited from robust theoretical underpinnings and an iterative approach, with methods being informed by evolving theories in the literature and by findings that were arising as the research progressed. This was described in detail in Chapter 4. The use of the same framework for analysis in the systematic review and first set of patient interviews allowed comparisons

between the two, and as this was not a stroke-specific framework, this will allow comparison with other conditions ¹¹. Data saturation with regard to treatment burden was reached after the first set of interviews in Chapter 7. The use of a different method of analysis for the second set allowed clarification that data saturation had not been reliant on the coding framework, and also allowed an exploration of patient capacity. One limitation of this thesis was that patient capacity was explored using only one method; however, valuable information was gained and this work provides a useful stepping stone for future exploration.

Having clinical as well as research interests has undoubtedly influenced this thesis in many ways. The possible influences of my employment as a general practitioner (GP) on the patient interviews were described in Chapter 4. Experience of treating patients in the National Health Service (NHS) contributed to the a priori ideas about treatment burden that informed the methodology used in this thesis. My role as a GP may have influenced how patients described their experiences of treatment burden during the interviews. An experience and understanding of the healthcare system undoubtedly aided the qualitative analyses. However, as the aim was to explore treatment burden and patient capacity from the patient perspective, careful attention was paid at all times to ensure that findings arose from the data to maximise credibility of results.

8.4 How findings fit in with current knowledge

As previously described in Chapter 2, the hypotheses and research questions that underpin the work described here arose from an article published by May et al. in 2009 that described the concepts of treatment burden and minimally disruptive medicine (MDM) ⁹. During the research process two important conceptual models were also highly influential on this work: Burden of Treatment Theory (BoTT) ¹⁴ and the Cumulative Complexity Model (CuCoM) ¹³. Both of these models highlight the influences of healthcare workload, patient capacity and the provision of health services on treatment burden.

In comparison to earlier work on those with heart failure ¹¹, the work described in this thesis uncovered that more emphasis is placed by stroke patients on the development of coping strategies and goals for rehabilitation, as well as on

adjusting to life after the illness has presented. These variances may reflect differences in onset and trajectory of these two chronic diseases, with stroke typically causing a sudden disruption in someone's life followed by slow improvement in symptoms with rehabilitation, whereas heart failure tends to be more insidious in onset with a subsequent gradual deterioration in symptoms.

As discussed in Chapter 2, several other research groups have become interested in the investigation of treatment burden in those with chronic disease. The work described here resonates with key themes relating to healthcare workload and care deficiencies found by others^{96;112;113 114 98 92;93 12;94;95} despite some variation in the conceptualisation of findings, for example others have amalgamated aspects of patient capacity and care deficiencies and labelled these as factors that exacerbate treatment burden^{93;94;96}. Patient capacity is the concept that has been least examined by other groups, although certain aspects have been explored, for example financial status, social support and patient activation^{92-96;114}. One important finding in this thesis that resonates with the work of others is that treatment burden is very sensitive to changes in service provision⁹²⁻⁹⁶. This is important as recent shifts from intensive care environments, such as rehabilitation centres, to self-help and community-based services may fundamentally change the burden of treatment from professionals to patients and caregivers.

None of the studies mentioned above have investigated treatment burden in stroke, and therefore stroke-specific problems such as the difficulties faced by those with aphasia are lacking^{96;112;113 114 98 92;93 12;94;95}. However, a meta-review of qualitative systematic reviews that explored self-management support following stroke was recently published²²³. This found 7 reviews that reported 130 unique studies, and although it was not aimed at exploring treatment burden specifically, many findings resonate highly with the work described in this thesis, for example poor information provision following stroke, a lack of patient-centred focus during rehabilitation, and a need for improved social and psychological support.

8.5 Future research requirements

Scrutiny of the taxonomies and conceptual model created has revealed potential areas of future research. An important future step in the exploration of treatment burden and patient capacity is the creation of patient-reported measures that would enable healthcare providers to identify problematic areas for patients. Before this, however, a more detailed exploration of these concepts is required. For example, the subjective and objective nature of different aspects of burden warrants exploration⁹³, as this will affect methods of measurement. The constantly fluctuating nature of treatment burden and patient capacity also raises difficulties with regard to quantification, for example participants in this study found it hard to differentiate which burdens mattered most to them, and this was probably because they were asked about their experience over a long period of time. It may be that a focus on a shorter time frame is more useful, and the optimal time for measurement is yet to be determined, as is how focussed measurements should be. Additionally, this thesis did not seek to explore the consequences of treatment burden in stroke and this warrants further exploration. Exploratory qualitative work has suggested that for those with chronic disease, treatment burden can influence social roles, psychological health, adherence to medications, service use and the experience of family and carers^{93;94;96}.

Although conceptualisation of treatment burden has evolved considerably over the past six years in the medical and sociological literature, conceptualisation of patient capacity has lagged behind. As discussed in Chapter 2, capacity has been defined as the ability to successfully manage health in the context of everyday life, but how we define successful management remains unanswered. Those who favour biological models of illness would suggest that this equates to the ability to adhere to therapies recommended by health professionals and reach targets set by governing bodies. However, those who favour more holistic models of healthcare would suggest that successful management means the ability to meet targets that are meaningful and important to patients^{174;490}. The work described here explored factors that influence capacity in those with stroke, but it does not explore the true meaning of capacity to patients and this deserves further investigation.

This thesis quantified multimorbidity and prescribing in stroke, but quantification of other aspects of treatment burden is required, for example number of clinic visits, time spent on rehabilitative therapies, and out of pocket expenses. The influence of treatment burden and patient capacity on health-related outcomes such as hospital admission and mortality also deserves exploration.

Here an exploration of treatment burden in those with stroke has been described. However, it is not unreasonable to hypothesise that investigation of those with other types of chronic disease would uncover similar experiences, with the exception of certain disease specific factors, such as the treatment of aphasia. Further exploration of the experience of treatment burden for those with other long-term conditions is warranted, with commonalities and differences between the treatment burdens endured by those with different morbidities or combinations of morbidities worth exploration. A deeper understanding of treatment burden would allow healthcare providers to react to high burden or to pre-empt and prevent it. Suggestions as to how treatment burden may be alleviated are discussed above; however, exploration of whether the implementation of such interventions has an impact on patient experience or health-related outcomes deserves investigation through both quantitative and qualitative methods.

8.6 Conclusion

This work has used qualitative and quantitative methods to uncover the considerable treatment burden experienced by those with stroke, shown to be heavily influenced by the quality and configuration of health and social care services. Taxonomies of treatment burden and patient capacity in stroke have been created along with a conceptual model. Scrutiny of these has led to identification of potential areas for improvement in health and social care provision and future research suggestions. The future development of methods of measurement of treatment burden and patient capacity would allow these factors to be incorporated into quality measures and process indicators²⁹. It is possible that by addressing treatment burden in stroke, particularly for those who are highly comorbid, improvements can be made to the patient experience, adherence to therapies, and health-related outcomes.

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An Exploration of Treatment Burden and Patient Capacity in People with Stroke

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Submitted in fulfilment of the requirements for the Degree of
Doctor of Philosophy (PhD)

General Practice and Primary Care
Institute of Health and Well-being
University of Glasgow

October 2016

VOLUME 2 - APPENDICES

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Appendix 1 - R-AMSTAR scores for each qualitative systematic review
(Relevant qualitative syntheses on treatment burden and patient capacity in stroke)

	Eilersten ²⁰⁶	Hafsteinsdottir ²⁰⁷	Hole ²⁰⁸	Lamb ²⁰⁹	Luker ²¹⁰	McKevitt ¹⁸⁴	Mold ²¹¹	Murray ²¹²	Peoples ²¹³	Reed ²¹⁴	Rosewilliam ²¹⁵	Salter ²¹⁶	Sarre ²¹⁷	Satink ²¹⁸	Sugavanam ²¹⁹	Walsh ²²⁰	Williams ²²¹	Woodman ²²²
Was an appropriate and detailed design provided?	4	4	4	4	4	4	2	4	4	4	4	4	4	4	4	4	4	4
Was there duplicate study selection and data extraction?	2	4	1	3	4	2	1	4	1	4	4	4	4	3	4	2	1	4
Was a comprehensive literature search performed?	2	4	3	2	4	4	3	4	4	3	3	4	3	4	4	4	4	4
Was the status of publication (i.e. grey literature) used as an inclusion criterion?	2	3	2	4	4	2	2	2	2	3	2	1	2	1	2	2	2	3
Was a list of studies (included and excluded) provided?	2	1	1	4	2	2	1	2	2	4	2	2	2	2	2	2	2	2
Were the characteristics of the included studies provided?	3	2	2	1	4	2	1	4	2	4	2	2	3	4	2	4	4	4
Was the scientific quality of the included studies assessed and documented?1	2	3	3	4	4	1	1	1	1	4	3	4	3	4	4	4	4	4
Was the scientific quality of the included studies used appropriately in formulating conclusions?	2	2	2	4	3	1	1	4	2	4	4	4	1	3	2	2	2	3
Were the methods used to combine the findings of the studies appropriate?	4	3	4	4	2	4	1	4	4	4	4	4	3	3	3	3	4	3
Was the conflict of interest stated?	3	3	2	2	2	2	2	1	4	3	3	1	3	3	3	3	2	2
Total score/40	26	29	24	32	33	24	15	30	26	37	31	30	28	31	30	30	29	33

Appendix 2 - Table of morbidities examined

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Condition	Variable Definition
Hypertension	Read code ever recorded
Depression	Read code recorded in last 12 months OR ≥ 4 anti-depressant prescriptions (excluding low dose tricyclics) in last 12 months
Painful condition	≥ 4 prescription only medicine analgesic prescriptions in last 12 months OR ≥ 4 specified anti-epileptics in the absence of an epilepsy Read code in last 12 months
Asthma (currently treated)	Read code ever recorded AND any prescription in last 12 months
Coronary heart disease	Read code ever recorded
Treated dyspepsia	≥ 4 prescriptions in last 12 months BNF 0103% excluding antacids AND NOT (≥ 4 NSAIDS OR ≥ 4 aspirin/clopidogrel)
Diabetes	Read code ever recorded
Thyroid disorders	Read code ever recorded
Rheumatoid arthritis, other inflammatory polyarthropathies & systematic connective tissue disorders	Read code ever recorded
Hearing loss	Read code ever recorded
Chronic obstructive pulmonary disease	Read code ever recorded
Anxiety & other neurotic, stress related & somatoform disorders	Read code in last 12 months OR ≥ 4 anxiolytic/hypnotic prescriptions in last 12 months OR ≥ 4 10/25mg amitriptyline in last 12 months & do not meet the criteria for 'Pain'
Irritable bowel syndrome	Read code ever recorded OR ≥ 4 prescription only medicine antispasmodic prescription in last 12 months
New diagnosis of cancer in last five years	Read code first recorded in last 5 years
Alcohol problems	Read code ever recorded
Other psychoactive substance misuse	Read code ever recorded
Treated constipation	≥ 4 laxative prescriptions in last year
Stroke & transient ischaemic attack ^{a,b}	Read code ever recorded
Chronic kidney disease	Read code ever recorded
Diverticular disease of intestine	Read code ever recorded
Atrial fibrillation	Read code ever recorded
Peripheral vascular disease	Read code ever recorded
Heart failure	Read code ever recorded
Prostate disorders	Read code ever recorded
Glaucoma	Read code ever recorded
Epilepsy (currently treated)	Read code ever recorded AND antiepileptic prescription in last 12 months
Dementia	Read code ever recorded
Schizophrenia (and related non-organic psychosis) or bipolar disorder	Read code ever recorded/recorded in last 12 months (code dependent) OR Lithium prescribed in last 168 days
Psoriasis or eczema	Read code ever recorded AND ≥ 4 related prescriptions in last 12 months (excluding

	simple emollients)
Inflammatory bowel disease	Read code ever recorded
Migraine	≥ 4 prescription only medicine anti-migraine prescriptions in last year
Blindness & low vision	Read code ever recorded
Chronic sinusitis	Read code ever recorded
Learning disability	Read code ever recorded
Anorexia or bulimia	Read code ever recorded
Bronchiectasis	Read code ever recorded
Parkinson's disease	Read code ever recorded
Multiple sclerosis	Read code ever recorded
Viral Hepatitis	Read code ever recorded
Chronic liver disease	Read code ever recorded

^a Those with TIA were excluded and only those with stroke counted in this thesis.

^b Stroke was excluded from the morbidity count in this thesis.

Appendix 3 – Prospero protocol

PROSPERO - Print review

Page 1 of 8

Review title and timescale

1 Review title

Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.

[Identifying treatment burden in stroke patients, a systematic review](#)

2 Original language title

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date

Give the date when the systematic review commenced, or is expected to commence.

[15/02/2011](#)

4 Anticipated completion date

Give the date by which the review is expected to be completed.

[30/06/2011](#)

5 Stage of review at time of this submission

Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes
Prospective meta-analysis	No	No

Provide any other relevant information about the stage of the review here.

[Review is complete, methods paper in press, results paper soon to be submitted for publication.](#)

Review team details

6 Named contact

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

[Katie Gallacher](#)

7 Named contact email

Enter the electronic mail address of the named contact.

katie.gallacher@glasgow.ac.uk

8 Named contact address

Enter the full postal address for the named contact.

[Academic Unit of General Practice and Primary Care University of Glasgow 1 Horselethill Road G12 9LX](#)

9 Named contact phone number

Enter the telephone number for the named contact, including international dialing code.

[0141 330 8323](#)

10 Organisational affiliation of the review

Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

[University of Glasgow, Mayo Clinic Rochester, University of Southampton](#)

Website address:

11 Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Dr	Katie	Gallacher	University of Glasgow
Dr	Deborah	Morrison	University of Glasgow
Professor	Patricia	Erwin	Mayo Clinic
Dr	Bhautesh	Jani	University of Glasgow
Professor	Carl	May	University of Southampton
Dr	David	Eton	Mayo Clinic
Dr	Sara	McDonald	Univeristy of Glasgow
Professor	Victor	Montori	Mayo Clinic
Professor	Frances	Mair	University Glasgow
Professor	David	Batty	University College London
Professor	Peter	Langhorne	University of Glasgow

12 Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.

[Funded by Chief Scientist Office Scotland \(CAF/10/03\)](#)

13 Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

Are there any actual or potential conflicts of interest?

[None known](#)

14 Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details
Dr	David	Batty	University College London
Professor	Peter	Langhorne	University of Glasgow

Review methods

15 Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

Review Question What treatment burdens are experienced by stroke patients? Objectives To identify the components of treatment burden: 1) Logistical burdens e.g. interacting with health care organisations, carrying out administrative work involving insurance companies or others, organising appointments or visits from health professionals, organising rehabilitation, arranging transport, funding care. 2) Technical burdens e.g. enacting lifestyle changes, performing rehabilitation exercises, modifying environments, taking medications, using assistive technologies. 3) Relational burdens e.g. enrolling family, friends and health professionals for support, initiating interactions with possible carers and supporters, maintaining relationships during rehabilitation. 4) Sense making burdens e.g. conceptualising problems, understanding and learning about management strategies, knowing when to seek help, differentiating between treatments.

16 Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

Databases to be searched: Scopus, CINAHL, Embase, Medline & PsycINFO. Restrictions: - English Language - Publication date 2000 and onwards Grey literature/unpublished studies (dissertations/theses, conference proceedings or published abstracts, treatment guideline documents) will not be sought.

17 URL to search strategy

If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

18 Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Stroke is a common cause of morbidity worldwide, with stroke patients undergoing long term complicated management plans. Treatment burden is the material practices that patients have to perform to undertake self care and respond to the requirements of healthcare providers. This systematic review will comprehensively cover the qualitative literature that explores the treatment burden of stroke as experienced by stroke patients.

19 Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion: Studies from any geographical location Adults (18 yrs or older) diagnosed with at least one CVA /CVD / stroke (including ischaemic, intracerebral haemorrhage or subarachnoid haemorrhage) at any anatomic location, as per WHO's definition 'rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin.' Being treated in any 'usual care' setting: primary; secondary; tertiary care, e.g. in the hospital, hospice, community, home or rehabilitation. Receiving care typical for that geographical location i.e. not as part of experimental or pilot studies. Exclusion: Children (<18 yrs). No CVA diagnosis. Diagnosis of TIA, subdural haematomas, infarction / haemorrhage due to infection or tumour, cerebral palsy or any other neurological deficit.

20 Intervention(s), exposure(s)

Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

Any care given in a usual care setting which is typical for the geographical location in which the study took place, and not given as part of experimental or pilot studies.

21 **Comparator(s)/control**

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

N/A

22 **Types of study to be included initially**

Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

Studies seeking to understand the patient experience, through direct contact with patients or direct observation, using any form of qualitative method to describe patterns or themes raised by participants will be included. For example, original qualitative studies, studies involving secondary qualitative analysis of qualitative data, qualitative studies that are part of a mixed methods study (e.g. the study also has a quantitative component). Studies using the following methodologies will be excluded: lexical studies that analyse natural language data presented as quantitative results; studies without a sampling procedure; qualitative studies that do not involve direct contact or observation of participants.

23 **Context**

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24 **Primary outcome(s)**

Give the most important outcomes.

Components of treatment burden: 1) Logistical burdens e.g. interacting with health care organisations, carrying out administrative work involving insurance companies or others, organising appointments or visits from health professionals, organising rehabilitation, arranging transport, funding care. 2) Technical burdens e.g. enacting lifestyle changes, performing rehabilitation exercises, modifying environments, taking medications, using assistive technologies. 3) Relational burdens e.g. enrolling family, friends and health professionals for support, initiating interactions with possible carers and supporters, maintaining relationships during rehabilitation. 4) Sense making burdens e.g. conceptualising problems, understanding and learning about management strategies, knowing when to seek help, differentiating between treatments.

Give information on timing and effect measures, as appropriate.

25 **Secondary outcomes**

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.

None

Give information on timing and effect measures, as appropriate.

26 **Data extraction, (selection and coding)**

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Title, abstract and full paper screening will be carried out by two researchers independently using Distiller software. Data extraction and data analysis will be carried out using a combination of Distiller software and Word. A formal data extraction instrument will be used. Any disagreements will be discussed with a third party.

27 Risk of bias (quality) assessment

State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

Studies will be assessed for quality using guidelines discussed by Popay, Williams and Rogers (1). This will be carried out by two independent reviewers and any differences discussed with a third party. (1) Popay J, Rogers A, Williams G. Rationale and Standards for the Systematic Review of Qualitative Literature in Health Services Research. *Qualitative Health Research* 1998; 8(3):341-351.

28 Strategy for data synthesis

Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

Data will be synthesised using a framework underpinned by NPT. (1) (2) This framework will be used to categorise any treatment burdens described in the literature, and any treatment burdens falling outside of the framework will be carefully noted. The resultant chart will then be used to define concepts and create a typology of treatment burden as experienced by stroke patients. It is important that interpretation is influenced not only by pre-conceived ideas of treatment burden as outlined above but by burdens emerging from the data. (1) May C, Finch T. Implementing, embedding, and integrating practices: an outline of Normalization Process Theory. *Sociology* 2009; 43(3):535-554. (2) Normalization Process Theory <http://www.normalizationprocess.org/bibliography.aspx>

29 Analysis of subgroups or subsets

Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.

None planned

Review general information**30 Type of review**

Select the type of review from the drop down list.

[Other](#)

31 Language

Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.

[English](#)

Will a summary/abstract be made available in English?

[Yes](#)

32 Country

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.

[Scotland](#)

33 Other registration details

List places where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute). The name of the organisation and any unique identification number assigned to the review by that organization should be included.

[None](#)

34 Reference and/or URL for published protocol

Give the citation for the published protocol, if there is one.

Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

35 Dissemination plans

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

[We plan to publish in a peer reviewed journal, as well as disseminate findings through the Scottish Stroke Research Network.](#)

Do you intend to publish the review on completion?

[Yes](#)

36 Keywords

Give words or phrases that best describe the review. (One word per box, create a new box for each term)

[stroke, treatment burden, patient experience](#)

37 Details of any existing review of the same topic by the same authors

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

[None](#)

38 Current review status

Review status should be updated when the review is completed and when it is published.

[Completed but not published](#)

39 Any additional information

Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)

This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.

Give the URL where available.

Appendix 4 - Search strategy for the systematic review

Search strategy.

Details of the strategies employed for searching Medline, Embase, PsycINFO, CINAHL & Scopus databases.

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1948 to Present # Searches Results Search Type

1 *cerebrovascular disorders/ or exp *brain ischemia/ or exp "**intracranial embolism and thrombosis"/ or exp *intracranial hemorrhages/ or exp *stroke/

2 *stroke/co, di, dh, dt, nu, pc, px, rh, th

3 (cerebrovascular disorders/co, di, dh, dt, nu, pc, px, rh, th or exp brain ischemia/co, di, dh, dt, nu, pc, px, rh, th or exp "intracranial embolism and thrombosis"/co, di, dh, dt, nu, pc, px, rh, th or exp intracranial hemorrhages/co, di, dh, dt, nu, pc, px, rh, th) and stroke*.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

4 1 or 2 or 3

5 limit 4 to (english language and humans and yr="2000 - 2013")

6 (burden* adj2 (treat* or therap*)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

7 activities of daily living/ or health behavior/ or health, knowledge, attitudes, practice/ or lifestyle/ or occupational therapy/ or palliat*.mp. or patient education as topic/ or exp rehabilitation/ or exp physical therapy modalities/ or self care/ or barthel*.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

8 Disabled Persons/ or Disability Evaluation/ or work capacity evaluation/ or functional disability.mp.

9 social support/ or exp family/px or exercise/ or "physical education and training"/ or physical endurance/ or fatigue/ or physical fitness/ or long term care/

10 exp Gait/ or exp Gait Disorders, Neurologic/ or exp Accidental Falls/

11 self administration/ or (treatment adj3 (regimen* or regime* or tasks or work)).mp. or unnecessary*.mp. or unmet.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

12 exp cognition disorders/ or independen*.mp. or dependenc*.mp. or socioeconomic factors/ or life change events/ [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

13 5 and 6

14 5 and 7

15 5 and 8

16 5 and 9

17 5 and 10

18 5 and 11

19 5 and 12

20 5 and (travel*.mp. or automobile driving/ or mobility limitation/ or transportation/) [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

21 5 and (recover* or challeng* or goal*).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

22 5 and (interpersonal relations/ or social isolation/ or cost of illness/ or schedul*.mp.) [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

23 or/13-22

24 (focus group* or ethnograph* or phenomenol* or observation* or (grounded adj theory) or (framework adj analysis) or (thematic adj analysis) or (constant adj comparison)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

25 adaptation, psychological/ or adheren*.mp. or nonadheren*.mp. or patient compliance/ or noncomplan*.mp. or inconvenien*.mp. or negotiat*.mp. or (patient adj2 (care or experience or understand* or expectation* or perspective*)).mp. or patient satisfaction/ or personal autonomy/ or physician-patient relations/ or professional-patient relations/ or dissatis*.mp. or quality of life/ [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

26 self concept/ or self care/ or self-management/ or suffer*.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

27 attitude/ or attitude to health/

28 (questionnaire* or survey* or qualitative* or interview*).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

29 23 and (25 or 26 or 27) and (24 or 28)

30 23 and (exp leisure activities/ or health status/ or well-being.mp.) and (24 or 28) [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

31 29 or 30

32 Health Services Accessibility/

33 23 and (32 or continuity of patient care/ or disrupt*.mp.) and (24 or 28) [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

34 5 and (communication* or literac*).mp. and (24 or 28) [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

35 31 or 33 or 34

36 5 and sickness impact profile/

37 5 and needs assessment/

38 35 or 36 or 37

EMBASE 1988 to 2013 Week 08 # Searches Results Search Type

1 *cerebrovascular disorders/ or exp *brain ischemia/ or exp "**intracranial embolism and thrombosis"/ or exp *intracranial hemorrhages/ or exp *stroke/

2 *stroke/co, di, dm, dt, rh, th

3 cerebrovascular disorders/co, di, dm, dt, rh, th or brain ischemia/co, di, dm, dt, rh, th or exp "intracranial embolism and thrombosis"/co, di, dm, dt, dm, rh, th or exp intracranial hemorrhages/co, di, dm, dt, rh, th

4 1 or 2 or 3

5 limit 4 to (english language and humans and yr="2000 - 2013")

6 ((burden* adj2 (treat* or therap*)) or hassle* or medication adherence or medication compliance or medication concordance or physiotherapy or occupational therapy).mp. or rehabilitation/ [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

7 activities of daily living/ or health behavior/ or health, knowledge, attitudes, practice/ or lifestyle/ or occupational therapy/ or palliat*.mp. or patient education as topic/ or exp rehabilitation/ or exp physical therapy modalities/ or self care/ or barthel*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

8 Disabled Persons/ or Disability Evaluation/ or work capacity evaluation/ or functional disability.mp.

9 social support/ or exp family/px or exercise/ or "physical education and training"/ or physical endurance/ or fatigue/ or physical fitness/ or long term care/

10 exp Gait/ or exp Gait Disorders, Neurologic/ or exp Accidental Falls/

11 self administration/ or (treatment adj3 (regimen* or regime* or tasks or work)).mp. or unnecessary*.mp. or unmet.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

12 exp cognition disorders/ or independen*.mp. or dependenc*.mp. or socioeconomic factors/ or life change events/ [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

13 5 and 6

14 5 and 7

15 5 and 8

16 5 and 9

17 5 and 10

18 5 and 11

19 5 and 12

20 5 and (travel*.mp. or automobile driving/ or mobility limitation/ or transportation/) [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

21 5 and (recover* or challeng* or goal*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

22 5 and (interpersonal relations/ or social isolation/ or cost of illness/ or schedul*.mp.) [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

23 or/13-22

24 (focus group* or ethnograph* or phenomenol* or observation* or (grounded adj theory) or (framework adj analysis) or (thematic adj analysis) or (constant adj comparison)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

25 adaptation, psychological/ or adheren*.mp. or nonadheren*.mp. or patient compliance/ or noncomplan*.mp. or inconvenien*.mp. or negotiat*.mp. or (patient adj2 (care or experience or understand* or expectation* or perspective*)).mp. or patient satisfaction/ or personal autonomy/ or physician-patient relations/ or professional-patient relations/ or dissatis*.mp. or quality of life/ [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

26 self concept/ or self care/ or self-management/ or suffer*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

27 attitude/ or attitude to health/

28 (questionnaire* or survey* or qualitative* or interview*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

29 23 and (25 or 26 or 27) and (24 or 28)

30 23 and (exp leisure activities/ or health status/ or well-being.mp.) and (24 or 28) [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

31 29 or 30

32 Health Services Accessibility/

33 23 and (32 or continuity of patient care/ or disrupt*.mp.) and (24 or 28) [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

34 5 and (communication* or literac*).mp. and (24 or 28) [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

35 31 or 33 or 34

36 5 and sickness impact profile/

37 5 and needs assessment/

38 35 or 36 or 37

39 limit 38 to (human and yr="2000 - 2013")

40 39 not case report/

41 ((experience or recovery or service or patient*) adj3 stroke*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

42 (exercise or lifestyle or patient education* or social support or social isolation or self care or burden or community support or cost of illness or drug costs or imipact or inconvenience or negotiat* or patient experience or patient perspective or patient preference or patient satisfaction or dissatis*).mp. or professional-patient relations/ or physician patient

relations.mp. or quality of life.mp. or recovery*.mp. or suffer*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]

43 5 and (41 or 42)

44 43 and 24

45 39 or 44

46 (*cerebrovascular disorders/ or exp *brain ischemia/ or exp ***intracranial embolism and thrombosis"/ or exp *intracranial hemorrhages/ or exp *stroke/) and 45

PsycINFO 1987 to Feb Week 3 2013 # Searches Results Search Type

1 *cerebrovascular disorders/ or exp *brain ischemia/ or exp "**intracranial embolism and thrombosis"/ or exp *intracranial hemorrhages/ or exp *stroke/

2 [*stroke/co, di, dm, dt, rh, th]

3 [cerebrovascular disorders/co, di, dm, dt, rh, th or brain ischemia/co, di, dm, dt, rh, th or exp "intracranial embolism and thrombosis"/co, di, dm, dt, dm, rh, th or exp intracranial hemorrhages/co, di, dm, dt, rh, th]

4 1 or 2 or 3

5 limit 4 to (english language and humans and yr="2000 - 2013") [Limit not valid in PsycINFO; records were retained]

6 ((burden* adj2 (treat* or therap*)) or hassle* or medication adherence or medication compliance or medication concordance or physiotherapy or occupational therapy).mp. or rehabilitation/ [mp=title, abstract, heading word, table of contents, key concepts]

7 activities of daily living/ or health behavior/ or health, knowledge, attitudes, practice/ or lifestyle/ or occupational therapy/ or palliat*.mp. or patient education as topic/ or exp rehabilitation/ or exp physical therapy modalities/ or self care/ or barthel*.mp. [mp=title, abstract, heading word, table of contents, key concepts]

8 Disabled Persons/ or Disability Evaluation/ or work capacity evaluation/ or functional disability.mp.

9 social support/ or exp family/px or exercise/ or "physical education and training"/ or physical endurance/ or fatigue/ or physical fitness/ or long term care/

10 exp Gait/ or exp Gait Disorders, Neurologic/ or exp Accidental Falls/

11 self administration/ or (treatment adj3 (regimen* or regime* or tasks or work)).mp. or unnecessary*.mp. or unmet.mp. [mp=title, abstract, heading word, table of contents, key concepts]

12 exp cognition disorders/ or independen*.mp. or dependenc*.mp. or socioeconomic factors/ or life change events/ [mp=title, abstract, heading word, table of contents, key concepts]

13 5 and 6

14 5 and 7

15 5 and 8

16 5 and 9

17 5 and 10

18 5 and 11

19 5 and 12

20 5 and (travel*.mp. or automobile driving/ or mobility limitation/ or transportation/) [mp=title, abstract, heading word, table of contents, key concepts]

21 5 and (recover* or challeng* or goal*).mp. [mp=title, abstract, heading word, table of contents, key concepts]

22 5 and (interpersonal relations/ or social isolation/ or cost of illness/ or schedul*.mp.) [mp=title, abstract, heading word, table of contents, key concepts]

23 or/13-22

24 (focus group* or ethnograph* or phenomenol* or observation* or (grounded adj theory) or (framework adj analysis) or (thematic adj analysis) or (constant adj comparison)).mp. [mp=title, abstract, heading word, table of contents, key concepts]

25 adaptation, psychological/ or adheren*.mp. or nonadheren*.mp. or patient compliance/ or noncomplan*.mp. or inconvenien*.mp. or negotiat*.mp. or (patient adj2 (care or experience or understand* or expectation* or perspective*)).mp. or patient satisfaction/ or personal autonomy/ or physician-patient relations/ or professional-patient relations/ or dissatis*.mp. or quality of life/ [mp=title, abstract, heading word, table of contents, key concepts]

26 self concept/ or self care/ or self-management/ or suffer*.mp. [mp=title, abstract, heading word, table of contents, key concepts]

27 attitude/ or attitude to health/

28 (questionnaire* or survey* or qualitative* or interview*).mp. [mp=title, abstract, heading word, table of contents, key concepts]

29 23 and (25 or 26 or 27) and (24 or 28)

30 23 and (exp leisure activities/ or health status/ or well-being.mp.) and (24 or 28) [mp=title, abstract, heading word, table of contents, key concepts]

31 29 or 30

32 Health Services Accessibility/

33 23 and (32 or continuity of patient care/ or disrupt*.mp.) and (24 or 28) [mp=title, abstract, heading word, table of contents, key concepts]

34 5 and (communication* or literac*).mp. and (24 or 28) [mp=title, abstract, heading word, table of contents, key concepts]

35 31 or 33 or 34

36 5 and sickness impact profile/

37 5 and needs assessment/

38 35 or 36 or 37

39 limit 38 to (human and yr="2000 - 2013")

40 39 not case report/

41 ((experience or recovery or service or patient*) adj3 stroke*).mp. [mp=title, abstract, heading word, table of contents, key concepts]

42 (exercise or lifestyle or patient education* or social support or social isolation or self care or burden or community support or cost of illness or drug costs or impact or inconvenience or negotiat* or patient experience or patient perspective or patient preference or patient satisfaction or dissatis*).mp. or professional-patient relations/ or physician patient relations.mp. or quality of life.mp. or recovery*.mp. or suffer*.mp. [mp=title, abstract, heading word, table of contents, key concepts]

43 5 and (41 or 42)

44 43 and 24

45 39 or 44

46 limit 45 to all journals

CINAHL

S22 or S27 Limiters - Published Date from: 20000101-20131231; English Language; Human

Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S28 S22 or S27 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S27 S1 and S26 and S11 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S26 S23 or S24 or S25 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S25 disappoint* or dissatisf* or emotional or eating or frustrat* Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S24 (MH "Quality of Life+") OR (MH "Quality of Working Life") OR (MH "Quality of Life (Iowa NOC)") OR (MH "Attitude to Life") Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S23 function* or negotiat* or patient* Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S22 S13 or S21 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S21 S1 and S11 and S20 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S20 S14 or S15 or S16 or S18 or S19 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S19 (MH "Recovery") Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S18 (MH "Patient Satisfaction") Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S17 "patient experience" or "patient satisfaction" or "patient dissatisf*" Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S16 (MH "Patient Education+") OR (MH "Patient Discharge Education") OR (MH "Patient Education (Iowa NIC) (Non-Cinahl)+")
Limiters - Published Date from: 20000101-20131231; English Language

Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S15 (MH "Patient Care Plans+") OR (MH "Discharge Planning+") Limiters - Published Date from: 20000101-20131231; English Language

Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S14 (MH "Life Style+") Limiters - Published Date from: 20000101-20131231; English Language

Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S13 S9 and S11 Limiters - Published Date from: 20000101-20131231; English Language

Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S12 S9 and S11 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S11 (MH "Qualitative Studies+") OR (MH "Clinical Nursing Research") OR (MH "Clinical Research+") Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S10 ch Search modes - Boolean/Phrase

View Results (0) View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S9 S1 and S8 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S8 S2 or S3 or S4 or S5 or S6 or S7 Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S7 (MH "Social Support (Iowa NOC)") OR (MH "Norbeck Social Support Questionnaire") OR (MH "Social Support Index") OR (MH "Support, Psychosocial+") OR (MH "Coping Support (Saba CCC)") Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S6 lifestyle Search modes - Boolean/Phrase

View Results View Details Edit Interface - EBSCOhost

Search Screen - Advanced Search

Database - CINAHL

S5 (MH "Health Knowledge") Search modes - Boolean/Phrase

[View Results](#) [View Details](#) [Edit Interface](#) - EBSCOhost

[Search Screen](#) - Advanced Search

Database - CINAHL

S4 (MH "Health Behavior+") OR (MH "Health Behavior Component (Saba CCC)+") OR (MH "Health Seeking Behavior Alteration (Saba CCC)") OR (MH "Domain IV: Health-Related Behaviors Domain (Omaha)+") OR (MH "Health Behavior (Iowa NOC) (Non-Cinahl)+") OR (MH "Health Knowledge and Behavior (Iowa NOC) (Non-Cinahl)+") OR (MH "Health Promoting Behavior (Iowa NOC)") Search modes - Boolean/Phrase

[View Results](#) [View Details](#) [Edit Interface](#) - EBSCOhost

[Search Screen](#) - Advanced Search

Database - CINAHL

S3 "burden of treatment" or "burden of therapy" or hassle* or inconvenien* or "treatment burden" Search modes - Boolean/Phrase

[View Results](#) [View Details](#) [Edit Interface](#) - EBSCOhost

[Search Screen](#) - Advanced Search

Database - CINAHL

S2 (MH "Altered Activities of Daily Living (NANDA) (Non-Cinahl)+") OR (MH "Self Care: Activities of Daily Living (Iowa NOC)") OR (MH "Self-Care: Instrumental Activities of Daily Living (Iowa NOC)") OR (MH "Activities of Daily Living+") OR (MH "Activities of Daily Living (Saba CCC)") OR (MH "Activities of Daily Living Alteration (Saba CCC)") OR (MH "Instrumental Activities of Daily Living (Saba CCC)") OR (MH "Instrumental Activities of Daily Living Alteration (Saba CCC)") Search modes - Boolean/Phrase

[View Results](#) [View Details](#) [Edit Interface](#) - EBSCOhost

[Search Screen](#) - Advanced Search

Database - CINAHL

S1 (MM "Stroke") OR (MM "Stroke Patients") Search modes - Boolean/Phrase

[View Results](#) [View Details](#) [Edit](#)

Search ID# Search Terms Search Options Actions

S15 S9 or S14 Search modes - Boolean/Phrase

[View Results](#)

S14 S1 and S11 Limiters - Published Date from: 20000101-20131231; English Language; Peer Reviewed; Research Article

[View Results](#)

S13 S1 and S11 Limiters - Published Date from: 20000101-20131231; English Language; Peer Reviewed; Research Article

S12 S1 and S11 Search modes - Boolean/Phrase

[View Results](#)

S11 (MH "patient centered care") or (MH "community health services") or (MH "health resource utilization") or (MH "community reintegration") or (MH "patient attitudes") or (MH "recovery") or (MH "patient satisfaction") Search modes - Boolean/Phrase

View Results

S10 S1 and S6 Search modes - Boolean/Phrase

View Results

S9 S6 and S7 Limiters - Published Date from: 20000101-20131231; English Language; Peer Reviewed; Exclude MEDLINE records

View Results

S8 S6 and S7 Search modes - Boolean/Phrase

View Results

S7 S1 or S2 Search modes - Boolean/Phrase

View Results

S6 S3 or S4 or S5 Search modes - Boolean/Phrase

View Results

S5 (MH "Interviews+") Search modes - Boolean/Phrase

View Results

S4 (MH "Scales") OR (MH "Questionnaires+") Search modes - Boolean/Phrase

S3 (MH "Qualitative Studies+") Search modes - Boolean/Phrase

View Results

S2 (MM "Stroke") Search modes - Boolean/Phrase

View Results

S1 (MH "Stroke Patients") Search modes - Boolean/Phrase

SCOPUS

TITLE-ABS-KEY-AUTH(stroke AND burden* AND (rehab* OR poststroke)) AND PUBYEAR AFT 1999

TITLE-ABS-KEY((stroke* OR poststroke OR "cerebrovascular accident*")) AND ((rehabilitat* OR satisfact* OR dissatisfact* OR recover* OR surviv* OR work OR occupation* OR "return to work" OR community OR support OR recover* OR independen* OR dependen* OR driving OR coping OR frustrat* OR attitude* OR communicat* OR activities* OR adapt* OR burden* OR self OR impact OR inconven* OR mood* OR emotion* OR sexual* OR eating OR dysphag* OR dysfunction* OR disappoint* OR expectation* OR intimacy OR incontinen* OR depress* OR fatigue* OR preference OR quality OR suffer* OR unmet) AND (qualitative* OR survey* OR interview* OR questionnaire* OR perspective* OR scale* OR narrative* OR focus OR observational OR framework OR thematic OR "grounded theory" OR population* OR cohort* OR follow*)) AND TITLE(aphasi* OR "post-stroke" OR poststroke OR (stroke AND (surviv* OR recover* OR rehab* OR needs OR goal* OR patient* OR surviv*))) AND PUBYEAR AFT 1999 AND LANGUAGE(english) AND NOT (PMID(1* OR 2* OR 3* OR 4* OR 5* OR 6* OR 7* OR 8* OR 9*)) AND NOT TITLE-ABS-KEY("case report*" OR mice OR rats) AND (EXCLUDE(DOCTYPE, "ip")) AND (EXCLUDE(SUBJAREA, "ENGL"))

Appendix 5 - Data extraction instrument

ARTICLE DETAILS			
Study Title.			
Authors.			
Journal, Vol, Issue, Page nos.			
Year.			
DOI / article ID			
Setting	community		
	hospital inpatient (general or unspecified ward)		
	stroke unit		
	rehab ward		
	care home		
	outpatient rehabilitation centre		
	outpatient clinic		
	other		
unclear			
STUDY DETAILS	Provided	Not provided	Unclear
What is the research question or research objective/ s? (e.g. to find out how stroke patients manage their illness?)			
How are participants sampled? (e.g. theoretical, purposive, random.			
How is data collected? (e.g. interviews, questionnaires.)			
How is data analysed? (e.g. grounded theory, thematic analysis.)			
What is the overall conclusion or recommendations of the study?			
What (if any) study limitations are declared?			
How is the study funded? Are any conflicts of interest declared?			
PARTICIPANT DETAILS			
Inclusion criteria			
Exclusion criteria			
Number of participants			
Min age of participants			
Max age if participants			
Mean age of participants			
Number of males			
Number of females			
Employment	employed		
	unemployed		
	retired		
	other		
	unclear		
Marital status	married / civil partnership		
	living with partner		
	divorced		
	separated		

	widowed	
	single	
	other	
	unclear	
Socioeconomic status		
Type of housing	owned	
	council	
	care home	
	private rent	
	lives with home owner	
	other	
	unclear	
	warden supervised	
Ethnicity	white british	
	white european	
	white american	
	white other	
	african american	
	native american indian	
	black caribbean	
	black african	
	chinese	
	asian	
	mixed	
	other	
unclear		
Comorbidities	yes	
	no	
	unknown	
	unclear	
Min number of co-morbidities		
Max number of co-morbidities		
Types of co-morbidities	hypertension	
	CHD	
	diabetes	
	asthma	
	COPD	
	chronic renal failure	
	PVD	
	TIA	
	previous stroke	
	other	
unclear		
Min number of medications		
Max number of medications		
Mean number of medications		
Mobility	idependently mobile	
	walks with stick	
	walks with frame	
	wheelchair	
	other	
	unclear	

Min time since stroke		
Max time since stroke		
Mean time since stroke		
Min time in hospital		
Max time in hospital		
Mean time in hospital		
Pathophysiology of stroke	infarct	
	intracerebral haemorrhage	
	subarachnoid haemorrhage	
	other	
	unclear	
Anatomical type of stroke	total anterior	
	partial anterior	
	posterior	
	lacunar	
	brainstem	
	left	
	right	
	other	
	unclear	
Physical disability	right hemiplegia	
	left hemiplegia	
	visual field defect	
	sensory deficit	
	neglect	
	dysphagia	
	other	
	unclear	
Speech problems	Dysphasia	
	Dysarthria	
	Other	
	Unclear	
	aphasia	
Cognition	memory problems	
	disinhibition	
	confusion	
	other	
	unclear	
Psychological consequences	low mood	
	fatigue	
	poor motivation	
	poor concentration	
	anxiety	
	other	
	unclear	
STUDY RESULTS: TYPES OF TREATMENT WORK	QUOTE	NPT (code to subdomain e.g. CAIW)

Appendix 6 - Details of participants in each study in the systematic review (UC= unclear)

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
Recovering from stroke	Kirkevold ³⁹⁵	Norway	Two stroke medical centres	9 (6M 3F)	40-83 (67.9)	UC	UC	UC	1-4 weeks	2 Right Hemiplegia, 6 Left Hemiplegia, 1 Sensory Deficit, 1 Neglect, 2 dysphagia , 2 reduced balance / coordination, 1 urinary incontinence, 1 dizziness, 1 dysarthria, 1 aphasia.
	Ch'ng ³⁹⁴	Australia	Community	26 (12M 14 F)	22-79 (60.88)	UC	3 previous stroke	UC	6 months - 12 years (4.4 years)	Modified Rankin score at time of stroke 0-5 mean 4.19. Mean physical health score on the SF-12 of 37.71 indicating significantly poorer physical health than similarly aged adults in the general population.
	Bendz ⁴⁰²	Sweden	Community	10 (6M 4F)	58-65	UC	UC	UC	Approx 3-4 months	UC
	Lynch ⁴⁴⁴	US	Community and out patient	9 (5M 4F)	(54.7)	1 White American, 8 African American	UC	UC	2 -29 years (11.9 years)	Modified Rankin Scale: 1 not significant, 12 slight, 9 moderate, 9 moderately severe.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Burton ⁶⁵	UK	Community (initial interview in hospital)	1M	78	UC	Hypertension	Antihypertensive medication	UC	Dysarthria.
	Clarke ⁴²⁶	Canada	Community	8 (3M 5F)	60-81 (69)	8 White Canadian	UC	UC	7 months - 9 years (4.8 years)	5 Left hemiplegia (3 hemiparesis), 1 left-field defect, 1 right vision field loss, 1 marked hemispatial neglect, 1 seizures, 1 problems in face recognition, 1 dysarthria.
	Flinn ⁴⁴⁷	US	Community	18 (3M 15F)	UC	UC	UC	UC	UC	1 aphasia.
	Dalvandi ⁴⁵⁴	Iran	Community	10 (6M 4F)	55-70	UC	UC	UC	3-6 months	UC
	White ⁴⁴⁰	Australia	Community	31 (17M 14F)	37-94 (72)	1 Indian, 1 British, 1 Czechoslovakian, 1 German, 1 Austrian, 1 Italian, 25 Australian	Co-morbidities were present in the majority of participants	UC	Under 1 year	Modified Rankin Score: 21 were independent; 10 were dependent.
	Kirkevold ⁴⁵⁰	Norway	Community	32 (15M 17F)	UC	UC	UC	UC	Under 2 years	12 were fatigued and 20 were non fatigued.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
The interaction between patient and health services	Bendz ³⁹³	Sweden	Community (asked about community and hospital experience)	15 (9M 6F)	UC	UC	5 previous stroke, 3 depression	UC	UC	UC
	Widar ⁴⁰⁰	Sweden	Community	43 (30M 13F)	33-82	UC	UC	UC	Approx 2 years	UC
	Roding ³⁹⁹	Sweden	Community	5 (3M 2F)	37-54 (43.2)	UC	UC	UC	1-1.5 years (1.2 years)	UC
	White ⁴³⁵	Australia	Community	12 (6M 6F)	43-92 (71.2)	UC	UC	UC	1-3 years	UC
	Mangset ⁴⁴⁹	Norway	Stroke unit and community	12 (5M 7F)	60-87 (77)	UC	UC	UC	UC	4 impaired language.
	Cowdell ⁴²⁰	UK	Inpatient rehabilitation	7 (gender unclear)	UC	UC	UC	UC	UC	UC
	Salisbury ⁴²²	UK	Outpatient	13M	43-79 (64)	UC	UC	UC	2-9yrs (4.6 years)	UC
	Knight ⁴³⁶	Australia	Stroke unit	7 (3M 4F)	41-90 (62.4)	UC	UC	UC	15 days maximum	4 hemiparesis side not specified, 2 aphasic (1 mild expressive, 1 mild expressive and receptive).
	Hjelmblick ⁴¹³	Sweden	Outpatient	4 (2M 2F)	58-84	UC	UC	UC	1.5-3 months	1 right hemiparesis, 1 visual field deficit, 1 balance problems, 1 dysphasia.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Kitson ⁴⁰⁵	UK	Hospital	15 (6M 9F)	mid 30s to mid 80s	UC	UC	UC	UC	Moderate to severe impairment in physical function post acute stage.
Return to work / retirement	Medin ³⁹⁷	Sweden	Out patient	6 (gender unclear)	UC	UC	UC	UC	UC	2 aphasia.
	Lobeck ⁴²³	UK	Stroke unit	7M	64-70	UC	UC	UC	6-12 months	UC
	Wolfenden ⁴⁴²	Australia	Community	5F	34-44 (39.4)	UC	UC	UC	12 months - 9 years	UC
	Hartke ⁴⁴⁸	US	Hospital	12 (8M 4F)	31-67 (51)	6 Caucasians, 5 African Americans, 1 Asian	UC	UC	0.5-16 years (4.5 years)	UC
Nursing home experience	Proot ³⁹⁸	Netherlands	Nursing home	17 (10M 7F)	50-85 (72.5)		UC	UC	UC	UC
	Proot ⁴⁵¹	Netherlands	Nursing home	22 (12M 10F)	50-85 (72)	UC	19 with multi-morbidity, in particular diabetes, visual impairments, cardiovascular disease, osteoarthritis	UC	UC	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Proot ⁴⁵²	Netherlands	Care home	20 (12M 8F)	50-85 (72.4)	UC	UC	UC	UC	UC
Coping Strategies	Alaszewski ³⁹²	UK	Community	31 (14M 17F)	38-89 (68.2)	UC	UC	UC	UC	UC
	Widar ⁴⁰⁶	Sweden	Community	43 (30M 13F)	33-82	UC	UC	UC	Approx 2 years	Pain -average of 20 months' duration of pain. Fifteen participants were classified as central post-stroke pain (CPSP), 18 as nociceptive pain mainly in the shoulder/arm, and 10 as tension-type headache. Four participants had two types of pain (central and nociceptive) and two of them were classified as central pain by support from quantitative sensory testing (QST).
	Rochette ⁴²⁷	Canada	Hospital and community	10 (5M 5F)	61-86 (73.7)	UC	UC	UC	2 weeks maximum	UC
	Carlsson ⁴⁰⁸	Sweden	Community	18 (11M 7F)	30-69 (52)	UC	UC	UC	UC	UC
	Popovich ⁴⁴⁶	US	Hospital and community	60 (gender unclear)	UC	UC	UC	UC	UC	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Jones ⁴²⁴	UK	Stroke unit	10 (6M 4F)	29-75 (61.8)	8 White British, 1 White European, 1 Black Caribbean	UC	UC	6 weeks-13 months	4 right hemiparesis, 6 left hemiparesis, 1 neglect, 4 aphasia.
Living with aphasia	Hjelmblick ⁴⁰⁴	Sweden	Community	1M	58	UC	UC	UC	3 months	Severe aphasia with great impairments in all domains.
	Brown ⁴⁵³	NewZealand	Community	25 (13M 12F)	38-86 (63.2)	UC	UC	UC	UC	25 aphasia.
	Worrall ⁴³⁷	Australia	Community	50 (24M 26F)	63.9	UC	UC	UC	UC	50 aphasia.
	Johansson ⁴¹⁷	Sweden	Community	11 (7M 4F)	48-79 (65.4)	UC	UC	UC	13-75 months (38 months)	Aphasia type: 4 anterior; 6 posterior; 1 global. Aphasia severity: 2 mild; 5 moderate; 4 severe.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Grohn ⁴⁴³	Australia	Community, rehabilitation facility and aged care facility.	15 (8M 7F)	47-90 (66.3)	UC	UC	UC	Under 3 months	All aphasic, Western Aphasia Battery-Revised Aphasia Quotient scores 26.7-99.3 (mean 73.2). 6 had no difficulty carrying out self-care activities. 5 had slight difficulties with dressing and bathing. 1 had slight difficulty with eating. 2 were unable to walk independently. 1 was fully dependent.
Physiotherapy / exercise	Hale ¹⁹³	New Zealand	Community and out patient	6 (gender unclear)	UC	UC	UC	UC	UC	UC
	Damush ⁴⁴⁵	US	Local community, county and veteran hospitals	13 (8M 5F)	(59)	2 White American, 11 African American	UC	UC	12 months maximum	6 reported slight disability 4 moderate disability.
	Olaleye ⁴⁵⁵	Nigeria	Outpatient	8M	26-70 (47.4)	UC	UC	UC	4-41 months (18.4)	Physical impairments (left or right hemiplegia). 2 required walking sticks.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
Motivation / hope in recovery	Maclean ³⁹⁶	UK	Stroke unit	22 (13M 9F)	38-86	15 White British, 4 Black Caribbean, 1 Black Africa, 2 Asian	UC	UC	UC	High motivation group Barthel median 14/20 (range 4-20) low motivation group median Barthel 7/20 (range 3-10).
	Cross ⁴³¹	Canada	Stroke unit	10F	71-100 (81)	UC	UC	UC	1-13 years	visual field deficit, paralysis, weakness, speech problems.
Reintegration into the patient's lifeworld and community	Wood ⁴⁰¹	Canada	Community (initial interview in hospital)	10 (6M 4F)	31-79	8 Caucasian, 1 East Indian, 1 Aboriginal	UC	UC	UC	Left Hemiplegia 10.
	Eriksson ⁴¹²	Sweden	Stroke unit	4 (3M 1F)	50-61	UC	UC	UC	1 month maximum	UC
	Wallenbert ⁴¹⁶	Sweden	Inpatient rehabilitation	7 (4M 3F)	42-82	UC	UC	UC	(6.88 years)	6 right hemiparesis.
	Reid ⁴³²	Canada	Community	18 (7M 11F)	50-88 (67)	17 White Canadian, 1 Asian	Previous stroke, arthritis, cataracts	UC	UC	6 right hemiparesis, 11 left hemiparesis, 1 'one stroke each side'.
	Wottrich ⁴¹⁸	Sweden	Community (initial interview in rehabilitation ward)	5 (2M 3F)	44-70	UC	UC	UC	1-4 months	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Yeung ⁴⁵⁶	China	Community	15 (7M 8F)	(64.7)	UC	UC	UC	UC	Median Modified Barthel Index whilst in hospital was 95. All experienced residual problems including limb weakness, memory loss, dizziness, fatigue, and sleeping disturbance.
	Sumathipala ⁴²⁵	UK	Community	35 (17M 18F)	34-100 (69)	24 White, 6 Black Caribbean, 3 Black African, 1 Filipino, 1 Chinese	29/35 had other existing health problems including diabetes, heart problems and arthritis.	UC	1-11 years (2)	Barthel Index Scores 3-20 (mean 16.3). 2 had mild expressive communication difficulties. Compared to South London Stroke population, more had difficulties walking unaided or were wheelchair users.
	Anderson ⁴³³	Canada	Community	9 (6M 3F)	53-64 (58.2)	UC	UC	UC	1-6 years	Variable, ranging from mild physical disabilities and aphasia to one sided spasticity, neglect and severe fatigue. 3 self rated severity of stroke as mild, 3 as moderate, 3 as severe (these participants used a cane or walking aid).

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
Gender differences	Andersson ⁴⁰⁷	Sweden	Inpatient rehabilitation	10 (5M 5F)	66-75	UC	UC	UC	UC	UC
	Lofmark ⁴¹⁰	Sweden	Outpatient	12 (5M 7F)	75-83	UC	UC	UC	UC	UC
The patient's interpretation	Kessler ⁴²⁸	Canada	Community	12 (10M 2F)	44-74 (54)	UC	UC	UC	3-11 years (6.5 years)	4 participants had deficits in communication.
	Casey ³¹⁴	Ireland	Community	20 (10M 10F)	65-88 (77.8)	UC	UC	UC	3 months - 9 years (2.65 years)	5 Right hemiplegia, 5 Left hemiplegia (some degree of paralysis) 2 'difficulty seeing', 2 'lose balance', 2 'speech difficulties'.
	Townend ⁴²¹	UK	Community	89 (53M 26F)	32-90 (median 71)	UC	22 previous stroke	UC	UC	UC
	Hjelmblick ⁴¹⁴	Sweden	Stroke unit	19 (8M 11F)	56-89	UC	UC	UC	UC	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Gallagher ⁴³⁴	Canada	Community	9 (gender unclear)	42-82	UC	UC	UC	0.5-4 years (median 1 year)	1 had been locked in, 3 aphasic, 4 had right-sided weakness and 4 left-sided weakness. All required admission to a rehabilitation unit following the acute stroke unit due to physical impairment. Half had some degree of aphasia during initial stroke period, but all were able to communicate at time of interview.
Returning to driving	Patomella ⁴⁰⁹	Sweden	Community	4M	46-83 (64)	UC	UC	UC	UC	1 Left Hemiplegia, 3 none
	White ⁴⁴¹	Australia	Community	22 (10M 12F)	50-94 (71)	UC	Co-morbidities were present in the majority of participants	UC	Under 1 year	Modified Rankin Score: 7 dependent (and did not return to driving). Residual symptoms included visual disturbance, hemiparesis and spasticity.

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
Multimorbidity	Wood ¹⁶⁵	Canada	Community	5 (3M 2F)	68-71 (72)	UC	Each participant had 2-5 co-morbidities. 2 diabetes, 5 knee arthritis. Some participants experienced arthritis affecting the back, shoulder, and hands. 1 atrial fibrillation, 5 raised lipids, 1 gastro-intestinal reflux, 1 heart murmur, 1 depression.	1-3 medications (mean 2.2)	UC	UC
Using a wheelchair	Barker ⁴³⁰	Canada	Community	10 (8M 2F)	70-80 (75.5)	8 White Canadian, 2 Black American	UC	UC	2-16 years (5.6.years)	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Barker ⁴²⁹	Canada	Community	10 (8M 2F)	70-80 (75.5)	8 White Canadian, 2 Black American	UC	UC	2-16 years (5.6.years)	UC
Eating difficulties	Perry ⁴¹⁹	UK	Community	113 (66M 47M)	(67.5)	94 White British, 7 Black British, 7 White Non-British origin, 5 Indian or Pakistani	UC	UC	6 months	107 slight, 6 moderate eating difficulties. 85 upper limb motor/sensory involvement. (20 arm functionally useless) 29 visual/perceptual deficits. 11, 20 and 21 difficulties with lip closure, chewing and swallowing respectively. 5 required prompting to maintain mealtime attention. 1 postural instability.31 communication difficulties.
	Medin ⁴¹¹	Sweden	Community	13 (6M 7F)	60-87	UC	UC	UC	6 months minimum	Dysphagia, aphasia, dysarthria.
	Medin ⁴¹⁵	Sweden	Stroke unit	14 (7M 7F)	59-87	UC	4 previous stroke	UC	UC	14 dysphagia
Goal setting	Gustafsson ⁴³⁸	Australia	Inpatient rehab and outpatient rehab	16 (11M 5F)	(69)	UC	UC	UC	(61 days)	UC

Research category	First author	Country of origin	Setting	No of participants and gender M=male F=female	Age range in years (mean)	Ethnicity	Co-morbidity	Medication	Time since stroke (mean)	Physical disability as a consequence of stroke
	Laver ⁴³⁹	Australia	Community, stroke unit and outpatient	15 (9M 6F)	36-70	UC	UC	UC	UC	UC
Medications	Chambers ³⁷	UK	Community	26 (14M 12F)	22-88 (63.4)	UC	UC	(mean 5.7)	11.9-14.8 months (mean 13.5 months)	Frenchay test score mean 18.6. National Institute of Health Stroke Scale ranged from 0-5 out of 42, so participants were at the lower end of stroke severity.

Appendix 7 - Methods and results for each study in the systematic review (UC = unclear)

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
Recovering from stroke	Kirkevold ³⁹⁵	To describe the characteristics of the illness trajectory of stroke during the first year. Aimed at generating a theoretical account of essential characteristics of the adjustment process that patients go through during the first year following a stroke.	Convenience sampling.	Repeated in-depth semi-structured interviews.	Transcribed interview data were analysed and interpreted based on the principles of hermeneutic analysis.	First-time stroke survivors. The primary nurse, in collaboration with the attending physician, screened each new patient for his or her cognitive and language ability to participate in conversation such as in-depth interviews. Sufficient language ability to participate in in-depth qualitative interviews. Once the patient had consented, a trial interview was conducted before final decision was made about inclusion.	The presence of additional interfering illnesses (cancer, dementia).	The adjustment process to stroke seems to be gradually evolving and prolonged over most of the first year. This involves hard physical and psychosocial work on the part of patient. A necessary pre-requisite for adjustment is a realistic conception of the illness and its implications. This takes time and experience to achieve.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Ch'ng ³⁹⁴	(1) What challenges, both physical and emotional, are perceived after stroke and how do these change over time? (2) What do those who have suffered a stroke perceive has helped them cope with these challenges over time? (3) What sort of psychological support do those who have suffered a stroke perceive would have been beneficial for them during recovery?	Purposive sampling.	Focus groups.	Open, axial and selective coding to develop a set of themes.	In stroke support group. One focus group included only participants recruited from a support group targeted at young people and the mean age of this group was 32.40 years.	UC	Initially, participants described uncertainty and confusion dealing with their physical symptoms and the challenges of medical care. As recovery progressed, there was increasing realization of physical limitations and the impact of these on their lives. This was accompanied by distress as participants confronted their losses and struggled with attempts to 'get back to normal'. Acceptance emerged as a critical factor in this process. New ways of doing things and engagement in new roles and activities contributed to acceptance and ultimate adjustment. Acceptance appeared to facilitate new approaches to coping. Social support and psychological support promoted coping, acceptance and adjustment.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Bendz ⁴⁰²	To explore how stroke survivors under 65 understand and deal with the activities of the rehabilitation process and how they experience having had a stroke. The second aim was to explore how the same patients and their rehabilitation processes were described in medical records, and ultimately to compare the two results.	Convenience sampling.	Interviews.	Discourse analysis.	All patients hit by a stroke for the first time before the age of 65 and cared for at one Swedish hospital during 1 year were included in the study. The criteria for inclusion were a stroke diagnosis, ability to talk and an understanding of Swedish or English.	UC	Although both groups focus on the recovery of the fragmented body, the meaning of recovery for them is slightly different. The stroke survivors arratives are sometimes characterised by frustration because they were left to manage unfamiliar problems by them- selves. Health care providers must develop strategies that allow the stroke survivors to achieve an authoritative and knowledgeable position.
	Lynch ⁴⁴⁴	To identify dimensions of QoL that are important to patients after stroke in order to support development of a disease-specific HRQL measure for stroke.	Purposive sampling.	Focus groups.	Two coders identified themes independently, compared codes, and resolved disagreements.	Age 18 years or older, English-speaking, diagnosed with stroke by a physician, not currently hospitalized or living in an inpatient setting, cognitively able to grant informed consent, and physically able to engage in a 60–90 min round-table discussion.	Symptoms such as severe aphasia and chronic fatigue.	Key themes identified by patients were: social support, coping mechanisms, communication, physical functioning and independence, altered social relationships.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Burton ⁶⁵	To explore the application of the Corbin and Strauss Chronic Illness Trajectory Framework for stroke.	Participant from previous study.	Interviews in hospital and then at monthly intervals over a period of 14 months.	Corbin and Strauss Chronic Illness Trajectory Framework applied to a vignette describing the experiences of one stroke patient. Open codes were reviewed and condensed where possible into a coding frame of themes and sub-themes.	One stroke patient from a previous study of patients' experiences of stroke recovery.	UC	The trajectory framework is shown to be a useful structure that has the potential to enhance the appropriateness of nursing interventions for stroke patients. Patients, having entered the trajectory, do not actually emerge from it over time. The stroke survivor will continue to be a survivor of stroke. This has relevance to the reported psychological trauma of having been through and survived a life threatening situation, and may persist into subsequent acute and chronic illness patterns.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Clarke ⁴²⁶	To understand well-being following a stroke in later life.	Purposive sampling.	Open-ended in-depth interviews.	The first transcripts were coded for concepts or themes, which were documented in a coding memo. In subsequent interviews, attention was paid to the appearance of similar concepts as well as to the emergence of new concepts, continuously making comparisons between the coding scheme and interview transcripts in an iterative process.	Community dwelling stroke survivors who were previously admitted for a stroke at Sunnybrook, and Women's College Health Sciences Centre in Toronto, Canada, at least 60 years of age.	Subjects were not eligible if they had severe cognitive impairments or communication problems (i.e., aphasia) that would limit their ability to reveal their subjective experiences.	Emphasizes the substantial impact that a stroke can have on subjective well-being in later life. Yet, with the help of various social resources, individuals engage in a dynamic process of adaptation and adjustment in order to enhance their sense of self and report a positive sense of well-being.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Flinn ⁴⁴⁷	To qualitatively explore the experience and impact of post stroke fatigue among individuals who had sustained a stroke, were living in the community and were experiencing post-stroke fatigue.	Purposive / Geographic sampling.	Focus groups.	Content analysis.	Male and female adults post-stroke who were beyond the acute care phase of stroke rehabilitation, living within their communities and able to voluntarily participate in this study.	UC	The key finding about the experience of post-stroke fatigue is that after stroke, individuals do not know that they are going to become fatigued, they do not know what to do about it, they cannot find help and they feel troubled when they either limit activities or rest during the day. This leads to speculation as to the problem and cause, with a continual search for acknowledgement and a solution to the challenges they experience in daily life. Expectations for pre-stroke level of participations are high. OT practitioners need to aware of these issues and services need to expand.
	Dalvandi ⁴⁵⁴	To illuminate life experiences and perceptions after stroke among stroke survivors. The research questions are: How do participants experience life after stroke? Which problems are important for them?	Purposive sampling.	Semi-structured interviews.	Grounded theory: Open coding, subcategories, conceptual categories, axial coding, selective coding carried out.	Discharged from hospital since February 2007 through July 2007, were 55–70 years old, had suffered a stroke within the past 3–6 months, were able to communicate and resided in an urban area in Tehran.	UC	When stroke survivors were faced with functional disturbances, they tried to solve this problem. However, they were not able to cope with the new situation because they were faced with a lack of socio-economic support in the form of financial help, social insurance and not receiving any help from others. They lacked care and rehabilitation and as a result, they experienced life disintegration.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	White ⁴⁴⁰	To explore the experience of post-stroke fatigue in community-dwelling stroke survivors with and without post-stroke mood disturbance within one year of stroke.	Purposive sampling.	Semi-structured interviews.	Inductive thematic approach using modified grounded theory.	Hospital admission and history and examination consistent with stroke.	Significant cognitive impairment (MMSE <24) or unable to communicate sufficiently to participate in an interview as determined by a speech pathologist.	Three trajectories emerged regarding the participants' experiences of fatigue including experience of fatigue, coping strategies and knowledge. The results of this study suggest that in spite of reasonable objective physical recovery post-stroke, fatigue in community-dwelling stroke survivors may be disabling. The essential role of health professionals in this context is to provide support and education regarding fatigue and to promote participation after stroke in therapy programs. Routine practice for stroke services should include fatigue advice prior to discharge.
	Kirkevold ⁴⁵⁰	To describe how fatigue is experienced by stroke survivors, how they understand and deal with fatigue and how fatigue impacts their daily life.	Purposive sampling.	Semi-structured interviews.	A grounded theory approach.	Stroke patient, able to communicate.	Dementia or other severe cognitive impairment.	Patients clearly described and differentiated their experience between: (1) tiredness as an ordinary life event and (2) fatigue as a post stroke life condition. Three fatigue-transforming strategies were identified, being on a mission, settling for less and stalling. Stalling seemed to put the stroke survivors in a particularly vulnerable situation. Over time, some participants moved between these two tiredness/fatigue manifestations and their range of strategies.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
The interaction between patient and health services	Bendz ³⁹³	To capture both similarities and critical differences between how people who have had a stroke and the health care professionals understand what is involved in suffering a stroke.	Convenience sampling.	Interviews with open-ended questions, 3 months, then 6 months then 1 year after the admission.	Phenomenographic study - individual descriptions were organized into descriptions of the concepts then into categories and subcategories. Before the process of categorization was finalized the preliminary categories and subcategories were brought back and tested against the material of each person.	Inclusion required that the patients could understand and express themselves verbally, had experienced a stroke before the age of 65 and were cared for at a Swedish hospital during one particular year.	UC	Three main categories emerged, which the patients and the health care professionals shared: Category I, "A stroke hits people without any warning"; Category II, "People who have had a stroke lose their normal functions"; and Category III, "Physical training is the means to recover". The goal for stroke patients was either to recapture their former social position or to adapt to another life situation. Rehabilitation must be based on interaction and negotiation between the patient and the health care professionals about realistic goals and relevant activities.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Widar ⁴⁰⁰	To describe how persons with long-term pain after a stroke experience their care.	Convenience sampling.	Open question interview.	The most information-rich narratives were selected for deeper investigation. The analysis was conducted inductively by means of qualitative content analysis.	Stroke patients suffering from long-term (>6months) pain, 2 years after stroke. The participants had been diagnosed as having suffered cerebral infarcts or haemorrhages. All were able to independently take part in a conversation and none had any other major pain condition.	UC	Being listened to, believed in, given sufficient time and support and given information (including next of kin) are of importance for caring. This study also reveals the importance of accessibility and continuity for the participant's confidence and well-being. Efforts in obtaining pain-relief based on professional knowledge have to do with the quality of care of patients with long-term pain.
	Roding ³⁹⁹	To describe and analyse how younger stroke patients had experienced rehabilitation and the time after stroke and to develop a hypothesis about their life situation.	Purposive sampling.	Thematised, in-depth interviews.	Grounded theory. Constant comparison.	Able to communicate. Approximately two years since stroke onset. From the northern part of Sweden.	UC	Young stroke patients are frustrated and invisible due to the fact that the rehabilitation setting does not acknowledge the different needs of young stroke patients compared with older patients.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	White ⁴³⁵	To explore the experiences of community dwelling stroke survivors with the local health system.	Purposive, maximum variation sampling.	Semi-structured interviews at one, three, and five years after stroke.	Open coding, constant comparison, axial coding, iterative mapping of codes (concurrent with the process of constant comparison) and the identification of major categories and their relationships and interactions.	Admission to hospital, alive at discharge, and history and examination consistent with stroke as determined by a stroke physician.	Severe cognitive impairment (as determined by the Mini-Mental State Examination and inability to give informed consent), and current residence in a nursing home, that is, only community-dwelling stroke survivors (including hostels) were contacted.	The results support the need for community services that help maintain stroke survivors in the community and promote independence and occupational engagement. Participants in each cohort experienced concern regarding communication discrepancies. Similarly, it was apparent that community dwelling stroke survivors felt the need to access ongoing health services in order to maximise community participation and goal achievement, even many years after stroke. Poor knowledge about stroke was evidenced throughout the phases of care in this study. This is of concern with regard to timely and appropriate access to health services, especially at stroke onset. No differences between those at 1,3 or 5 years post stroke.
	Mangset ⁴⁴⁹	To identify factors influencing elderly stroke patients' satisfaction with their rehabilitation following a stroke.	Purposive sampling.	Two semi-structured interviews per participant.	Analysis was performed in accordance with an approach described by Malterud, and was based on Giorgi's phenomenological method.	First time stroke, age 60 years or older and ability to give informed consent.	Patients with severe speaking problems or cognitive impairment.	Being treated with respect and dignity is the core factor influencing elderly stroke patients' perception of the quality of their rehabilitation process. Trivial daily care experiences influence patients' satisfaction. A merely functional approach to stroke rehabilitation should be expanded into an approach that includes the patients' perspective.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Cowdell ⁴²⁰	To discover whether inpatients on a stroke rehab ward in an acute hospital setting perceived a need for recreational activity during their rehab following stroke.	Purposive sampling.	Interviews using open-ended questions.	Grounded theory. Constant comparison.	Patient has suffered a stroke and this was primary reason for current admission. Need to have been inpatient on stroke rehab ward for 2 weeks.	Aphasia.	The experience of hospital rehabilitation could be improved. An environment that integrates therapy and recreation encouraged and supported by all members of staff would be appropriate. The focus should be on augmenting current therapies rather than simply adding further activity.
	Salisbury ⁴²²	To explore the individual's perceptions and views of lived experiences of a specific phenomena, namely the healthcare system and services received after stroke.	Purposive sampling.	Semi-structured interviews.	Interpretative Phenomenological Analysis (IPA)	Patients and carers who had attended an outpatient clinic for more than 6 months.	Patients with severe communication difficulties were excluded, but in recognition of this, some of the carers approached and included in the study looked after relatives with marked communication difficulties.	An overarching theme of 'After the stroke' was identified and six sub-themes: (1) 'What is wrong?'; (2) 'Help came quickly'; (3) 'Something is still wrong'; (4) 'In the hospital'; (5) 'I'm taking them home'; (6) 'Back at home'. The results indicated a failure to meet some of the current stroke guideline recommendations. These valuable results highlight the complexity of delivering evidence-based stroke services to meet the needs of both healthcare providers and recipients of the service.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Knight ⁴³⁶	1. (i) How much health info is provided to patients? (ii) Do patients with aphasia receive less info? 2. (i) What are patients' perceptions of information provision. (ii) Are perceptions of health information of patients with aphasia different? 3. (i) What knowledge do patients have on discharge. (ii) Do patients with aphasia report less?	UC	Participant observation and qualitative semi-structured interviews.	Time recordings for each observation, topics of health information were categorized and counted, qualitative analysis of the descriptions of communicative interactions (a form of thematic analysis)	Medical diagnosis of CVA or TIA, Participants also required a medical and cognitive status conducive to providing informed written consent. Participants with aphasia (Group A) were required to have reliable yes/no responses.	Unable to give consent, no diagnosis of CVA or TIA.	1)the variability in the quality of health information provided to stroke patients; 2) how the frequency of health information exchanges was affected by participants' role, participants' characteristics, health professional characteristics, and environmental characteristics; and 3) how the frequency and quality of health information provided was affected by the presence of transmission barriers. Patients with aphasia received less information compared to stroke patients without aphasia. The informational needs expressed by participants may indeed reflect a lack of health information provision rather than patients forgetting that health information was given.
	Hjelmbli nk ⁴¹³	To explore the meaning of stroke symptoms and treatment to patients who delayed hospital arrival for more than 24 hours.	Convenience sampling.	Two interviews.	Empirical Phenomenological Psychological method (EPP).	Delayed arrival to hospital for 24 hours; neurological symptoms evident; ability to require treatment; absence of neglect symptoms.	UC	Health care information about how to act in cases of early stroke symptoms may need to imbue people with an understanding of how early treatment of neurological symptoms and preserved control of life are intimately connected. Furthermore emergency care of acute stroke patients might need to take place in an organisation where patients are sure to be met by physicians as a person by a person.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Kitson ⁴⁰⁵	1. Do people who have survived the acute stage of stroke talk about fundamentals of care? 2. How do they talk about them? 3. What are most frequently described? 4. What sort of language is used? 5. How do stroke survivors talk about their experiences with staff? 6. Does the Fundamentals of Care Template adequately reflect what stroke survivors describe?	Purposive sampling.	Narrative and semi-structured interviewing .	Secondary analysis - data re-analysed using a Template which encapsulates the fundamentals of care as defined by nursing professionals, followed by thematic analysis.	UC	UC	Survivors of strokes have vivid and often distressing recollections of their experiences of the fundamentals of care. For every description of a physical need (elimination, eating and drinking, personal hygiene) there were lucid accounts of the psychosocial and emotional impact (humiliation, distress, lack of dignity, recovery, confidence). Linked to the somatic and emotional dimensions were narratives around the relationship between the patient and the carer (nurse, doctor, allied health professional). Positive recollections of the fundamentals of care were less evident than more distressing experiences.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
Return to work / retirement	Medin ³⁹⁷	To gain knowledge and understanding about how young stroke survivors experience their return to work process.	Convenience sampling.	Open-ended interview.	Analysed using empirical phenomenology . This implies an analysis in several steps: the reading of interviews, division into meaning units, transformation, synthesis and general structure.	Age (30 – 65), first-ever stroke in 2001, being part of the study population, working at the time of their stroke, being able to speak Swedish, and having the cognitive ability to take part in a face-to-face interview. All had participated in a case control study comprising all stroke patients in this age group, both employed and non-employed, at these two hospitals, and aimed at exploring possible associations between work-related stress, organizational change and risk of stroke among people aged 30 – 65.	UC	Return to work was a process that comprised a step-by-step return over a long period of time. The informants reported lack of information about the cognitive deficits they subsequently suffered from after their stroke. The rehabilitation was not age-adapted and it was insufficient for their needs. The individual's possibility to return to work was perceived as enhanced by self-efficacy in combination with external support.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Lobeck ⁴²³	To explore how men manage when two significant life events, stroke and retirement, occur within a close time proximity.	Purposive sampling.	Semi-structured interviews.	Interpretive phenomenological analysis (IPA).	Men of retirement age; retiring at time of stroke; 6 months post-stroke; cognitively able, have spouse or partner.	UC	The themes suggested that significant interplay existed between the meanings made of the two life events. The emergent themes implied that stroke had a profound impact on the men's lives and affected them on a number of levels. The experience of suffering a stroke also led to some positive reframing of life.
	Wolfenden ⁴⁴²	1. Do younger stroke survivors perceive a change in identity post-stroke, and if so, what meaning do they give this experience? 2. What factors are perceived to have influenced identity re-establishment? 3. What are the experiences of identity reestablishment and returning to employment for young survivors of stroke?	Purposive sampling.	Semi-structured interviews.	Thematic analysis.	(1) aged between 21 and 55 years; (2) experienced stroke 1–10 years ago; (3) returned to paid employment within 10 years of stroke, although it was not necessary to have sustained employment; and (4) expressed an ability and willingness to reflect on post-stroke experience, including identity and return to work.	UC	Participants actively pursued identity continuity while managing biographical disruption. Resumption of life roles and responsibilities were important for identity re-establishment, but fraught, particularly the return to work. The findings suggest that psychosocial rehabilitation could play a greater role in supporting survivors' resumption of valued life roles, including return to work.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Hartke ⁴⁴⁸	To describe the facilitators and barriers that stroke survivors encounter in their efforts to return to work after stroke.	Purposive sampling.	Semi-structured interviews.	Modified grounded theory analysis.	A minimum of 3 months post stroke, 18 years or older, having returned to work or with intention to.	Anything more than mild-moderate cognitive and communication deficits as measured by the National Institutes of Health Stroke Scale or FIM cognition and communication items assessed at the time of consent.	Seven themes were identified in an analysis of interview transcripts: financial, impairments as barriers, interpersonal support, therapy supporting RTW, organizational influences, work/job specific issues, and psychological issues. These themes confirm and expand on existing qualitative data that focus on survivors' perceptions of their work potential and efforts by emphasizing the need to focus beyond the survivors and their work to include other people and organizations to facilitate RTW.
Nursing home experience	Proot ³⁹⁸	To determine which facilitating or constraining factors regarding patient autonomy during rehabilitation are identified by stroke patients in rehabilitation wards in nursing homes.	Convenience sampling.	Interviews and field notes, on admission, during rehabilitation, and at discharge.	Grounded theory. Constant comparison.	Consecutive patients with a confirmed diagnosis of stroke who were admitted to one of the rehabilitation wards participating in the study were included if they were able to communicate, if they were Dutch and spoke their mother tongue, if the rehabilitation goal was to return to their own home or an old people's home, and if participating in the study was not a heavy burden for the patient.	Severe multi-morbidity (somatic, psychiatric and/or psycho-geriatric) which would interfere with participation in the study. Participation was contingent on informed consent.	This study indicated that the stroke patient's autonomy (dimensions: self determination, independence and self care) increases during rehabilitation due to patient factors (conditions and strategies of the patient) and environmental factors (nursing home and strategies of health professionals and family). Health professionals should be attentive to the stroke patient's actual autonomy (self-determination, independence and self-care) and avoid paternalism regarding aspects other than treatment.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Proot ⁴⁵¹	Seeks to pinpoint which dimensions of autonomy are identified by stroke patients rehabilitating in nursing homes and to determine which factors, in the stroke patients' perception, facilitate or constrain patient autonomy on admission.	Convenience sampling	Interviews: 21 interviews on admission, 17 interviews during rehabilitation, and 20 interviews at discharge.	Constant comparative method as described in grounded theory (Strauss & Corbin, 1990).	Patients with a confirmed diagnosis of stroke who were admitted to one of the rehabilitation wards participating in this study were included if they were able to communicate (opinion of speech therapist, patients with aphasia were not excluded on principle), if they were Dutch and spoke their mother tongue, if the rehabilitation goal was to return to their own home or an elderly care facility, and if the selector(s) took the view that participating in the study was not a heavy burden for the patient.	Patients were excluded if they had severe multimorbidity (somatic, psychiatric, and/or psychogeriatric), which would interfere with study participation.	Identifies three dimensions of autonomy: self-determination, independence, and self-care. Patient and environmental factors influencing patient autonomy on admission were found. On admission, the development of patient autonomy heavily depends on the environment, which entails that facilitating environmental factors should be maintained and constraining environmental factors should be changed or minimized. Regarding the health professionals' strategies, support and supervision are to be provided, balanced, and tailor made, which requires attentiveness. Health professionals should give patients more information regarding the methods used.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Proot ⁴⁵²	To explore stroke patients' experiences of health professionals' approach towards autonomy in a longitudinal way.	Convenience sampling.	Open-ended interviews.	Constant comparative method described by Strauss and Corbin.	Consecutive patients with a confirmed diagnosis of stroke who were admitted to one of the rehabilitation wards participating in this study were included if they were able to communicate (opinion of a speech therapist; patients with aphasia were not excluded on principle), if they were Dutch and spoke their mother tongue, if the rehabilitation goal was to return to their own home or an elderly persons' care facility, and if the selector(s) took the view that participating in the study was not a heavy burden for the patient.	Patients were excluded if they had severe multimorbidity (somatic, psychiatric and/or psychogeriatric) that would interfere with their participation.	Health professionals should tailor their interventions to stroke patients' changing autonomy. Multidisciplinary guidelines could sustain health professionals in this. In the rehabilitation phase, patients are able to decide for themselves, except regarding treatment and rehabilitation procedures. Leaving room for patients to plan and decide on their own stimulates autonomy. Step by step shared decision-making with regard to treatment becomes possible. If health professionals continue to decide for patients, patients may be less prepared for autonomous living after discharge. Giving information (including progress evaluation) and discussion is a prerequisite for patients' active participation in rehabilitation and in shared decision-making.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
Coping Strategies	Alaszewski ³⁹²	To investigate the impact of stroke on the lives of survivors, the coping strategies they developed and the effectiveness of professional support.	Purposive sampling.	Focus group and individual interviews.	The research team analysed the content of the interviews and diaries thematically using constant comparison based on Grounded Theory.	Stroke survivors.	UC	The stroke undermined ontological security and increased awareness of and anxiety about everyday activities both in and outside the home, created awareness of a new danger, that of having another potentially fatal stroke, and could damage social standing. Survivors used a variety of strategies to manage such uncertainties. They shortened their time horizons, either abandoning longer-term plans or discussing them in very vague and general terms. They concentrated either on the present, "taking each day as it comes" or developed goals to structure the short-term future. These short-term goals involved challenges and there was in some cases the possibility of a harmful outcome.
	Widar ⁴⁰⁶	To describe pain, coping strategies, and experienced outcomes of coping with the three previously classified long-term pain conditions after a stroke.	Convenience sampling.	Two interviews per participant held two years after stroke.	Latent content analysis.	On the inpatient register at a neurological clinic in a university hospital in Sweden, consisting of those diagnosed with cerebral infarct or haemorrhage.	Patients with other pain conditions and those who were not independently able to take part in a conversation.	Persons with pain after a stroke should not be treated as a homogeneous group. Living with long-term pain requires coping strategies to the specific type of pain experienced and the problems related to it.

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	Rochette ⁴²⁷	To improve our understanding of the adaptation process, including primary appraisal (what meaning is given to the situation) and coping strategies (how the situation is dealt with), from the crisis period to 6months post-stroke, in individuals admitted to an acute care hospital for a first episode.	Purposive sampling.	Interviews 2-3 weeks after stroke then 3 and 6 months later.	Exhaustive coding specifically, putting a label to a word, a phrase or a paragraph to identify a specific meaning. These labels, or codes, formed a codification grid which evolved throughout the coding process. Codes were then grouped under categories. This final version, the classification grid, was made up of the essential themes that emerged from the participants' interviews.	The sample was composed of 10 individuals admitted to an acute care hospital for a first stroke. Participants were recruited during the first 2 weeks after their stroke.	UC	Appraisal and coping strategies are shown to be interrelated in a complex fashion. The fear of another stroke is particularly overwhelming, especially in the initial period post-stroke, and serves as a source of motivation for active compensation coping strategies, such as adopting healthy behaviours. Effective coping post-stroke, potentially leading to an optimal quality-of-life, is mainly characterized by a process of multiple comparisons, enabling a reset of one's expectations in order to bring them more into line with the new reality. Appropriate and individualized information about stroke, and how to potentially prevent another stroke, should be an integral part of the rehabilitation process.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Carlsson ⁴⁰⁸	To investigate from the actor's perspective how and why persons with mild stroke coped with their new life situation as they did during the first year after stroke.	Purposive sampling.	Interviews with open questions.	Inspired by the grounded theory method (Corbin and Strauss).	Diagnosis of Asthen Emotional syndrome, no or as few other stroke related impairments as possible, diversity in age and a diversity of vocational/occupational situations.	Participants with other intervening illnesses and diagnoses were excluded, as were participants with aphasia and cognitive impairment on a level where interpretation of the interview data was not considered valid.	The respondents experienced a complex coping situation. The core category of 'striving to manage an everyday life of uncertainty' emerged, connecting and covering the experiences of the respondents' coping efforts. Despite appearing to have recovered from their stroke after 1 year, they still had to cope with persisting cognitive and emotional dysfunctions that made it difficult to participate in life situations. The core category was built up of three descriptive categories: (1) individual concerns of coping, (2) relational concerns of coping and (3) environmental conditions for coping.
	Popovich ⁴⁴⁶	To investigate how patients in the US perceived their stroke experiences by examining coping strategies and hopes for recovery. In addition, factors that inspired hope during recovery were identified.	UC	Interviews.	Coded using a priori codes previously identified in a pilot study of stroke patients. A coding manual was developed, including category and subcategory codes with definitions and examples of each code.	Diagnosis of embolic or ischaemic stroke, hospitalized.	UC	Stroke patients believe hope is important for recovery. Hopes focussed on becoming medically stable, recovering, regaining independence, and returning to prestroke activities. Hopes are derived from family/friends, spiritual beliefs / practices, positive attitudes, seeing recovery, being independent and from interactions with staff. The goals of rehabilitation encompassed the patients sources of hope.

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	Jones ⁴²⁴	To learn more about individual beliefs and personal strategies used to support the period of recovery after stroke.	Purposive sampling.	Two in-depth interviews with each participant.	Phenomenological approach for content analysis.	UC	Severe memory and language impairments.	All individuals identified a number of specific factors which had supported or hindered their own recovery. There were a diversity of both internal/personal and external factors which may not be surprising, given the complexity of stroke, but all participants stressed the importance of both factors.
Living with aphasia	Hjelmbli nk ⁴⁰⁴	To explore what rehabilitation means to an aphasic stroke patient.	Unclear, case-study approach.	The informant was interviewed twice.	Empirical, Phenomenological and Psychological method (EPP) allowing for interpretation.	Case study of one aphasic patient.	UC	The patient had a well definable loss of his language. Hence, he could act autonomously in the spatial world. Yet his body's tool for access to the world of human relations was damaged. This very well defined loss turned the focus of the meaning of the rehabilitation to a simplification: repairing the language. The needs of aphasic patients should be taken into account when planning rehab.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Brown ⁴⁵³	To explore, from the perspectives of people with aphasia, the meaning of living successfully with aphasia.	Maximum variation purposive sampling.	(1) semi-structured in-depth interviews and (2) participant-generated photography (with photographs taken forming the basis of a second interview).	Interpretative phenomenological analysis (IPA). Photographs discussed and became part of text.	Chronic aphasia as a result of stroke. Tested on Western Aphasia Battery and those above cut-off included.	Dementia or cognitive impairment; uncorrected visual or hearing impairments	The concept of living successfully with aphasia is complex, and highly individualised. Four core themes related to living successfully with aphasia emerged from the data: doing things; meaningful relationships; striving for a positive way of life; and communication.
	Worrall ⁴³⁷	The primary aim of this study was to gain an understanding of what people with aphasia want from aphasia services, and to code their goals according to the WHO International Classification of Functioning, Disability and Health (ICF).	Maximum variation purposive sampling.	In-depth interviewing .	Qualitative content analysis, goals of a 30% consecutive subsample were coded using the ICF.	Aphasia, post-stroke; ability to communicate for interview.	Severe impairment.	The rehabilitation experiences of participants with aphasia described nine broad categories of goals post-stroke. The priorities of return to pre-stroke life, communication, and physical function and health might be expected in the aftermath of stroke but the broader life goals in the areas of social life, work, and leisure, as well as altruism are not so well recognised in rehabilitation. The need for information about aphasia and stroke was also emphasised by participants in this study. Goals could be linked to all ICF components within the ICF, with the majority linked to Activities and Participation.

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	Johansson ⁴¹⁷	To explore how people with aphasia experience conversations with different people and how they handle communication difficulties in everyday life. A secondary aim is to study how they perceive their own and their partners' use of communication strategies.	Purposive sampling.	Semi-structured interviews and field notes.	Content analysis.	Participants with aphasia due to a stroke, occurred at least 12 months before interview. Older than 17 years, living at home, with a significant other that they communicate with regularly. Use Swedish as their everyday language.	Other speech or language difficulties (such as severe dysarthria). Alcohol or drug abuse problem, dementia, other significant cognitive dysfunction, or significant hearing or vision impairments (as determined by the recruiting speech-language pathologist).	Informants appreciated having conversations despite the fact that they perceived their aphasia as a serious hindrance. Different factors related to the informants, the conversation partners, the conversation itself and the physical environment were perceived to impact on conversations. The importance of the communication partners' knowledge and understanding of aphasia and their use of supporting conversation strategies were acknowledged by the informants. The informants' views on using communication aid devices or strategies varied considerably. Four themes that characterized the informants' narratives were: loss and frustration, fear and uncertainty, shared responsibility based on knowledge, and longing for the past or moving forward.

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	Grohn ⁴⁴³	To explore the perspective of people with aphasia on factors that facilitate successful living during the first 3 months post-onset.	Convenience sampling.	Semi-structured interviews.	Thematic analysis.	Diagnosis of aphasia as a result of stroke within the past 3 months, 18 years or older, the ability to participate in an interview (with communication supports if necessary).	Concomitant cognitive disorders such as dementia.	A number of themes were identified from the interviews, including: a need to do things in order to be actively engaged in rehabilitation; increase independence and have a purpose in life; the importance of social support; the value of rehabilitation; a need to adapt and make adjustments; and having a positive outlook. These results suggest that a range of service delivery models need to be considered during the early stages post-stroke in order to address individual needs and so that long-term outcomes of people with aphasia may be improved.
Physiotherapy / exercise	Hale ¹⁹³	To explore participants perceptions of outpatient hospital and home based physiotherapy.	Convenience sampling.	In-depth interviews.	Phenomenographic methodology . Common themes identified, grouped into categories and coded. Conceptual framework constructed.	Recruited from rehab department 1) a primary diagnosis of stroke 2) receiving outpatient physio 3) residing at home.	UC	Neither a hospital or home based setting alone appeared optimal for patients, both settings had advantages and disadvantages. Both options should be discussed and made available to patients. Patients need to be supported in the transition from inpatient to outpatient rehabilitation.

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	Damush ⁴⁴⁵	To elicit barriers to and facilitators of exercise after stroke.	UC	Focus group sessions.	UC	Adults who had experienced a diagnosis of stroke or TIA and received care at a local community, county or veteran hospital during the past year.	UC	Participants across the group reported three barriers and three facilitators to exercise after stroke. Exercise activity can provide a purpose and structure to a stroke survivor's daily schedule, which may be interrupted after stroke. In addition, receiving social support from peers and providers, as well as offering stroke-specific exercise programming, may enhance physical activity of stroke survivors including those with disabilities.
	Olaleye ⁴⁵⁵	To explore the factors that were perceived to affect people with stroke in Nigeria in participating in their physiotherapy exercise.	Convenience sampling.	Semi-structured interviews and field notes.	Thematic analysis.	Stroke patient attending a physiotherapy outpatient department.	Cognitive difficulties, not able to speak English, attending the outpatient clinic from the wards.	The factors that were perceived to affect the participants' participation in their outpatient physiotherapy sessions encompassed three dimensions: the internal and personal, the relational and experiential and external factors. These dimensions were interconnected with the internal and personal factors being central to the participants' participation.

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Motivation / hope in recovery	Maclean ³⁹⁶	To explore the beliefs of stroke patients who were identified as having “high” or “low” motivation for rehabilitation and investigated the determinants of their motivation.	Purposive sampling.	Semi-structured interviews.	Interviews were analysed by content, transcripts were read for emergent themes, which were then coded, codes were then compared with those in each other interview to create broader categories that linked codes across interviews (constant comparison).	Stroke patients on the stroke unit considered to have high or low motivation.	Patients with severe cognitive or language difficulties or medical conditions held to affect engagement with rehabilitation (for example, depression).	There are some differences in beliefs between stroke patients identified as having low or high motivation for rehabilitation. Patients with stroke identified as having high motivation for rehabilitation were found to align themselves more closely to the aims and methods of rehabilitation professionals. These beliefs seem to be influenced by the environment in which the patient is rehabilitated. Professionals and carers should be made aware of the ways in which their behaviour can positively and negatively affect motivation.

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	Cross ⁴³¹	To determine what factors influence hope in the later stages of recovery.	Purposive sampling.	Semi-structured interviews.	Phenomenology .	60 years and over; women; 6months post stroke.	UC	These women described hope as an integral factor in fostering optimal recovery beyond 1 year post stroke. 3 interconnected factors (ie external, internal, and personal) worked in conjunction to foster hope in these women post stroke.

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Reintegration into the patient's lifeworld and community	Wood ⁴⁰¹	To examine the process of community reintegration over the first year post stroke from the patient's perspective.	Purposive sampling from trial participants.	Semi-structured interviews on five occasions - in the hospital (pre discharge) and at two weeks, three months, six months and one year post stroke rehabilitation.	Guided by methods described by Corbin and Strauss, open, axial and selective coding were used.	Participants had sustained their first major unilateral hemispheric stroke, were English speaking, scored 24 points on the Mini-Mental State Examination, ²⁵ were discharged home and had adequate verbal communication (i.e. without evidence of receptive or expressive aphasia).	Patients discharged to long-term care and those who reported serious comorbidities or unstable medical conditions were excluded.	This study exposed the progression of goals that community-dwelling stroke survivors aimed to achieve during the first year post discharge from inpatient rehabilitation. The expectations set by the stroke survivor themselves are most important to community reintegration....an important goal for stroke rehabilitation is to engage formal and informal caregivers in facilitating realistic and achievable goal setting. The transition to the community poses a substantial challenge for stroke survivors due to reduced sources of self efficacy and fewer opportunities to develop confidence for community living.
	Eriksson ⁴¹²	To explore the phenomenon of occupational gaps in the lived experience of performing everyday occupations during the first year after stroke.	Purposive sampling.	Four interviews.	Empirical, Phenomenological and Psychological method (EPP).	First stroke less than 1 month earlier; 20-65 years; limitations in performance of daily activities.	UC	Five main characteristics were identified: 1. encountering occupational gaps in formerly taken-for-granted activities; 2. striving to narrow gaps in desired occupations; 3. recognizing oneself in doing; 4, searching for a new sense of self through doing; and 5. creating strategies to enable doing. The findings show the importance of being able to preserve some sense of self in everyday doings after a life course disruption caused by stroke.

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	Wallenbert ⁴¹⁶	To explore and gain an understanding of how habits are experienced when performing daily occupations after a stroke.	UC	Open-ended questions, structured interview.	Constant comparative analysis - grounded theory.	Clients at rehab unit having some difficulty performing activities after stroke.	Aphasia; severe cognitive problems.	The findings show that the participants experienced frustration when performing daily occupations because changes in their performance meant that former habits could not automatically be re-established; daily occupations had to be re-organized and planned with greater deliberation than had been required prior to the stroke. In re-establishing their daily occupations, the participants experienced an ongoing conflict about whether or not to develop new habits. . This dilemma led to a sensation of waiting: waiting to get better, waiting for another solution and waiting for the treatment to make an impact. As a result, few new habits were established in daily occupations.
	Reid ⁴³²	Examines the experiences of older stroke survivors. The purpose of this study was to examine the person-environment fit as it intersected with role performance in older people with stroke living at home.	Purposive sampling.	Interviews.	Grounded theory analysis.	English speaking; stroke diagnosis; 50 years and over; normal mini mental.	UC	Stroke survivors manage their lives as they carry out their old and new roles. Their lack of control and independence makes them vulnerable as they strive to maintain some sense of dignity and autonomy. Life is worth living after a stroke and many stroke survivors had a positive outlook.

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	Wottrich ⁴¹⁸	To investigate how stroke survivors describe their expectations regarding how life would appear when coming home, and how these expectations were met on discharge from the rehabilitation clinic and during their first 3 months at home.	Purposive sampling.	Semi-structured interviews.	Content analysis.	Stroke in-patient on the rehabilitation wards, able to convey experience and interested in participation.	Severe aphasia and dementia.	On discharge from the rehabilitation clinic, the informants described experience of being at a dividing line between the safety of the ward and the unknown at home. Expectations for improvement were high. A few weeks later, they described being on parallel tracks in life, waiting for improvement and adjusting to life at home. Three months after discharge, they were still waiting for improvement and had begun to realize that life might never be the same as before the stroke.
	Yeung ⁴⁵⁶	To explore the phenomenon of concerns as experienced by Chinese stroke survivors during hospitalization and in transition to home.	Purposive sampling.	In-depth interviews.	Thematic analysis.	Chinese, age over 18 years, first stroke, Mini-Mental State Examination score 21 or over, able to communicate, no debilitating co-morbidity, discharged home.	Transient Ischaemic Attack or co-existing mental disorders.	Stroke survivors' physical, psychological, socio-cultural and spiritual concerns in hospital and transition to home emerged from the data analysis. The four major themes identified were: (a) dynamic interplay of holistic concerns, (b) cultural expression of illness experiences, (c) social support 'paradox' and (d) caring gaps in clinical management.

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	Sumathipala ⁴²⁵	To investigate how contextual factors, as described by the ICF, impact on stroke survivors' functioning and how needs are perceived in the long-term after stroke.	Purposive sampling.	Semi-structured in-depth interviews.	Thematic analysis drawing on the ICF framework.	Stroke at least 12 months prior to study.	UC	Long-term needs related to activities of daily living, social participation, mobility aids, home adaptations, housing, financial support, rehabilitation, information and transport. Participants identified a range of ICF environmental and personal factors including 'support and relationships,' 'products and technology,' 'services, systems and policies,' 'attitudes,' life experiences, social position and personal attitudes. Interactions between these contextual factors shaped functioning and how long-term needs were perceived. Social support from family and friends was a key facilitator of functioning for most participants, buffering the impact of disabilities and mediating perceived needs. Needs were not always stroke-specific as many participants experienced other health problems.

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	Anderson ⁴³³	To present issues surrounding stroke survivors' lack of community engagement in the context of a socio-ecological model.	Purposive sampling.	Semi-structured interviews.	Situational analysis grounded theory methods.	1 -6 years post stroke, 50-70 years old, residing in their own homes in an urban area.	In long-term care, severely aphasic.	Resuming activities was an iterative process of scaffolding small tasks into activities through bargaining for access to practical support and inclusion into social situations. Although participants geared up to manage their condition and access activities, for the most part they were not in charge of the services and supports they required. They had little control over who was accepted to rehabilitation, for which services they qualified or disability policies.
Gender differences	Andersson ⁴⁰⁷	To explore, from a gender perspective, older peoples' experiences of nursing care after a stroke.	Convenience sampling.	Interviews.	Qualitative content analysis.	66 years of age or older and ability to understand and take part in an interview in Swedish.		There are gender differences in older patients' experience of nursing care after a stroke. Older patients' perceptions of nursing care are linked with their gender and to experiences of their lived bodies before they had the stroke. Nurses need to increase their awareness and knowledge about similarities and gender differences between the experiences and needs of older men and women.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Lofmark ⁴¹⁰	To analyze from a gender perspective how older women and men responded to treatment and care after stroke in the acute care setting, characterized by a medical hierarchic structure.	Maximum variation purposive sampling.	Two interviews, one on stroke ward and one at home.	Constant comparison - grounded theory.	UC	UC	4 subcategories identified as negotiations grounded in data: striving for autonomy, following the rules, building alliances, and criticizing the care. The subcategories were related to each other, resulting in a core category labelled 'Negotiations Within the Medical Context'. Overall, no major differences were found within the group of women and within the group of men in relation to marital status, social class, or level of disability concerning how they negotiated within the medical context.
The patient's interpretation	Kessler ⁴²⁸	To explore whether the change that occurs following stroke follows a process similar to transformative learning.	Convenience sampling.	Semi-structured interviews.	Constant comparative method according to the procedures for Grounded Theory outlined by Corbin and Strauss.	UC	UC	Meaning perspectives, as frames of reference for interpreting the dimensions of work, family role, illness/health, identity, living and recovery, transformed or emerged following stroke. The process of transformation started with the contributing factors defined as triggers: experience of limitations and feeling vulnerable. Transformation was then facilitated by knowledge, and choices to action that occurred in a cyclical manner with support creating an environment that enabled knowledge seeking and acquisition, decision-making and action.

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	Casey ³¹⁴	To explore Irish older people's perception of their health and level of independence following a stroke, as well as illuminate the factors that enhanced or diminished their ability to maintain quality-of-life after their stroke.	Purposive sampling.	Semi-structured interviews.	Guided by the grounded theory approach using the constant comparative technique.	Over the age of 65, who were living with a stroke and who were willing and able to participate.	UC	Many participants reported a profound sense of loss in terms of identity and role function but despite their disability most continued to have a positive concept of health and adopted a functional approach, toward independence. The availability of transport and social connections had a significant impact on quality-of-life. Most participants were still struggling to adapt to their disability and subsequent experiences in a rather unsupportive environment. The need for health professionals to counsel stroke survivors and support them as they advance.
	Townend ⁴²¹	To investigate fear of recurrent stroke and beliefs about its causes and prevention in persons who have had a stroke.	Convenience sampling.	Both structured and semi-structured interviews.	Framework - constant comparison.	Stroke survivors; able to communicate.	Aphasia; not definitive stroke.	Many patients fear a recurrent stroke. They lack a sense of control over its causes and have fears associated with idiosyncratic and fatalistic beliefs. There is a need to elicit and address individuals' own fears and beliefs about stroke before providing information about evidence-based secondary prevention.

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	Hjelmbli nk ⁴¹⁴	To explore the meaning of rehabilitation to older Swedish stroke survivors, from the time of acute stroke to the end of rehabilitation.	Convenience sampling.	Two structured interviews.	Grounded theory analysis.	UC	UC	Older Swedish stroke survivors strive for a socially integrated life. Therapists should understand the meaning of stroke rehabilitation from the stroke patient perspective. Survivors need opportunities to practice mutual play activities, exchange everyday narratives and share positive feelings with friends and families, ideally in places where survivors have previously experience joy with those close to them.
	Gallagher ⁴³⁴	To examine the emotional process of stroke recovery, personally experienced by stroke survivors.	Convenience sampling.	Individual formatted unstructured interviews and one focus group.	Grounded theory analysis.	Participants in a stroke recovery programme.	UC	The central problem experienced by these stroke survivors was being less than 100%. The basic social process used to address this problem was becoming normal, which is composed of three stages: recognizing stroke will not go away, choosing to work on recovery, and working on being normal. Physical and emotional recovery is inseparable, and recovery is directed towards regaining the ability to perform these certain things.

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Returning to driving	Patomella ⁴⁰⁹	To describe and expand our understanding of the lived-experience of driving ability after stroke in the context of undergoing a driving evaluation.	Purposive sampling.	Interviews were done on three occasions.	Empirical, Phenomenological, Psychological (EPP) method as developed by Karlsson.	(a) the diagnosis of a first time stroke, (b) being referred for a driving evaluation, (c) finished the first part of the driving evaluation (medical examination and neuropsychological testing), (d) planned to undergo an on-road driving evaluation and (e) being able to understand the interview questions and describe their experiences in Swedish.	UC	The information given and the routines for the procedures used from the initial advice to the time after finishing a driving evaluation could be developed to support the client in order to better handle the process and a possible revocation of the driving licence. Emotional support needs to be offered to those clients who have difficulties to go on with their lives after a revocation of their licence. A holistic perspective needs to be adopted that investigates not only the driving abilities but also how everyday life can be managed without the car.
	White ⁴⁴¹	To explore the impact of driving issues post-stroke in community-dwelling stroke survivors.	Purposive sampling.	Semi-structured interviews.	Inductive thematic approach using modified grounded theory.	Hospital admission and history and examination consistent with stroke.	Significant cognitive impairment (MMSE <24) or unable to communicate sufficiently to participate in an interview as determined by a speech pathologist.	Emergent key themes included impact on quality-of-life, personal impacts, change to role performance and knowledge. Participants received inconsistent advice regarding return to driving. Confidence and availability determined public transport use. Driving advice should be standard practice prior to discharge. Allied health professionals can play an essential role in interventions addressing community participation, driver re-training and alternative transport use.

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Multimorbidity	Wood ¹⁶⁵	To understand the experience of living with pre-existing knee arthritis while recovering from a first stroke.	Opportunistic purposeful sampling.	Interviews in the hospital (pre-discharge) and in their homes at 2 weeks and 3 months post-discharge.	Phenomenology in Practice approach.	All had sustained their first major unilateral hemispheric stroke, were English speaking, scored over 24 points on the Mini-Mental Status Examination, were discharged home, and had adequate verbal communication skills.	Participants who were discharged to a long-term care facility or reported other serious medical conditions, such as cancer or unstable heart conditions, were excluded.	Participants felt that arthritis was holding them back in their recovery from stroke. They did not alter their expectations for recovery despite their inability to fully participate in rehabilitation due to arthritis. Options for managing their aggravated knees during stroke recovery were few. Participants proactively “experimented” with alternative techniques, with varied success.
Using a wheelchair	Barker ⁴³⁰	To investigate the lived experience of senior stroke survivors who used prescribed wheelchairs in their home and community. To help to understand the factors influencing community participation among elderly stroke survivors.	Convenience sample.	Semi-structured interviews, data sheet, photograph of wheelchair, field notes.	Constant comparative inductive method of analysis. Findings examined within the International Classification of Functioning, Disability and health framework.	65 years or older; living at home; using wheeled mobility; needing assistance with daily living; living in metropolitan area of Canada; speaking and understanding English; cognitively competent.	UC	Overall, the wheelchair, manual or power, was an enabler of community participation. However, wheelchair use also created problems such as limiting destinations and creating increased dependence on others.

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	Barker 429	To gain understanding of the lived experience of senior stroke survivors who used prescribed wheelchairs in their homes and communities.	Convenience sample.	Semi-structured interviews, data sheet, photograph of wheelchair, field notes.	Constant comparative inductive method of analysis. Findings examined within the International Classification of Functioning, Disability and health framework.	65 years or older; living at home; using wheeled mobility; needing assistance with daily living; living in metropolitan area of Canada; speaking and understanding English; cognitively competent.	UC	Three different categories of acceptance of wheelchair use were identified; reluctant acceptance, grateful acceptance, and internal acceptance. Increased mobility, varied social response, and loss of some valued roles were common to all three wheelchair acceptance categories. Aspects of level of burden, freedom, and spontaneity varied in degree among the three acceptance categories. As the wheelchair provided opportunity for increased continuity in the lives of these stroke survivors, it appeared to be accepted more fully and viewed more positively. Prestroke lifestyle and values need to be carefully considered in order to maximize acceptance of wheelchair use among senior stroke survivors.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
Eating difficulties	Perry ⁴¹⁹	To investigate patients' perceptions of eating difficulties 6 months after stroke.	Convenience sampling.	Semi-structured interviews.	Thematic analysis.	Clinical diagnosis of acute stroke with or without computerized tomogram confirmation.	Comprehension and communication were assessed using validated measures: the Mental Status Questionnaire (MSQ) and Frenchay Aphasia Screening Test (FAST). Unless a live-in carer was able to respond on behalf of stroke survivors, patients were excluded if they had scores <17 (if aged 20–60 years) or 16 (if aged 61–70 years) or 15 (age 71 and over) for the combined comprehension and expression subscales of FAST and/or a score of <7 on MSQ.	All aspects of the stroke experience affected eating – physical impairment and restricted function, psychological and cognitive changes, social relationships and participation. Response. For both stroke survivors and those who care for them, the limited attention that food and eating-related issues has received is an important oversight.
	Medin ⁴¹¹	To explore the experience and management of eating situations among persons affected by stroke, 6 months after stroke onset.	Convenience sampling.	Semi-structured interview.	Constant comparison - grounded theory.	UC	UC	Old value and habits and/or involvement from other people were the basis of mastering eating situations. New ways of mastering were also found, and some persons accepted and got used to the new situation and some had regained former routines.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Medin ⁴¹⁵	The aim of this study was to explore the experience of eating difficulties among patients with stroke 3 months after stroke onset.	Theoretical sampling.	Semi-structured interviews.	Constant comparison.	Patients with observed eating difficulties.	Non-Swedish speakers.	This study highlights the complexity of having eating difficulties after stroke. Aspects related to the participants' striving for control are based on different strategies to eat safely and properly. Nurses can use this knowledge to support patients in their strive for control by observing them in eating situations. In addition, nurses can also ask them to describe and make explicit the experience of eating situations after stroke.
Goal setting	Gustafsson ⁴³⁸	To explore the goals set by clients during inpatient and outpatient phases of stroke rehab and to explore the goals of the therapy programmes, as reported by the clients.	Convenience sampling.	Semi-structured interviews.	Template analysis, thematic analysis.	Experienced a stroke and identified by OT has having adequate communication and cognition to participate in the interview.	Inadequate communication and cognition, no diagnosis of stroke or uncertain diagnosis.	Trends in goal setting seen. In patients generally wanted to return to previous meaningful activities and goals. Outpatients begin to accept deficits and a function and structure level at a time when services are often being withdrawn. They should be given an opportunity for patient directed rehab. There is a discrepancy between goals for recovery and perceived goals. Better collaboration is needed.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
	Laver ⁴³⁹	To describe the participants' readiness and ability to set goals over time in the first 6 months following stroke.	Convenience sampling.	Semi-structured interviews.	Content analysis.	New stroke diagnosis; 18-70 yrs old; rehab programme; cognition.	UC	People who have just had a stroke need time to understand many of the terms and concepts that treating clinicians use, and new models need to acknowledge the importance of health literacy if both patients and carers are to participate in the rehabilitation process. People that have had a stroke have an important role to play in the development of these new models.

Research category	First author	Research question	Sampling	Data collection	Data Analysis	Inclusion criteria	Exclusion criteria	Summary of findings
Medications	Chambers ³⁷	To investigate factors that may explain variance in adherence to medication in stroke patients.	Purposive sampling.	Semi-structured interviews.	Thematic analysis.	No stroke prior to index event, diagnosed with an ischaemic stroke in the past 15 months, not resident in a nursing or residential home, living within and having a permanent residential address. In addition, only patients who scored over approximately a 50 mile radius of Edinburgh.	Less than 13/20 on the Frenchay Comprehension test .	Those with poor adherence to medication reported both intentional and non-intentional non-adherence. Two main themes emerged: the importance of stability of a medication routine and beliefs about medication and treatment. High adherers reported remembering to take their medication and seeking support from both family and health professionals. They also had a realistic understanding of the consequences of non-adherence, and believed their medicine did them more good than harm. Low adherers reported forgetting their medication, sometimes intentionally not taking their medication and receiving poor support from medical staff. They disliked taking their medication, had limited knowledge about the medication rationale or intentions, and often disputed its benefits.

Appendix 8 - Published papers from the systematic review

Gallacher *et al.* *BMC Medical Research Methodology* 2013, **13**:10
<http://www.biomedcentral.com/1471-2288/13/10>



CORRESPONDENCE

Open Access

Qualitative systematic reviews of treatment burden in stroke, heart failure and diabetes - Methodological challenges and solutions

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Abstract

Background: Treatment burden can be defined as the self-care practices that patients with chronic illness must perform to respond to the requirements of their healthcare providers, as well as the impact that these practices have on patient functioning and well being. Increasing levels of treatment burden may lead to suboptimal adherence and negative outcomes. Systematic review of the qualitative literature is a useful method for exploring the patient experience of care, in this case the experience of treatment burden. There is no consensus on methods for qualitative systematic review. This paper describes the methodology used for qualitative systematic reviews of the treatment burdens identified in three different common chronic conditions, using stroke as our exemplar.

Methods: Qualitative studies in peer reviewed journals seeking to understand the patient experience of stroke management were sought. Limitations of English language and year of publication 2000 onwards were set. An exhaustive search strategy was employed, consisting of a scoping search, database searches (Scopus, CINAHL, Embase, Medline & PsycINFO) and reference, footnote and citation searching. Papers were screened, data extracted, quality appraised and analysed by two individuals, with a third party for disagreements. Data analysis was carried out using a coding framework underpinned by Normalization Process Theory (NPT).

Results: A total of 4364 papers were identified, 54 were included in the review. Of these, 51 (94%) were retrieved from our database search. Methodological issues included: creating an appropriate search strategy; investigating a topic not previously conceptualised; sorting through irrelevant data within papers; the quality appraisal of qualitative research; and the use of NPT as a novel method of data analysis, shown to be a useful method for the purposes of this review.

Conclusion: The creation of our search strategy may be of particular interest to other researchers carrying out synthesis of qualitative studies. Importantly, the successful use of NPT to inform a coding frame for data analysis involving qualitative data that describes processes relating to self management highlights the potential of a new method for analyses of qualitative data within systematic reviews.

Keywords: Qualitative systematic review, Normalization process theory, Stroke, Treatment burden

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Background

Treatment burden

Recently, there has been a growing literature that describes the concept of *treatment burden*. Treatment burden can be defined as the “workload” of health care that patients must perform in response to the requirements of their healthcare providers as well as the “impact” that these practices have on patient functioning and well being. “Workload” includes the demands made on a patient’s time and energy due to treatment for a condition (s) (e.g. attending appointments, undergoing investigations, taking medications) as well as other aspects of self-care (e.g. health monitoring, diet, exercise). “Impact” includes the effect of the workload on the patient’s behavioural, cognitive, physical, and psychosocial well-being [1,2]. Two patients with equivalent “workloads” may be burdened in different ways and to different extents, this can be explained by differences in their “capacity”, meaning their ability to handle work (e.g. functional morbidity, financial/social resources, literacy) as well as the burden of the illness itself [2]. It has been posited that treatment burden is important because for many people with complex, chronic co-morbidities it may reduce their capacity to follow management plans [3]. Those individuals with chronic illness who view their management plans as being excessively demanding are less likely to adhere to therapies [4,5]. Thus, increasing treatment burden, which is more likely in those with multiple chronic conditions, may lead to suboptimal adherence and consequently negative outcomes [3]. This can lead to further burden of illness and more intensified treatments, further increasing the burden on the patient. Treatment burden is therefore part of a dynamic state involving a complex set of personal, social and clinical factors contributing towards the patient’s experience [2].

A range of treatment burdens or workload factors for those with chronic disease have been described which include: *logistical burdens*, for example organising appointments or visits from health professionals, organising rehabilitation, arranging transport; *technical burdens*, for example enacting lifestyle changes, performing rehabilitation exercises, modifying environments, taking medications; *relational burdens*, for example enrolling family, friends and health professionals for support, initiating interactions with possible carers and supporters; and *sense making burdens*, for example conceptualising problems, understanding and learning about management strategies, knowing when to seek help, differentiating between treatments [6-9].

Although aspects of treatment burden have been described we do not yet have a full understanding of the phenomenon, and in particular, what might be the generic or disease specific features. Our aim is to explore treatment burden as a concept, with the aim of informing the

development of a method of measurement [10], in order to aid clinicians and policy makers in decreasing treatment burden for patients [11]. It is for this reason that we have conducted three systematic reviews of the qualitative literature relating to patient experiences of living with stroke, heart failure and diabetes. These three chronic diseases were chosen as we hypothesised that they all involve conceivably complicated, long term management plans that require significant personal investment from patients [12-14].

Systematic review of qualitative studies

We chose to examine the qualitative literature as this type of research suitably lends itself to uncovering and exploring patients’ perceived needs and behaviours, providing conceptual depth about the patient experience. However, conducting a qualitative systematic review remains challenging and contentious. Increasing numbers of qualitative studies have led to a demand for reliable methods for appraising and synthesising qualitative research similar to the systematic review and meta-analysis of quantitative studies [15,16]. However, there are opposing views on whether this is appropriate or even possible, due to deep seated epistemological and ontological differences [17].

There are a range of methods available for the synthesis of qualitative research [18]. With regards to searching the literature, there are two main schools of thought: those who advocate using purposeful sampling to retrieve materials until data saturation is reached [19]; and those who aim to retrieve all of the relevant studies in a field rather than a sample of them [20]. The first approach is often taken by authors of narrative reviews, reviews using an extremely large and diverse set of resources [21], or those aimed at developing concepts and theories rather than summarizing research carried out to date [22]. Studies aimed at comprehensively summarizing the literature should include a comprehensive and rigorous database search using predefined index/subject heading/free text terms, informed by an initial scoping search [22-26].

Finding relevant qualitative studies has been reported as an arduous task due to inadequate refinement of the electronic indexing of qualitative articles [22,27]. Those papers found in journals also often lack abstracts or include titles based on patient quotes, making it difficult to establish relevance of the paper in question [22]. Several papers have been published outlining strategies for searching through well known databases for relevant qualitative studies [28-31].

Due to these difficulties, other techniques have become established as helpful in the searching process, which can involve either electronic or hand searching [25,26]:

- Reference or footnote tracking (looking back at studies referenced in articles found).

- Citation tracking (looking forward at studies that have subsequently cited articles found, using a citation database).
- Personal knowledge and personal contacts.
- Contacting the authors of known papers or experts in the field.
- Hand searching relevant journals.
- Internet browsing such as berry picking (a method of searching where one search may lead to another and 'clusters' of papers are often found together).

Indeed, in their systematic review of complex evidence, Greenhalgh et al. found that only 30% of their primary sources were found by the traditional method of using a predefined search strategy and that 51% were found by other predefined methods such as reference, footnote and citation tracking [25].

There are opposing thoughts on whether quality appraisal of qualitative research is appropriate. Those against it believe that each piece of research tells its own story and cannot be compared to another [16]. Others, however, believe it to be an essential component of rigorous qualitative synthesis [15], albeit amongst these supporters there is no consensus on how to enact quality appraisal, unlike the widely agreed checklists available for quantitative research, such as the Cochrane Risk of Bias Tool [32-34].

Methods of data synthesis are also highly debated, with a great array of documented options and somewhat confusing terminology [18]. Most consist of a 'compare and contrast' exercise, which can range from descriptive techniques that aim to summarize similarities and differences between studies and interpretive techniques that additionally aim to develop new understandings and perspectives while preserving meaning from the original studies [23,24]. Examples of techniques used include meta-ethnography [35], critical interpretive synthesis [36], thematic synthesis [37], grounded theory [38], meta-narrative review [39], realist synthesis [21], cross case analysis [40], meta-synthesis [41], and meta-study [42]. Meta-ethnography has emerged as one of the more popular methods of data synthesis [27,35]. This is an interpretive method that seeks to create higher order interpretations, and tends to be suited to researchers using inductive methods of research seeking to explore a phenomenon rather than answer a predefined question [18].

It has been suggested that Normalization Process Theory (NPT) [43,44] could potentially offer new ways to approach the analysis of qualitative data gathered as part of a systematic review and that it could have a role in helping to interpret data when considering how patients or carers manage/deal with a range of conditions and self care issues [45]. NPT has a robust theoretical basis and explains how the work of enacting an ensemble of

practices (in this case the components of treatment burden) is accomplished through the operation of four mechanisms: 'coherence' (sense making work); 'cognitive participation' (relationship work); 'collective action' (enacting work); and 'reflexive monitoring' (appraisal work) [43]. NPT has previously been used successfully to aid conceptualisation of the qualitative literature relating to the implementation of new technologies by framework synthesis [45-47]. Framework synthesis is a method of synthesis derived from qualitative framework analysis [48,49]. It is an appropriate method for researchers with some degree of knowledge in their chosen area, with a predefined framework being applied to data to gain a deeper understanding of a particular phenomenon. Care must be taken, however, not to 'shoe horn' findings into the framework, and this is one challenge of using such a method. A novel aspect of our reviews is that we have used NPT as a conceptual and coding framework and we describe this approach within this paper.

Aims

The aim of this paper is to describe and discuss the methods used and instruments developed to undertake qualitative systematic reviews of the treatment burdens identified in three different common chronic conditions. The approaches used for data collection and analysis were the same for all three. A particularly novel aspect of these reviews is the use of a coding framework underpinned by NPT. In this paper we use the stroke review as our exemplar.

Methods

Searching for papers

Qualitative studies using techniques involving direct patient contact or observation such as interviews and focus groups, seeking to understand the patient experience of stroke management were sought. An exhaustive search strategy was deemed suitable, as the aim was to summarise the literature on this topic. Limitations of English language and year of publication 2000 and onwards were set. There were no geographical restrictions.

'Scoping searches' were carried out with the aim of identifying key papers and familiarising reviewers with key terms. This consisted of: searching our own files; internet searching using the 'berry picking' method (a method of searching where one search may lead to another and 'clusters' of papers are often found together) [26]; a preliminary search of databases via Ovid; the use of the 'related articles' function in Pubmed (<http://www.ncbi.nlm.nih.gov/pubmed/>) and Web of Science (<http://wok.mimas.ac.uk/>); and consultation with experts in the field.

A formal database search strategy was created in consultation with an information scientist, informed by key words and phrases found during the scoping search.

Additional file 1 shows the full search strategy created using a combination of free text search terms and subject headings. Databases searched were Scopus, CINAHL, Embase, Medline & PsycINFO. The search initially centred around three main concepts: 'stroke'; 'treatment burden'; and 'patient experience' then the concept 'qualitative methods' was added to increase sensitivity and specificity. Reference, footnote and citation tracking were then carried out on included papers. The references were also searched of 10 reviews found during the scoping search that examine the qualitative literature on the patient experience of stroke, none directly aimed at understanding treatment burden, but on related topics.

Paper screening

Each title, abstract and full paper was screened by two individuals (KG, DM, BJ, SM) with a third party involved for any disagreements (FM). Additional file 2 illustrates inclusion and exclusion criteria used. Inclusion of studies was limited to those that involve direct patient contact or observation such as interviews or focus groups, with qualitative methods of analysis that seek to identify themes or patterns discussed by participants. Studies using telephone, postal or internet questionnaires were excluded, as were those using document analysis, quantitative patient-reported measures, simple counts of patient responses, and language analysis presented as quantitative results. We included studies that explored the patient experience in any setting, but excluded those investigating the patient experience of pilot or experimental studies rather than 'real world' settings. This meant that qualitative studies as part of a mixed methods study would be included, but only if these pertain to usual patient care, rather than the patient experience of, for example, an experimental treatment regime.

Studies seeking to understand the patient experience of stroke management with a focus on treatment burden were included. Due to the novel nature of our research question, we found that screening papers consistently was difficult, as treatment burden was not typically the focus of the paper, with relevant information being somewhat 'hidden' in the results. We therefore found that screening often came down to a judgment about 'how relevant' a paper was. To improve consistency yet be as inclusive as possible we agreed that for inclusion, roughly over 30% of the results and discussion within a paper should focus on treatment burden. Due to the possible subjective nature of this decision, we only excluded papers that two reviewers excluded for the same reason, with any conflicts going to a third party for review.

Data extraction

Data extraction was conducted by two individuals (KG, DM, BJ, SM) with a third party involved for any disagreements (FM). Data extracted for analysis was limited to

data describing a range of treatment burdens. Clear criteria for inclusion and exclusion of data were used to inform decision making as illustrated in Additional file 3. Both researchers screened all data from the results and discussion of every included paper with a third party for disagreements, to ensure inclusion of all relevant data. The data extraction instrument developed and used is shown in Additional file 4. A careful note was made of any treatment burden data that fell outside our framework in order to assess if our framework was 'fit for purpose' and to ensure that no relevant data was missed.

Data analysis

A particularly novel aspect of this review was our approach to data analysis. To facilitate understanding of the components and dimensions of treatment burden, we utilised Normalization Process Theory (NPT).

Data were analysed using a coding frame informed by NPT, following the five stages of framework analysis: familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation [48]. The framework was underpinned by NPT and informed by a previous study that involved the analysis of semi-structured, qualitative interviews with heart failure patients [6], as well as our knowledge of the literature and clinical experience. It was then adapted and refined during analysis to create a stroke specific coding frame for treatment burden. This was used to identify, describe and understand the components of treatment burden experienced by patients with stroke. The coding frame underpinned by NPT developed for data analysis of the stroke literature is shown in Table 1. Analysis was conducted by two individuals (KG, DM, BJ, SM) with a third party involved for any disagreements (FM). As well as the regular meetings between the two coders, 'coding clinics' were held on several occasions, involving a group of six researchers (three of whom have considerable experience in this field) all coding transcripts separately and discussing any differences. Refinement of the coding frame and analysis was therefore iterative.

All data was coded according to the NPT framework, with data being coded under the four NPT domains (coherence, cognitive participation, collective action, reflexive monitoring) and their subconstructs (see Table 1). Several codes were created within each subconstruct, and these were subsequently grouped together under treatment burden headings. This created a taxonomy of treatment burden that reflects the original accounts of the patients being studied, so could be described as 'grounded' in the data, with the framework underpinned by NPT being used for initial extraction and organisation.

Quality appraisal

A quality appraisal instrument was created and based upon published guidance by well known qualitative

Table 1 NPT based coding framework

COHERENCE	COGNITIVE PARTICIPATION	COLLECTIVE ACTION	REFLEXIVE MONITORING
<i>(Sense-making work)</i> Understanding the prospect of having, what this means and how the condition may be managed.	<i>(Relationship work)</i> Investing personal and interpersonal commitment to living with the condition and its management.	<i>(Enacting work)</i> Investing effort and resources in management and carrying out necessary tasks.	<i>(Appraisal work)</i> Reflecting on the effects of therapies in retrospect and determining whether to modify them.
Differentiation	Enrollment	Skill set workability	Reconfiguration
Understanding and differentiating between risk factors, investigations, treatments and the roles of different health professionals and services. Prioritising treatments and activities.	Engaging with friends, family and health professionals with regards to diagnosis and illness management to enable them to provide support. Adjusting relationships to accommodate new roles as a result of illness during management.	Setting a routine to cope with symptoms, exacerbations, and emergency situations i.e. therapeutic interventions. Enacting activities with a view to achieving goals. Controlling risks associated with recovery.	Altering a set routine when required such as medication regimes or appointments, to fit in with daily activities or other arrangements. Learning a new way of doing things after stroke. Altering priorities and ways of thinking due to stroke management.
Communal specification	Activation	Contextual Integration	Communal Appraisal
Gaining information about illness management with the help of others, for example friends, family or health professionals. Receiving diagnosis, or misdiagnosis.	Arranging help (e.g. logistical, administrative, or expert) from health professionals, social services or friends and family.	Making sure you have the right financial and social resources, and integrating the illness into social circumstances. Managing potential environmental dangers through making resources available. Adjusting to new social role in society or life circumstances such as unemployment.	Discussing or altering current management plans already initiated, in discussion with health professionals or friends and family. Recalling previous events with friends and family.
Individual specification	Initiation	Intemational workability	Individual appraisal
Achieving your own understanding of illness management in personal terms, through personal research such as reading, or personal experience.	Using organisational skills to arrange one's own contributions to management, such as arranging prescriptions, social care and transport to appointments.	Taking treatments, enacting lifestyle changes, attending appointments, enduring side effects. Enduring poor health care or care that does not meet expectations (e.g. poor interactions). Enduring setbacks in recovery. Learning self care. The work of rehab. The work after discharge. Enduring intrusions and interventions from family members, including negative interactions.	Assessing individually whether to continue or alter current management plans. Recalling previous events. Monitoring symptoms and progress (but not as a routine, see below).
Internalization	Legitimation	Relational Integration	Systematization
Relating your experience to illness management, understanding any implications, knowing when to seek help, understanding one's own contributions to reducing risk, knowing limitations and risks due to stroke. Calculating safety risks. Maintaining motivations and determination. Developing expectations of health services. Making sense of progress in recovery and one's own contributions to this. Setting goals for recovery.	Seeking reassurance from others about appropriateness of management plans. Gaining confidence in the success of treatments. Dealing with stigmatisation or a mismatch in ideas and expectation from others. Reaching an understanding that treatments are 'the right thing to do'. Comparing yourself to others to validate treatments.	Maintaining confidence in health professionals and their interaction with each other. Maintaining confidence in care plan. Coping with multiple caregivers. Enduring system failures caused by poor communication/interaction by service providers.	Developing ways of keeping up to date with newly available treatments. Routine self monitoring.

researchers [17]. This is shown in Additional file 5. From this guidance, the authors developed an instrument consisting of eleven questions, each considering an aspect of quality such as rigour, validity, transparency and generalisability. Two researchers independently carried out quality appraisal and answers were compared and discussed. No scoring system or level of 'pass mark' was set as the value of this is uncertain [50]. Appraisal was therefore not carried out to exclude studies but to inform the discussion

and analysis. This involved creating a summary of the quality of included studies, in order to highlight any notable defects in the quality of the literature, as well as to inform our own future qualitative research in this area.

Results

Searching and screening

Our scoping search uncovered 10 key papers, 10 reviews and 20 potentially relevant papers. The initial search

which centred on the concepts of stroke; treatment burden; and patient experience retrieved over 30,000 papers. This was not deemed adequately specific or sensitive as some key papers were not retrieved. A second search strategy was then created, adding the concept 'qualitative methods' [28-31,51,52]. This significantly increased sensitivity and specificity of the search: 4346 papers were identified; all key papers were retrieved. Another 47 papers were identified from reference, footnote and citation tracking of all included papers. At full paper screen level, 33 out of 380 papers required review by a third party due to conflict between the first and second reviewer. 54 papers reached the final stage of data extraction and analysis (see Figure 1). Of these 54 papers, 51 (94%) were retrieved from our database search. The 3 papers included that were not found in our database search were found from reference searching (see Figure 1).

Data extraction and analysis

Table 1 displays the NPT coding framework used for analysis. No data on treatment burden was found that fell outside this coding framework, an important finding as this provides evidence that NPT is suitable for conceptualising the treatment burden faced by patients with chronic illness. We identified the following areas of treatment burden from the literature: *making sense of treatments* e.g. gaining information from health professionals; *planning recovery and care* e.g. setting goals; *interacting with others* e.g. coping with multiple caregivers; *institutional admissions* e.g. admission to hospital; *managing stroke in the community* e.g. risk factor

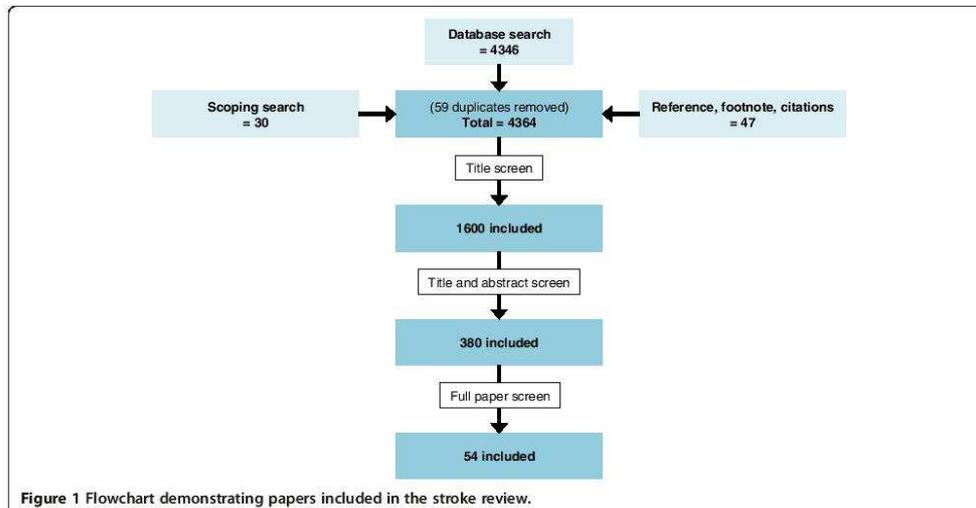
management at home; *reintegrating into society* e.g. addressing financial difficulties; *adjusting to life after stroke* e.g. planning a new daily structure to accommodate treatments; and *reflecting on management* e.g. making decisions about adherence.

The following examples are excerpts from included papers with a demonstration of how these were coded. See Table 1 for a detailed description of each code. The first is an example of Coherence; Communal Specification (COCS). This describes poor information provision from health professionals to patients, and is categorised in our treatment burden taxonomy as 'making sense of treatments':

Not being adequately informed concerned what the participants described as absent, contradictory or incomprehensible information. Some of them had not received any information other than what was given to them in a brochure about stroke. Others had wanted more detailed information about their brain injury, the reason for examinations performed, the results and the prognosis. Further, contradictory information with regard to the cause of their stroke and about their treatment was described [53].

The second is an example of Cognitive Participation; Legitimation (CPL). This demonstrates a mismatch in ideas and expectations between patients and health professionals and is categorised as 'interacting with others':

For them recovery involved dimensions that were not included in the health care professionals' concept. ...



The goal for them was either to recapture their former social position or to adapt to another life situation [54].

The third is an example of Collective Action, Interactional Workability (CAIW). This describes inadequate patient services and would be categorised under 'institutional admission':

Patients feel that therapy and supervised exercises in the ward facilitate regaining self-care, but they experience a lack of therapy and supervision, for example, when their therapist is ill or during weekends. In the patients' view, this problem can be solved but patients find it difficult to judge [55].

Lastly, the fourth is an example of Reflexive Monitoring, Systemization (RMSY). This demonstrates routine self monitoring of progress, and would be categorised as 'reflecting on management':

Mr Neville an 80 year old man set himself the target of walking unaided by the time he left hospital. ...He kept a diary of is progress which he made available to the research team [56].

Data on illness burden as opposed to treatment burden was excluded. The following is an excerpt from an included paper that demonstrates information about illness burden. This data was excluded:

The following respondent focused on the fact that she was not able to perform activities as easily and quickly as she used to. Though she was able to do most of what she wanted to, the fact that she did it slower and with more effort than before was a constant source of frustration [57].

Quality appraisal

Papers were generally of a reasonable quality: demonstrating that they had used information gained directly from patients themselves; displaying a clear explanation of methods used; and being transparent about generalisability. Aspects of quality less well demonstrated included: acknowledgment of the researchers influence on the analysis; and any note of conflicts of interest.

Discussion

The vast and multifarious options available regarding methodological approaches for qualitative systematic review can make this process a challenging and creative task. Methods must therefore be explicitly described for

transparency and reproducibility to be plausible and we have outlined the approach we adopted to maximise identification of eligible studies.

Methodological challenges

Creating an appropriately sensitive and specific search strategy was a significant challenge, as we were essentially searching for a topic that has not previously been defined or indexed in a body of literature that itself is not adequately represented or indexed. From this point of view the scoping search was invaluable, as it provided key papers and key words that could be used to create the search strategy. We found that adding 'qualitative methods' as a concept made our search strategy considerably more specific while retaining sensitivity, as demonstrated by the return of all the key papers identified in the scoping search. Indeed, our final results showed that 94% of papers were identified by our predefined database search. This contrasts with the findings of Greenhalgh et al [25] who found only 30% of papers using this method. This could be explained by differences in the topic under review as well as in inclusion criteria with regards literature sources, or it could be an indication of differing sensitivities of the search strategies.

Another difficulty to be addressed was that we aimed to study a phenomenon that has not previously been conceptualised. Very few papers seek to understand treatment burden in chronic illness specifically, although information on this is made available through the investigation of the patient experience of disease management. For example, it is common for a paper to explore the patient experience of recovery after stroke, encompassing the illness trajectory itself and its affect on the patient's lifeworld. Within the patient's story there is often valuable information on treatment burden, although this may not have been the explicit aim of the study. Thus we are attempting to apply a conceptual framework to a set of studies that have used alternative theories and methods to analyse the patient experience.

A third issue was that data extraction was complex, as within each paper there was a significant amount of irrelevant qualitative data difficult to separate from that on treatment burden due to the difference in focus between the primary studies and the review. There was considerable data on illness rather than treatment burden, and on lifeworld burden such as managing the home or maintaining employment, carried out in parallel to but not as a direct consequence of the illness. This is in keeping with the milestone work published by Corbin and Strauss on the three lines of work experienced by those with chronic illness [58]. Such burdens all merit further exploration but were not the focus of our work. There was also frequent exploration of the patient's views, ideas and expectations of services, although the

material practices that resulted from this were often not explored or documented, leading to a limited insight into the patient's world.

Fourth, the appropriateness and methodology of the quality appraisal of qualitative research is widely debated [27]. We decided to use a previously published method [17] which appealed to our desire for quality appraisal that can inform the overall analysis and discussion of the review, whilst avoiding the use of a formal checklist or scoring system that results in exclusion of studies [59]. The value of carrying out quality appraisal in this review is therefore debatable. It could be argued that it proved useful for enabling a better understanding of the included studies, and that appraisal would have highlighted any significant methodological flaws had any been present. There is evidence, however, that the appraisal of qualitative research is such a subjective process that reaching a strong agreement between researchers is unlikely [50,60]. This supports our decision not to exclude studies based on quality appraisal, but raises the issue of whether quality appraisal under these circumstances is a worthwhile process.

Finally, a particularly novel aspect of this review was our approach to data analysis. We analysed data using a coding framework underpinned by NPT, which has previously been shown to aid understanding of the organization and operationalisation of tasks (their implementation), how tasks are made into routine elements of everyday life (their embedding), and how practices are sustained and embedded into their social contexts (their integration) [43]. It has been successfully used to understand the 'work' involved in sickness careers [61] and to understand the treatment burden experienced by chronic heart failure patients [6]. We found this novel method of data analysis very useful and informative for identifying the components of treatment burden in chronic illness from the patient perspective. Our successful use of NPT in this context suggests that in addition to being useful for the analysis of primary studies, this theory lends itself suitably to the synthesis of qualitative studies [47]. Similar to other methods of framework analysis, this is particularly appropriate in the applied research arena, where *a priori* ideas and concepts exist yet researchers wish their findings to reflect themes that arise from within the data.

Limitations/strengths

We limited our search to publications from the year 2000 and onwards. As our reviews are aimed at understanding the current patient experience of stroke, heart failure and diabetes management with the aim of informing current clinical practice and policy, it was deemed most pertinent to review the literature over the past decade. This reflects patient experiences of

treatment burdens based on current health service practices rather than historical ones. Global management of these conditions has changed over time, for example, stroke management has changed greatly in recent years with the introduction of stroke units and community rehabilitation programs [62,63] and hence we believe this to be a reasonable approach but it could be viewed as a limitation. Also, we restricted our search to English language papers as we had no resources available for translation. There were no geographical restrictions set, but the language restriction will have imposed some geographical restrictions on our results. Important strengths are that we conducted an exhaustive search rather than a purposive approach, and the robust theoretical underpinning to our approach to data analysis. No formal assessments of sensitivity and specificity of our search strategy were carried out; specificity was estimated by assessment of the number of papers retrieved, and sensitivity by the return of all key papers identified in the scoping search. A more formal assessment would be essential to comprehensively validate the search strategy, and the absence of this could be considered a limitation.

All aspects of data extraction, quality appraisal and data analysis were carried out by two researchers, with a third party for disagreements. We chose to use this method to minimise bias on behalf of the researcher [64], and as a method of triangulation to enhance our analysis [15]. Our tight inclusion criteria allowed us to avoid collecting too broad a spectrum of methodologies, as high numbers of studies using extremely varied methods makes in depth analysis of the data and applicability of findings extremely challenging. Studies that were not in peer reviewed journals i.e. 'grey literature' were excluded to manage the scope of the review. This could be regarded as a limitation. Aspects of the screening process could be argued to be fairly subjective i.e. the inclusion of studies with roughly 30% or more relevant content. Bias was reduced by the use of two independent reviewers, both of whom had to answer 'exclude' based on the same criterion for a paper to be excluded. As a result, the number of studies included was considerable yet still feasible for the application of qualitative analysis. These exclusions and the exclusion of methodologies such as telephone and postal questionnaires could be regarded as limitations, as it is possible that some studies exploring treatment burden may have been missed, and it would be worthwhile for subsequent reviews to be carried out looking at these areas. These approaches helped us to maintain focus whilst producing a rich picture of stroke management.

The use of framework analysis in this systematic review was appropriate due to our *a priori* knowledge in this area. However, there is always a risk with framework

analysis that data has been 'shoe horned' into the framework, with the possibility that some data may be missed. However, although this work was deductive to some extent, we were careful to augment the framework during analysis, being careful to ensure that our findings were derived directly from the data, and importantly, made a careful note of any data that fell outside of our framework. We failed to find any such data, which suggests that the use of NPT as the underpinning theory for our analysis proved to be appropriate in this case.

Conclusion

We have described the methods used in one of three methodologically similar qualitative systematic reviews aimed at exploring treatment burden as experienced by patients with chronic disease. The exploration of a topic not previously conceptualised and the creation of our search strategy may be of interest to other researchers carrying out synthesis of qualitative studies. Importantly, the successful use of NPT to inform a coding frame for data analysis involving qualitative data that describes processes relating to self management highlights the potential of a new method for analysis of qualitative data within systematic reviews.

Additional files

Additional file 1: Search strategy. The full search strategy used in the stroke systematic review.

Additional file 2: Inclusion and exclusion criteria for papers. Criteria used to include and exclude papers in the stroke systematic review.

Additional file 3: Inclusion and Exclusion criteria for data extraction. Criteria used to include and exclude data within a paper in the stroke systematic review.

Additional file 4: Data extraction instrument. The instrument used to extract data from papers included in the stroke systematic review.

Additional file 5: Quality appraisal instrument. The instrument used to analyse the quality of papers included in the stroke systematic review, to inform discussion.

Abbreviations

NPT: Normalization process theory.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KG, FSM, CRM, VMM, and GDB were all involved in the design of the reviews, PE created the search strategies with contribution from KG, FSM, VMM, and DE. KG, BJ, DM, SM, FSM, FS all screened papers, data extracted and analysed data, CRM analysed data. All authors read and approved the final manuscript.

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Acknowledgements

We would like to acknowledge The International Minimally Disruptive Medicine Workgroup. We would like to thank the Chief Scientist Office Scotland for funding this study. We would like to thank Jane Goodfellow, University of Glasgow, for her help with the design of Figure 1.

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Received: 23 April 2012 Accepted: 15 October 2012

Published: 28 January 2013

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doi:10.1186/1471-2288-13-10

Cite this article as: Gallacher et al.: Qualitative systematic reviews of treatment burden in stroke, heart failure and diabetes - Methodological challenges and solutions. *BMC Medical Research Methodology* 2013 **13**:10.Submit your next manuscript to BioMed Central
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Uncovering Treatment Burden as a Key Concept for Stroke Care: A Systematic Review of Qualitative Research

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Abstract

Background: Patients with chronic disease may experience complicated management plans requiring significant personal investment. This has been termed 'treatment burden' and has been associated with unfavourable outcomes. The aim of this systematic review is to examine the qualitative literature on treatment burden in stroke from the patient perspective.

Methods and Findings: The search strategy centred on: stroke, treatment burden, patient experience, and qualitative methods. We searched: Scopus, CINAHL, Embase, Medline, and PsycINFO. We tracked references, footnotes, and citations. Restrictions included: English language, date of publication January 2000 until February 2013. Two reviewers independently carried out the following: paper screening, data extraction, and data analysis. Data were analysed using framework synthesis, as informed by Normalization Process Theory. Sixty-nine papers were included. Treatment burden includes: (1) making sense of stroke management and planning care, (2) interacting with others, (3) enacting management strategies, and (4) reflecting on management. Health care is fragmented, with poor communication between patient and health care providers. Patients report inadequate information provision. Inpatient care is unsatisfactory, with a perceived lack of empathy from professionals and a shortage of stimulating activities on the ward. Discharge services are poorly coordinated, and accessing health and social care in the community is difficult. The study has potential limitations because it was restricted to studies published in English only and data from low-income countries were scarce.

Conclusions: Stroke management is extremely demanding for patients, and treatment burden is influenced by micro and macro organisation of health services. Knowledge deficits mean patients are ill equipped to organise their care and develop coping strategies, making adherence less likely. There is a need to transform the approach to care provision so that services are configured to prioritise patient needs rather than those of health care systems.

Systematic Review Registration: International Prospective Register of Systematic Reviews CRD42011001123

Please see later in the article for the Editors' Summary.

Citation: Gallacher K, Morrison D, Jani B, Macdonald S, May CR, et al. (2013) Uncovering Treatment Burden as a Key Concept for Stroke Care: A Systematic Review of Qualitative Research. PLoS Med 10(6): e1001473. doi:10.1371/journal.pmed.1001473

Academic Editor: Janet Parsons, St. Michael's Hospital, Canada

Received: November 29, 2012; **Accepted:** May 9, 2013; **Published:** June 25, 2013

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Funding: This study was funded by the Chief Scientist Office <http://www.cso.scot.nhs.uk/> CAF/10/03. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: DTE is currently receiving federal funding from the U.S. National Institutes of Health (National Institute of Nursing Research) to conduct research on the burden of treatment concept. Grant number: 1R21NR012984-01A1. FSM and CRM have also received funding from the ESRC previously to help develop a NPT web enabled toolkit. All other authors have declared that no competing interests exist.

Abbreviation: NPT, Normalization Process Theory

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Introduction

The Concept of Treatment Burden

'Treatment burden' is a novel concept describing the self-care practices that patients with chronic disease must perform to enact management strategies and respond to the demands of health care providers and systems. Individuals will vary in their capacity to accommodate and enact such practices, which may have a marked impact on patient functioning and well-being [1–4], and on adherence to management plans [5–8]. Nonadherence to management strategies by patients with chronic disease is a global health problem [9] and has the potential to lead to negative outcomes for patients such as increased morbidity and wasted expenditure for health care systems [1,10]. There is growing interest in the concept of treatment burden internationally [1–4], and it has been hypothesized that treatment burden can overwhelm patients, exceeding their coping threshold and leading to poor adherence to therapies [7,11,12]. Coping thresholds are likely to vary substantially between patients, depending on environmental factors such as social support and financial constraints [5,13,14], and on internal factors such as health literacy and resilience [15,16].

There has recently been a growing interest in the development of a patient-reported outcome measure of treatment burden in chronic disease, to be utilised by health care providers alongside consideration of patient capacity [3,4]. It is well documented that the initial steps of development of such a measure are to explore the patient experience through qualitative methods [17]. This review explores the features of treatment burden in one chronic disease, stroke, but we expect many of the key concepts identified would be generic and relevant to those with other chronic diseases and multimorbidity [18].

Treatment Burden in Stroke

Cerebrovascular disease (stroke) is the leading cause of long-term disability in both the UK and the US [19,20]. Global projections to the year 2020 indicate that this disease burden will increase, in both westernised and resource-poor countries [21]. It is well documented that treatment for, and rehabilitation from, stroke can be an extended, arduous process, demanding significant personal investment from the patient [22,23].

There is a significant evidence base to support both rehabilitative and secondary preventative therapies in stroke [24,25], but to optimise effectiveness, the issue of nonadherence, and therefore treatment burden, must be addressed. Treatment burden has not been well examined in relation to stroke. Previous syntheses of qualitative studies in stroke have focussed either on the patient experience of illness rather than treatments [26,27,28] or on the experience of informal carers [29,30]. A few syntheses have explored the patient experience of stroke treatments, but these have concentrated either on one specific aspect of the management process [31–38] or specifically on the interaction between patient and health care providers [39–41]. One synthesis systematically reviewed all qualitative studies of stroke [23] including papers that examined the experience of patients, informal carers, and health professionals, but did not examine the issue of treatment burden. This systematic review therefore seeks to explore the qualitative literature on the patient experience of stroke management with the aim of identifying and describing treatment burden, in order to determine whether treatment burden is an important issue in the context of stroke care. To the best of our knowledge, this is the first such systematic review of qualitative studies of treatment burden in stroke.

Methods

A protocol was created and the review registered on PROSPERO, the International Prospective Register of Systematic Reviews (CRD42011001123, http://www.crd.york.ac.uk/NIHR_PROSPERO/display_record.asp?ID=CRD42011001123).

Search Strategy

The review methods have been described in detail elsewhere [42]. A comprehensive search strategy was used to identify qualitative studies seeking to understand the adult patient experience of stroke management. Limitations of English language, year of publication 2000 onwards, and publication in a peer reviewed journal were set. The English language restriction was due to a lack of funding for translation. The year of publication 2000 onwards was chosen to ensure that we collected information about current, rather than historical, patient care. A formal database search strategy using a combination of free text search terms and subject headings was created in consultation with an information scientist; this is shown in Text S1 [42]. Databases searched were Scopus, CINAHL, Embase, Medline, and PsycINFO. The search centred around four main concepts: stroke, treatment burden, patient experience, and qualitative methods. Reference, footnote, and citation tracking were also undertaken. Initially, the search was carried out to include literature published up until March 2011 [42], and this was then subsequently updated to February 2013.

Inclusion/Exclusion Criteria

We included qualitative studies that explored the adult patient experience of stroke management in any setting (e.g., primary care, secondary care, outpatient, nursing home) and provided information on treatment burden. Full details of inclusion and exclusion criteria for papers are shown in Table S1 and are discussed in detail elsewhere [42].

Data Screening, Extraction, and Analysis

Title, abstract and full paper screening, data extraction and analysis were undertaken by two individuals with a third party involved for any disagreements. Data extracted for analysis were limited to those describing a range of treatment burdens and to author comments rather than primary data or verbatim quotes. Details of the data extraction instruments developed and used are published elsewhere [42]. Data were analysed using framework synthesis [43,44] under a coding framework informed by Normalization Process Theory (NPT) [42]. NPT is a robust analytic framework for understanding the organisation and operationalisation of tasks or practices (their implementation), of making them routine elements of everyday life (their embedding), and of sustaining embedded practices in their social contexts (their integration) [45–47]. As we are conceptualising treatment burden as a set of practices performed by patients during their chronic disease management that must be implemented, embedded, and sustained in the patient's life, we thought this to be a suitable framework for analysis. NPT has been shown to effectively conceptualise the practices involved for patients during their sickness careers [48], and we have recently shown it to be effective in understanding the treatment burden experienced by chronic heart failure patients [2,49]. NPT was chosen over a stroke-specific conceptual framework as this enables the possibility of future comparisons between the experiences across a range of chronic diseases and multimorbidity.

During data analysis, data on treatment burden were extracted from the authors' results and discussion sections; each item was

then coded independently by two researchers using the coding framework underpinned by NPT (Table S2). This was adapted and refined during data analysis. A careful note was made of any treatment burden that fell outside the coding framework, in order to assess if the framework was 'fit for purpose'. The data, organised into framework codes, were then examined by the primary researcher, and themes created within and between codes by looking for regularities, irregularities, and relationships between components. As it was felt that data saturation had been reached through our initial search to 2011 which identified 54 papers, for papers identified in our update search to February 2013 one researcher read through the results and discussion sections of each paper and noted any new themes that arose.

A pragmatic approach was then taken to further analyse and reorganise themes into a taxonomy of treatment burden under headings that reflect different processes of stroke care. Themes were then examined in relation to our theoretical framework in order to develop a robust conceptual model of treatment burden in stroke. Several meetings were held between researchers to discuss the emergence of themes and the creation of the taxonomy and conceptual model. We then examined this taxonomy and conceptual model and noted any relationships between components or apparent causal processes, in order to make suggestions for future areas of research or improvements to health service delivery [42].

Quality Appraisal

Quality appraisal was based upon published guidance by well-known qualitative researchers [50]. The criteria used are shown in Table 1 and detailed elsewhere [42]. Two researchers independently carried out quality appraisal and answers were compared and discussed. Papers were not excluded based on quality appraisal because: (1) our aim was to develop as comprehensive a taxonomy of treatment burden as possible and we intended to minimise the risk of missing any key concepts; and (2) there is currently no consensus on the best way to appraise the quality of qualitative research for inclusion in systematic reviews [51].

Results

Retrieved Studies

In total, 5,892 papers were identified, and 69 subsequently met our inclusion criteria. Figure 1 demonstrates the inclusion and exclusion of papers at each stage of the screening process.

Study Details

None of the included studies stated the investigation of treatment burden as a research objective, but all contained substantial amounts of information on treatment burden in the results or discussion section [42]. Research objectives were noted to vary considerably between studies; to demonstrate this we have broadly categorised papers into the following areas of research (Tables S3 and S4): recovering from stroke, the interaction between patient and health services, return to work/retirement, nursing home experience, coping strategies, living with aphasia, physiotherapy/exercise, motivation/hope in recovery, reintegration into the patient's lifeworld and community, gender differences, the patient's interpretation, returning to driving, multimorbidity, using a wheelchair, eating difficulties, goal setting, and medications. This wide range of categories demonstrates the heterogeneity of included papers.

Key descriptive information of included papers is as follows. Country of study: Sweden (n = 19) [52–70]; UK (n = 12) [7,71–81]; Canada (n = 11) [82–92]; Australia (n = 10) [93–102]; US (n = 5)

[103–107]; Norway (n = 3) [108–110]; Netherlands (n = 3) [111–113]; New Zealand (n = 2) [114,115]; Iran (n = 1) [116]; Republic of Ireland (n = 1) [117]; Nigeria (n = 1) [118]; and China (n = 1) [119]. Participant numbers ranged from 1 to 113. Settings of studies: community (n = 34) [7,52,55–58,60,61,63,69,71,73,75,80,83,85–88,90–94,96,99–101,106,110,115–117,119]; outpatient (n = 5) [54,62,65,74,118]; care homes (n = 3) [111–113]; hospital (n = 6) [59,68,72,81,104,107]; stroke units (n = 8) [64,66,67,76,78,79,89,95]; stroke medical centre (n = 1) [108]; and mixed setting such as hospital and community (n = 12) [53,70,77,82,84,97,98,102,103,105,109,114]. Gender of participants: males and females (n = 56) [7,52,53,55–57,59,60,62–71,73,75,76,79–88,90,91,93–100,102–104,106–113,115–117,119]; male only (n = 6) [58,61,74,77,78,118]; female only (n = 2) [89,101]; unclear (n = 5) [54,72,92,105,114]. Ages of participants ranged from 22 to 100 years; this was unreported in a few studies (n = 7) [53,54,72,105,106,110,114]. Time since stroke (n = 41) [7,52,55–58,63–65,68–71,74,78–80,83–85,87–89,91–95,97,99–104,107,108,110,116–118] ranged from under 2 weeks to 16 years. Disability since stroke (n = 39) [7,54–56,58,61,63,65,67–69,71,76,77,79–83,85,89–92,95,96,99,100,102–104,106,108–110,115,117–119] was very variable. Ethnicity, when reported (n = 13), varied between studies [71,76,79,80,82,83,87,88,90,99,103,104,107]. Co-morbidities were seldom mentioned (n = 11) [53,67,73,77,80,86,90,93,99,100,112] nor were medications (n = 3) [7,77,86]. Qualitative data gathering methods: interviews (n = 63) [7,52–74,76–91,94–102,105,107–119]; focus groups (n = 4) [93,103,104,106]; interviews and focus groups (n = 2) [75,92]; additional field notes (n = 5) [69,87,88,111,118]; additional patient observation (n = 1) [95]. Data analysis: a variety of qualitative methods were used, and all sought to identify common themes raised by participants (details are described in Table S4). In one study, method of data analysis was not clear (n = 1) [104]. Inclusion and exclusion criteria, summary of findings, and study limitations are described in Table S4.

Quality Appraisal

A summary of the quality appraisal of included studies is shown in Table 1. Papers were generally of a reasonable quality, and aspects of quality that were most poorly demonstrated included acknowledgment of the researchers' influence on the analysis and any note of conflicts of interest.

Treatment Burden

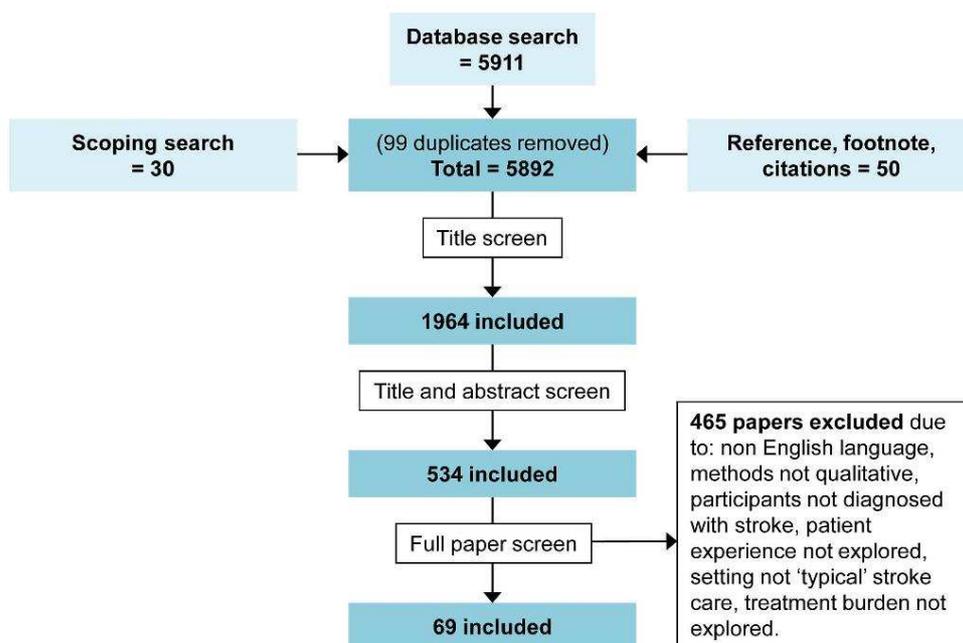
We identified four main areas of treatment burden from the literature: (1) making sense of stroke management and planning care; (2) interacting with others, including health professionals, family, and other stroke patients; (3) enacting management strategies, which includes (a) enduring institutional admissions, (b) managing stroke in the community, (c) reintegrating into society, and (d) adjusting to life after stroke; and (4) reflecting on management. Figure 2 shows a conceptual model of stroke treatment burden. A full taxonomy of treatment burden is shown in Table 2, and a longer version including quotations from included papers is shown in Table S5. No treatment burden was identified that fell outside our coding framework.

1) Making sense of stroke management and planning care. During the management of their stroke, patients are required to comprehend a large amount of information [52,62,65,73,79,95,106]. This is an aspect of treatment burden that commonly arises in the literature. Even before diagnosis has been achieved, patients assess symptoms and make decisions about seeking help [65,92]. They subsequently learn about their diagnosis of stroke, investigations, acute interventions, medications, and risk factor modification [52,62,95,106].

Table 1. A summary of the quality appraisal of included studies [50].

Appraisal Question	Yes	No	Unclear
Does the research, as reported, illuminate the subjective meaning, actions, and context of those being researched?	68	0	1
Are subjective perceptions and experiences treated as knowledge in their own right?	68	0	1
Is there evidence of adaptation and responsiveness of the research design to the circumstances and issues of real-life social settings during the course of the study?	39	27	3
Does the sample produce the type of knowledge necessary to understand the structures and processes within which the individuals or situations are located?	62	3	4
Is the description detailed enough to allow the researcher or reader to interpret the meaning and context of what is being researched?	66	3	0
Are any different sources of knowledge about the same issue compared and contrasted?	38	31	0
Has the researcher rendered transparent the processes by which data were collected, analysed, and presented?	67	2	0
Has the researcher made clear his or her own possible influence on the data?	24	43	2
Is it clear how the research moves from a description of the data, through quotation or examples, to an analysis and interpretation of the meaning and significance of it?	65	4	0
Are claims being made for the generalisability of the findings to either other bodies of knowledge or to other populations or groups?	50	17	2
Is there any other aspect of the study that may affect quality, e.g., conflict of interest?	1	31	37

Each study was appraised using the questions shown in the table. The number of studies with the answers 'yes', 'no', or 'unclear' are shown for each question.
doi:10.1371/journal.pmed.1001473.t001

**Figure 1.** Flowchart demonstrating the screening process of papers in the systematic review. Inclusions and exclusions are shown at each stage.
doi:10.1371/journal.pmed.1001473.g001

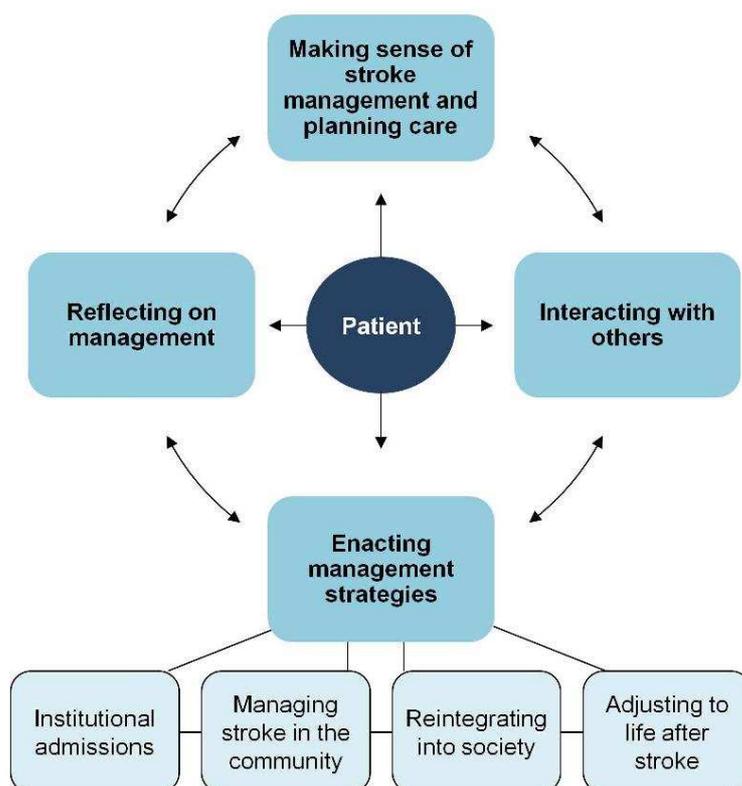


Figure 2. Conceptual model of stroke treatment burden. The arrows represent the possible pathways between components that stroke patients may follow. The 'enacting management strategies' component has four subcomponents. doi:10.1371/journal.pmed.1001473.g002

Patients report that they frequently encounter barriers to receiving information from health services in that the provision of information is lacking, inadequate time is allocated, timing is inappropriate, or information is given in a form that is incomprehensible [7,57,62,76,92,95,96,98–100,119]. One study reports that when asked about their stroke, women are more likely to describe poor information provision from medical staff [62]. Family education also appears to be insufficient, with patients describing how they researched information on behalf of their caregivers due to a lack of available information from health services [106]. The following quotation demonstrates environmental factors described by patients that can prevent the adequate exchange of information:

(Environmental or contextual) characteristics that resulted in shorter interaction time were the presence of other health professionals or significant others in the room, competing needs of another patient, and health professionals being called away. [95]

Patients also reported that access to information following the consultation is insufficient [93], resulting in the need for them to

spend time seeking information themselves [65,93,95,96,99] and attempting to make personal sense of the array of changes that are occurring in their lives [52,72,78,88,95,106,108,111,112].

Patients often have multiple health care providers, as they interact with a variety of services including health and social care. They describe it as challenging to make sense of and to differentiate between the roles of different individuals and services, for example whom to contact for advice once discharged from hospital [76,91,95,112]. A lack of continuity of care for patients and poor communication between services can result in patients receiving conflicting information from different parties, making it harder to understand the necessary processes that promote recovery [7,52,57,67,76,95]:

A few low motivation patients described some of the stroke unit professionals as giving out unhelpful "mixed messages." One patient reported that physiotherapists encouraged her to work at rehabilitation. On returning to the ward, however, she thought the nurses discouraged such effort by putting her to bed. This resulted in confusion regarding the correct way to behave. [76]

Table 2. Treatment burden identified from the literature.

Treatment burden category	Taxonomy
(1) Making sense of stroke management and planning care	Making sense of symptoms to aid diagnosis and seek help
	Understanding investigations, acute interventions, medications, risk factor modification, and medical terminology
	Information gathering from health professionals, enduring poor information provision
	Enduring poor information for carers and families from health services
	Carrying out research external to health services
	Understanding the roles of different health professionals
	Working out priorities for rehabilitation
	Goal setting
	Gaining motivation
	Taking responsibility and using initiative, drawing on former life skills
	Managing uncertainty of prognosis
	Problem solving
	Developing coping strategies
	Experiencing negative emotions associated with management strategy, e.g., guilt, frustration
Using spirituality	
(2) Interacting with others	Seeking advice or reassurance from health professionals
	Contacting health professionals for practical help
	Developing relationships with health professionals
	Coping with paternalism from health professionals
	Enduring a lack of understanding from health professionals
	Coping with mismatched ideas about management and recovery with others
	Misdiagnosis at initial presentation
	Having difficulty accessing services
	Experiencing poor communication between services
	Enduring poor continuity of care and consistency of services
	Arranging social care
	Gaining emotional support from friends and family
	Gaining practical support from family and friends
	Experiencing a strain on relationships due to management strategies
Protecting carers from their burden	
Gaining support from other stroke patients and support groups	
Experiencing stigmatisation due to management of physical disabilities	
3) Enacting management strategies	
(3a) Institutional admissions	Undergoing acute care
	Undergoing inpatient rehabilitation
	Fitting into ward routines
	Loss of autonomy and dignity as an inpatient
	Unfamiliar or unpleasant surroundings on the ward
	Admission to a care home
Learning self-care skills to prepare for discharge	
(3b) Managing stroke in the community	Discharge from hospital
	Poor access to services in the community
	Undergoing rehabilitation programmes in the community
	Taking and managing risks during rehabilitation
	Reaching goals
	Establishing and adhering to a medication regime
	Enduring medication side effects
	Managing risk factors
Adjusting diet	

Table 2. Cont.

Treatment burden category	Taxonomy
	Managing eating difficulties
	Managing psychological difficulties
	Managing pain
	Regaining communication skills
	Taking physical exercise
	Managing co-morbidities
	Adapting the home environment or finding new accommodation
	Enduring inadequate home services
	Coping with multiple health-related appointments
(3c) Reintegrating into society	Returning to driving or negotiating new methods of transport
	Returning to work
	Acquiring mobility and technical aids
	Negotiating environmental barriers to wheelchair use
	Managing financial difficulties
	Negotiating government benefit systems
(3d) Adjusting to life after stroke	New daily structure to accommodate illness management
	Relearning ways of doing familiar tasks
	Planning activities ahead of time
	Adopting strategies to deal with physical disabilities
	Adopting strategies to deal with cognitive disabilities
	Searching for a sense of self
	Developing acceptance
	Enduring a plateau in recovery
	Changing expectations and examining priorities over the recovery period
(4) Reflecting on management	Decision making about treatments
	Shared decision making about treatments
	Monitoring progress in recovery
	Gauging recovery by comparing self to others
	Self monitoring for further signs of stroke
	Maintaining confidence in care plan
	Keeping up to date with new treatments

A taxonomy of treatment burden in stroke, grouped within categories that correspond to the conceptual model of treatment burden shown in Figure 2.
doi:10.1371/journal.pmed.1001473.t002

Several investigators describe the cognitive processing that patients carry out when managing their stroke. They carefully plan their care, make calculated decisions about their contribution to management, prioritise treatments, and set goals for recovery [53,54,58,67,70,74–76,79,81–83,91,92,95–98,100,110]. Personal goals appear to commonly be focussed on reaching a former social status or role within the family [53,54,58,96,101]. One study reports that goal setting varies between men and women, with women focussing on resuming tasks within the home and men concentrating on the accomplishment of tasks outside the home environment [59]. Many patients describe a lack of support from health services for this stage and therefore take responsibility and initiative for their own care, drawing on former life skills to plan and organise their recovery [54,66,83,91,112].

Patients develop expectations of themselves and their health care providers and work at maintaining motivation during the long recovery process [76,91,93,99,104,118]. They slowly learn to cope with uncertainty during recovery [75,93] and problem solve as the need arises [79,92]. Stroke patients report experiencing

emotions associated with stroke management such as frustration at time being taken up by management strategies [68] and guilt at decisions made, for example planning for extended periods of rest during the day [70,74,106]. They develop coping strategies to manage emotion such as the use of relaxation techniques, humour, reasoning, positivity, waiting, altruism, and engaging in meaningful activities that give pleasure [56,66,68,72,78,81,93,96,102,103,107,115,118,119]. Some use spirituality and faith as a method of coping [66,88,89,103,118,119].

2) Interacting with others. Along with making sense of stroke and its management, much effort is allocated to engaging with a range of health professionals both in hospital and in the community for emotional support and practical help [7,57,62,65,74,81,89,92,93,102,106,118]. One study reports that women are more likely to describe the formation of an alliance with health care assistants on the ward, whilst men form alliances with nurses and therapists or other patients [62]. Some patients describe turning to health professionals to validate treatments as appropriate and worthwhile [52], allowing them to take a

paternalistic role by relying on their expertise [7,52,108,111,112]. Others complain about paternalistic care and spend time negotiating with health professionals, preferring a more equal relationship [52,79,92,112]. In one study, men more frequently report trying to exert influence over their care, with women taking a more passive role [62]. Whatever the patient preference, the literature suggests that patients are not adequately consulted about their desires to be involved in decisions about care or about their treatment priorities and goals, and this, along with a lack of information provision, can result in a mismatch in ideas between patients and therapists, leading to frustration for patients [53,81,91,92,96,102,119]:

All participants with aphasia naturally spoke of the importance of recovering their communicative function. They described intense feelings of frustration, hopelessness, isolation, and depression at not being able to talk. Many stressed that the aphasia was often of higher priority to them than their physical impairments which contrasted with health care systems' focus on physical recovery. [96]

Many patients report dissatisfaction in their contact with health professionals, complaining of misdiagnosis at initial presentation of stroke [74] and a lack of time and empathy from therapists [57,58,66,75,79,81,99,102,103,111,118,119]. It appears that poor interactions between patients and health professionals interferes with the development of trusting relationships, which in turn worsens communication and prevents patients gaining the knowledge they need for the recovery process [7,56,57,62,92]. It is perhaps not surprising that communication difficulties with health professionals are a particular issue for aphasic patients [58,96,115] as the following excerpt illustrates:

However, he described with contempt how he initially after the stroke had been observed by his therapists. He demanded to be met through dialogues that gave him relevant conversation, support and stimulation. Certainly, he understood the professionals' way of working, but he found it could be done in a more conversational and descriptive way that involved him as a person. The dialogues with professionals should involve him in what was going to happen in spite of his incapability to understand all that was said. [58]

Patients arrange social care [70,71,110] and describe relying heavily on family members for emotional and practical support when managing their stroke [7,57,59,69,70,77,80,82,83,92,93,100–102,107,110–112,115,118,119]; one study suggests this is particularly the case for women [59]. Aphasic patients describe using carers to help them with their communication [69,102]. Such reliance on others can put a strain on relationships as family and friends display overprotection, paternalism, and a lack of understanding about management strategies, and patients experience feelings of guilt about dependency [63,66,68–71,75,78,80,90,91,103,110,115]. Patients describe attempting to protect family from any carer burdens that they may face, for example by arranging respite care [58,77].

Patients report developing relationships with fellow patients and support groups who provide them with moral support [62,80,90,93,102,104,111,112,115], and whom they compare themselves to in order to gauge recovery or validate treatments [56,64,66,67,69,76,78,80,88–91,103,108]. Two papers report that younger, less disabled stroke patients feel uncomfortable attending therapies and support groups alongside older, more disabled patients to whom they struggle to relate [55,101]. Lastly, enduring

stigmatization from others due to the management of disabilities such as the use of a wheelchair or adapted cutlery was reported as a significant treatment burden by patients [52,56,63,71,74,80,88,99].

3) Enacting management strategies. Enacting work takes many forms and includes the work of enduring institutional admissions, managing stroke in the community, reintegrating into society, and adjusting to life after stroke. We now describe each of these in turn.

3a) Institutional admissions. Stroke patients undergo admission to hospital for acute care [74,108], then undertake extensive inpatient rehabilitation, attending therapists, taking medications, and working arduously to regain lost functions [53,54,57,77,81,82,102,103,108]:

During initial rehabilitation, the major focus is put on regaining the lost functions. The days are structured around training sessions, be they physical therapy, occupational therapy, speech therapy or ADL training. [108]

During the rehabilitation process they adjust to their new physical abilities and learn self-care practices to prepare for discharge [70,81,92,111]. They may then be admitted to a care home if discharge into their own home is not feasible [111,112]. Patients are required to fit into the routines set by institutions [62,95,108] and many describe enduring negative environmental circumstances such as unfamiliarity with various gadgets, long waiting times for personal care, inadequate support during mealtimes from staff, poor quality of hospital food, a lack of stimulating activities, and the loss of autonomy, privacy, and dignity whilst on the ward [71,72,76,81,93,111]. These complaints were similar in the hospital and nursing home setting, with a particular complaint in nursing homes being a lack of autonomy, with care that is regarded as too paternalistic [111,112]:

Care routines, no privacy, time constraints, and lack of familiar activities to perform limit autonomy. [111]

Patients may receive personal care from hospital staff whilst on the ward, and men report finding this harder to endure than women, describing a feeling of vulnerability. They develop strategies to cope with the situation [59]:

Men showed vulnerability. They wished to manage by themselves and felt vulnerable when they had to rely on nursing care that involved bodily care. They seemed to have various strategies for dealing with this situation: to accept it or to take command and say how they wanted to be treated. Men described embarrassment at being naked in front of nurses, and also that nurses were sometimes shy of their nude bodies. By conforming to the role of patient the tension could be eased. [59]

3b) Managing stroke in the community. The transition from inpatient care to the home is an important and often challenging time for patients [70,111,112]. Generally, patients report discharge services as poorly co-ordinated, badly managed, and inadequate for preparing patients for life back in the community [52,70,71,74,82,91,93,111]. Papers from a variety of countries and health care systems describe it as difficult for patients to gain access to advice and services once discharged into the community [52,71,91–93,95,116]:

One man, who was scared because he suffered a lot from unexpected bodily reactions, wanted to get into contact with his doctor.... He coped

with his agony on his own, but he felt abandoned and frustrated. Later on he made the point that attitudes towards handicapped people had changed in general.... He found that he had to struggle with his training and worked at rehabilitation more or less on his own. [52]

One study carried out in Nigeria reported that even physiotherapy services paid for by patients have inadequate equipment available [118]. Another paper from Canada describes how level of disability affects availability of certain services:

Although community gyms denied required help for the moderately disabled Mrs C, her impairments were not considered severe enough to qualify for the gym that (severely disabled) Mrs J was able to access. It was difficult for the participants to determine what criteria were in place in each situation and institution. They often learned what disability level qualified them for services in particular settings by trial and error. [91]

Once home, patients follow routines and integrate management strategies into their everyday lives, for example changing their diet, incorporating physical exercise, and managing risk factors [56,63,67,71,73,80,86,93,104,106]. Patients establish medication regimes and adopt strategies to adhere to these, such as relying on the colours of tablets, using cues as aids, and tying in regimes with daily activities [7]. They endure side effects of medications [7,31]. They undergo community rehabilitation, striving to achieve the goals that have been set for recovery through hard work and determination [54,75,82,89,91,92,102,110]. Patients experience a range of environmental risks due to their disabilities and are required to deal with these on a daily basis [99,92].

Patients are frequently required to acquire equipment and make adaptations to their home to accommodate new disabilities, with one complaint being that new equipment takes up too much space, jeopardising the comfort of their home [68,70,71,77,80,87,88,90]. Some patients are no longer able to mobilise around their current accommodation, yet waiting times for more suitable housing can be long and arduous [80]. Home care services such as personal care and meal delivery services are described as inadequate, with complaints over both the availability and standard of services, for example the same meal being delivered every day due to dietary restrictions [71,80,90].

In this period of time after discharge from inpatient care, the patient schedule is often extremely busy with health care appointments [91,93,108], with patients being required to negotiate numerous therapists [74,77,91,108]. As mentioned earlier, poor knowledge about available services, poor access to care, a lack of continuity, and poor communication between therapists are described as frequent and problematic issues [52,57,67,76,91,92,95]:

Not being given accessibility and continuity pertained to the difficulty of getting in contact with the professionals by telephone and making appointments, delayed appointments with the doctors and physiotherapists, and delays and uncertainties about promised treatments. [57]

Only one paper discusses the difficulties of managing comorbidities alongside stroke, with treatments conflicting with one another and predisposing disabilities interfering with rehabilitation [86].

3c) Reintegrating into society. Once home, patients strive to reintegrate into society. Following their stroke, they are usually prohibited to drive for a set period and may be required to take a

test set by driving authorities [61]. Many feel frustrated and unsupported by health services as they struggle to understand the logic behind the ban and assessment process, which can lead to rebellion against medical and legal advice with the continuation of driving [61,82,100]. Those who can no longer drive are required to negotiate other methods of transport, which can be difficult due to disabilities [80,100]. It is common for patients to aspire to return to work and regain their former social position, yet describe a lack of support and information from health services as well as friends, family, and work colleagues [54,101,107]. They acquire mobility aids for both inside and outside the home, but waiting times can be an issue for the acquisition of such items [77,87,88,90], and some patients describe having to either purchase these themselves or use inappropriate or unsafe aids putting them at risk of falls [80,100]. The use of wheelchairs was celebrated by many as a way back into society, but environmental barriers such as steps, steep slopes, and narrow doorways were commonly mentioned, although these seem to be less of an issue with powered devices [87,88,90,91].

With regards to financial issues, these are likely to vary from country to country depending on the health care system and welfare provision available [120]. Patients in Nigeria and Iran, both developing countries, describe a lack of rehabilitation facilities for those on low incomes, with poor access to care for those who do not have the means to pay for private services [116,118]:

They suffered from having no access to the few existing rehabilitation centres and suffered from low incomes, which made it impossible for them to get such services at their homes. They felt that the government should help them in providing these services as they would then enjoy a better quality of life and escape from physical, emotional and social limitations. [116]

However, patients in developed countries with government funded health care systems also report suffering financially due to the need to purchase special equipment such as mobility aids and adapted cutlery themselves, or relying on low technology devices due to a lack of economic resources [80,90]. Patients in developed countries describe the organizations that assist with the arrangement of financial benefits from government agencies as obstructive, poorly co-ordinated, and confusing to navigate [80,91,101,107]. One paper describes how less disabled patients can be denied government benefits, yet be unable to seek employment due to disabilities [101]. Additionally, a fear of losing financial benefits upon return to work due to the inflexibility of government policies can deter patients from returning to employment [91,107]. One paper gives an example of how conflicting policies can result in significant burden for the patient:

Mr. D...can walk only 100 yards, but he wants to shop independently for groceries. He asked his doctor to prescribe a battery operated scooter. At the state/provincial level, the health system would pay 80% toward an electric wheelchair, but not for a scooter. Mr. D withdrew the funds from his federal level retirement plan. This money was considered income at the federal government revenue level, and the state/provincial level income supports program for the severely handicapped. He lost income supports until he depletes his retirement funds. [91]

3d) Adjusting to life after stroke. Following a stroke, patients create a new daily structure to accommodate their new disabilities and treatments [52,68,96,99,104,108,110]. They re-

learn how to carry out once-familiar tasks [61,64,93,100], and spend extra time planning activities ahead of time [68,88,99] as well as adopting strategies to deal with physical and cognitive disabilities, such as taking periods of rest, learning how to get up from a fall, or creating lists or filing systems [56,58,69,70,75, 83,88,93,99,102,110,115]. Aphasic patients describe using strategies such as carrying communication cards, repeating words, gesturing, and using drawings or technical devices. Some patients, however, found the use of such strategies either inappropriate for their needs or too laborious to use [69].

Following a stroke, patients describe adapting psychologically to their circumstances. They manage this process by searching for a sense of self [64,66,70,78,87,90–92,101,106,110] and developing acceptance. Acceptance plays a huge part in the recovery process, with patients spending much time and effort working towards and achieving acceptance of their new life that has been altered by stroke and its management [68,88,93,99,115]. Patients appear initially to be unprepared for the slow pace of recovery, resulting in great disappointment as they meet with unexpected setbacks or a plateau in progress [58,82,86,92,111,118], but they describe changing their expectations and priorities over the rehabilitation period as they gain experience of their limitations [58,64,68,70,82, 90–92,99,100,107,108,110]:

Accepting adaptation was felt to represent giving up and relinquishing the struggle to get better. Thus the participants experienced a conflict about whether to develop new habits or not because they associated change with becoming dependent on technical aids, environmental adaptations, and other people. In other words, although adaptation and change seemed to be necessary, they also represented abandoning possible improvements and the hope for independence. [68]

4) Reflecting on management. Patients must make decisions about their health care, requiring an appraisal of their treatments, either with the help of health care providers [74,111], or based on their own judgements [7,56,58,65,81,99]. Sometimes decisions are made that deliberately contradict advice given by health professionals [7,54,58,71,99,111,118]. This appears often to be the consequence of a breakdown in communication between patient and health professional, or a lack of understanding on behalf of the patient, although informed patient preference is likely to also play a role:

Discontinuing medication, both prescribed and non-prescription analgesics, was reported by participants in all groups because of insufficient pain relief and side effects or fear of side effects. [56]

Patients commonly reflect on their achievements and self monitor progress to make judgements about their success [64,70,71,75,78,79,82,89,92,104,108,115,118], comparing their recovery to that of other stroke patients [56,64,66,67,76,78, 89,90] and monitoring for further signs of stroke [70,75]. Patients describe the need to maintain a confidence in their care plan [7,66,70,79,82,89], and one paper described patients keeping up to date with newly available treatments by asking health professionals for information [62].

Discussion

To the best of our knowledge, this is the first qualitative systematic review to explore treatment burden in stroke. None of the included papers comprehensively covered the entire patient experience of treatment burden; rather each one explored in depth

a particular aspect of management or the patient experience in a specific context. Therefore, this review offers a comprehensive taxonomy and conceptual model of treatment burden in stroke. Using this taxonomy, we have been able to examine relationships between components of treatment burden and theorize causal processes. In turn, we shall now make recommendations about areas of health care provision requiring attention from clinicians and policy makers, and areas where further research is required.

A key finding from this review is that stroke patients spend substantial time and effort seeking out, cognitively processing, and reflecting on information about the management of stroke. There is also evidence that the provision of this information by health services is currently inadequate on a global basis. This resonates with previous literature on treatment burden in heart failure patients [2,49]. It is clear that (1) access to information is poor, (2) time given for the exchange of information is inadequate, (3) the information given is not easily understood by patients and is not tailored to suit their needs, and (4) information is often given at times when patients are not able to process it. These four factors result in patients feeling poorly informed and consequently expending time and energy on researching their stroke management. Both communication during the clinical encounter and provision of information to patients must be improved by health services, as patients' understanding of the rationale behind therapies and their trust in management plans is pertinent to achieving optimum adherence [7]. Knowledge deficits mean patients are ill equipped to plan and organise their care, to develop coping strategies, and to set goals for recovery. The clinical implications of this knowledge deficit require further exploration. A recent Cochrane Review concluded that improved information provision to stroke patients showed no improvement in health-related behaviours, health service usage, or mortality. However, the review did demonstrate an improvement in patient knowledge (which could arguably lead to more informed decision making), increased patient satisfaction, and a small reduction in depression. It also suggested that interventions that actively involve the patient and carers with planned follow-up for reinforcement had a better effect on mood. The authors concluded that the best way to provide information is still unclear, and this needs further investigation [121]. We hypothesise that improved information provision as part of a more comprehensive intervention to decrease treatment burden on a wider level may be more effective, and this should be explored through both quantitative and qualitative research.

In addition to poor provision of information by health services, the exchange of information between patient and professional generally appears to be substandard, resulting in a mismatch in ideas regarding goals and care preferences. This leads to patient dissatisfaction, a prerequisite for nonadherence to subsequent management plans, as confidence and motivation are negatively affected [7]. It is therefore vital that health professionals spend time with patients to gauge their care preferences. Previous research has shown that during the consultation, patients are not always forthcoming with their own agendas [122]; therefore, eliciting their ideas, concerns, and expectations is an important skill on the part of the health professional, and one that requires to be learned and practiced. Additionally, busy clinics and ward rounds can bestow time constraints that hinder communication. Research aimed at improving communication must therefore include both patients and health professionals at the consultation level to achieve pragmatic interventions. Health service reconfiguration must prioritise enhanced communication between clinician and patient, with outcomes such as treatment burden, patient satisfaction, treatment adherence, and mortality being monitored.

The organisation of services at both macro and micro levels appears to significantly affect treatment burden. The papers in this review describe interactions between stroke patients and a variety of professionals including hospital doctors, nurses, general practitioners, speech and language therapists, physiotherapists, occupational therapists, and social workers. Because of the long-term nature of stroke rehabilitation, patients describe the importance of developing relationships with their therapists, but this is made difficult by poor continuity of care, in both the hospital and acute setting. Patients describe receiving 'mixed messages' from different carers who do not communicate with one another. Health professionals must establish good methods of communication with each other and provide individualised, holistic, patient-centred care. If case meetings cannot be carried out face to face then adequate secure methods of communication such as clinical email systems must be utilised.

These findings appear to resonate across various countries in our review; however, issues such as poor continuity of care are likely to depend on organisation of health care systems, which may vary substantially between countries and localities. Some services, for example, are available through government funded initiatives and others require payment at point of care, and the standard of these services are likely to vary considerably [120]. It would therefore be pertinent for future research to examine differences in stroke care provision between localities and any resultant effects on treatment burden. Research can then inform changes to practice and policy at a local level. Additionally, the use of certain technologies may be less available in low-income countries, so guidelines must take account of this.

Attending and planning appointments takes considerable time and effort from the patient, made all the more difficult by poorly organised, fragmented services. Patients are also required to manage often complicated medication regimes and endure any side effects. In westernised countries, patient care has moved away from being patient centred with subspecialisation of therapies and a focus on therapist- rather than patient-set goals [53]. As well as having an effect on treatment burden due to sheer volume of appointments and medications, therapies can contradict or interfere with each other and cause difficulties for patients. This is particularly relevant for stroke patients with multimorbidity who additionally have other treatment regimes to deal with simultaneously [123]. Any measurement of treatment burden developed must be able to take account of multimorbidity to truly reflect the burden experienced by patients. Appointments should be allocated in consultation with the patient as much as possible, with evidence-based strategies such as reminder systems being utilised to improve attendance [124].

Another important treatment burden relates specifically to hospitalisation experiences. The hospital stay itself is frequently described by patients as unpleasant, with a lack of autonomy over treatments and loss of control over daily routines. Again, this is likely to vary significantly between localities. In this review, stroke patients describe spending long periods of time on rehabilitation wards feeling understimulated and bored. Younger patients describe a lack of tailoring of rehabilitation services to suit their needs. Such issues should be addressed by health care providers, particularly as initial results of recent randomised control trials have shown improved functional recovery associated with very early mobilisation following stroke [125,126]. Improved communication between staff and patients would allow for patient autonomy, and recreational activities or time off the ward should be available to patients, in order to boost morale and maintain motivation.

In the community, social care systems such as home helps and meal delivery systems are described as being of a very poor

standard by patients, for example providing a very narrow range of food at inconvenient times of day. The provision of personal care such as help with showering also appears to be lacking. Improvements to these services are vital for adequate patient care as they provide the fundamental aspects of human functioning. Further qualitative work is required to explore these services in different localities, as information concerning this was limited within this review.

Patients describe having difficulty accessing care both as an inpatient and in the community. This resonates across both developed and developing countries in our review. Patients feel that time with therapists is too short, mirroring the lack of time spent imparting information as discussed above. Clinicians must ensure that time is available for consultations with patients. Although this may cost health services money in the short term, it will prevent nonadherence and therefore wasted expenditure in the longer term [127].

Discharge from hospital is described as a particularly difficult time for patients, with a sense of abandonment without adequate preparation. Patients feel that services are terminated prematurely, and they feel uncertain whom to contact should they need help and advice. This is a very important step in the recovery process, and discharge should be timed appropriately so that services are in place and patients are armed with the appropriate information. Disabled patients need to acquire technical aids and make adaptations to the house, or to move to more appropriate accommodation, and should be supported as much as possible during this time. A point of continuous contact such as a stroke liaison nurse can improve patient satisfaction and support the process of discharge and community rehabilitation [128]. Reintegrating into society, regaining driving ability, and employment are important steps in recovery, and patients need access to appropriate services for support.

Financial difficulties due to stroke management seemed to arise for patients in both developing and developed countries, although only two papers from developing countries were found, so this requires further exploration. In the developing countries, access to care appears to depend on the ability to self-fund therapies, whilst in countries with universal health care access, difficulties can arise when negotiating complicated systems; patients also often self-fund as a result of this.

Several papers discussed the psychological difficulties patients encounter during the recovery process, yet access to psychological therapy seems to be scarce. Patients describe spending time reflecting on their progress, adjusting to their new circumstances, and maintaining motivation. Better access to counselling or psychology services is therefore pertinent for stroke patients.

Two studies made gender comparisons of the patient experience of managing stroke [59,62], but little information was provided to allow comparisons based on other patient characteristics such as age, ethnicity, and socio-economic deprivation. Differences, if any, associated with such patient characteristics should be considered further, especially in relation to the development of any patient-reported outcome measure of treatment burden.

For the first time, our study approaches the management of stroke as a global set of practices carried out by patients in multiple contexts. The extent of treatment burden can be affected not only by the nature of illness but also by the micro- and macro-organisation of health services. We hypothesise that the components of treatment burden can amalgamate [12], and if treatment burden exceeds patient capacity, then nonadherence may occur [1], a problem in chronic disease management well recognised by the World Health Organisation but not yet fully understood [13]. We therefore propose that to improve patient adherence, we must

address the organisation and delivery of health services to minimise burden on patients.

Aspects of Treatment Burden Missing from the Literature

Certain aspects of stroke management were mentioned less often than anticipated: the process of acute care, medications, social care, the stroke liaison nurse, and the use of new technologies. Only one study addressed multimorbidity [36], although it is known that patients with stroke often suffer from multiple morbidities [129], each with its own management plan and demands that may interfere with one another. Further primary studies are required that explore these aspects of stroke management and the treatment burden that may arise for patients.

How This fits In with Current Knowledge

In comparison to our recent work on treatment burden in heart failure patients, there was less information available on the burden of medications, particularly polypharmacy, side effects, collecting prescriptions, altering routines as required, and drug interactions [2,49]. More emphasis was placed by stroke patients on the development of coping strategies and goals for rehabilitation, and on adjusting to life after the illness has presented. These changes may be due to differences in methodologies, or they may reflect the differences in onset and management of these two chronic diseases.

However, one important similarity between this review and previous work with heart failure patients is that the care of patients with both chronic diseases is very sensitive to investments in service provision. Shifts from intensive care environments, such as rehabilitation centres, to self-help and community-based services may fundamentally change the burden of treatment from professionals to patients and caregivers. As our review documents, patients and caregivers are already burdened and perceive they gain inadequate support from health care services. Further work toward understanding how policy changes in health care affect the balance of burden and capacity for patients and caregivers is essential to assess these dynamic interactions.

A recent systematic review explored the conceptualization of treatment burden in chronic disease. This review examined attributes, antecedents, and consequences of treatment burden [130] but differs to ours in that most studies included were quantitative and cover a wide range of chronic diseases without differentiating between these in the results. An interesting overview of the concepts of treatment burden is therefore described, rather than a deeper exploration into disease-specific aspects of treatment burden.

A recent paper by Eton et al [3] created a conceptual framework of treatment burden in patients with complex chronic disease that resonates highly with our results. Eton et al. carried out their study in the US where patients are required to negotiate with insurers and face financial challenges that are perhaps more profound than in countries with a universal health care system. The financial implications of chronic disease management for patients in differing countries appear to be poorly examined elsewhere in the literature, and this requires further exploration.

Another recent paper, by Tran et al. [4], sought to develop a method of measurement of treatment burden in multimorbid patients. Although there were many similarities to our results, two differences to highlight are that the measurement developed did not include information on making sense of treatments, as acknowledged by the authors, and the impact of health care organisation was not explicitly explored. Medication side effects were not included in the instrument because of the conceptual nature of the study, and financial implications did not arise in patient interviews, because of the universal health care system in France where the study was conducted.

Limitations/Strengths

The search was limited to publications from the year 2000 and onwards. This date was chosen because our review is aimed at understanding current, rather than historical, patient experiences of stroke in order to inform current clinical practice and policy. Global management of stroke has changed in recent years with the introduction of stroke units and community rehabilitation programmes [120,131], and hence we believe this to be justifiable, but appreciate that it could be viewed as a limitation. We restricted our search to English-language papers, but no geographical restriction was set, and our review includes papers from a variety of countries. However, the language restriction may have imposed a degree of geographical restriction, and there was a paucity of data from low-income countries. The exclusion of methodologies such as telephone and postal questionnaires could be regarded as a limitation, as some studies exploring treatment burden may have used these methods. Similarly, grey literature was excluded to manage the scope of the review.

Important strengths of our review are that we conducted an exhaustive search and our tight inclusion criteria allowed us to avoid collecting too broad a spectrum of methodologies, as high numbers of studies using extremely varied methods made in-depth analysis of the data and applicability of findings extremely challenging. Our approach helped us to maintain focus whilst producing a rich picture of stroke management. As a result, the number of studies included was considerable yet still feasible for the application of qualitative analysis. Finally, a particularly novel aspect of this review was our approach to data analysis using a coding framework underpinned by a robust theory, NPT. The use of framework synthesis [42] was appropriate as we had a preconceived research objective based on our knowledge of the literature and clinical experience, yet this method ensured that our results arose directly from the data. We found this approach highly pragmatic and useful, as have others, [44,132] and believe it enhanced transparency of coding. While the suppression of interpretive creativity [133] is a potential risk, we attempted to minimise this by paying close attention to any data that may have fallen outside the framework, and iteratively adapting the framework during analysis to ensure that analysis was somewhat inductive [42]. We found this novel method of data analysis very useful for identifying the components of treatment burden in stroke from the patient perspective, and did not find any aspects of treatment burden that fell outside this framework.

The large variation in research objectives of included studies means that a diverse range of treatment burdens are described. A major advantage to our review is that it pieces together information about treatment burden from various sources to create a more comprehensive picture than is usual for this type of study. However, one limitation is that the papers and therefore participants studied were heterogeneous, making comparisons between papers difficult, for example to compare papers from different countries. It is likely that there is significant variation in health system delivery between countries, including availability of services through state-sponsored insurance.

Both severity of stroke and level of disability are likely to influence treatment burden, yet both are generally poorly described in the included papers, and those that do describe them use varying measures and terminology. It could be argued that the most physically and mentally impaired may be the most burdened and the least likely to participate in research, a common problem in the research arena. For example, the papers that study aphasic patients describe a particular difficulty for these patients in communicating with therapists and carers, a perhaps unsurprising but important finding [58,96,115]. The

inclusion of papers that study aphasic patients and wheelchair users is almost certainly a strength of our review [58,87,88,96,115], but there is likely to be an over-representation of able-bodied patients. Time since diagnosis is also likely to influence treatment burden, as patients adjust to their condition and the process of rehabilitation. Interestingly, our quality appraisal instrument did not judge quality based on the detailed provision of patient characteristics. During appraisal, judgements were made about whether the sample was appropriate for the research objectives of that individual study, and if authors assessed generalisability accurately. In the qualitative research arena, focussing on these factors tends to be more pertinent than producing work that is generalisable to other populations, one argument made by those against qualitative syntheses [134]. We believe, however, that with transparency in reporting about generalisability, qualitative synthesis is invaluable for informing clinical practice and health policy.

Conclusion

We have created a comprehensive taxonomy of treatment burden underpinned by international research which has the potential to drive service improvement. The aim of this review is not to produce a taxonomy that is universally generalisable, but one that gives insight into the scope of burdens experienced by patients and can inform the development of measures and interventions. Our taxonomy suggests that treatment burden in stroke can be broadly categorised into: (1) making sense of stroke management and planning care, (2) interacting with others, (3) enacting management strategies, and 4) reflecting on management. Patients describe care as fragmented and lacking in continuity, with poor communication between patient and clinician and between health care providers. Information provision is generally poor, and patients would like clinicians to spend more time with them. There is considerable room for improvement in both inpatient and community services.

Treatment burden appears to be greatly affected by the micro and macro organisation of health services, which is likely to vary considerably between localities. Further work is recommended to better understand the patient experience of treatment burden in stroke in varying contexts and to explore how it may vary by patient demographic or clinical characteristics. Treatment burden should be investigated in relation to other chronic diseases, and importantly in patients with multiple morbidities. This could inform the generation of a patient-reported outcome measure to be utilised by both policy makers and health care providers, and could serve as a new goal for quality improvement.

Supporting Information

Figure S1 PRISMA flowchart.
(DOC)

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Table S1 Inclusion and exclusion criteria for papers. The inclusion and exclusion criteria used during the screening process.
(DOC)

Table S2 Coding framework informed by Normalization Process Theory. The framework used to code data from each included paper.
(DOCX)

Table S3 Participant details. Details of participants in each included study.
(XLSX)

Table S4 Study methods and results. Details of research methods and results for each included study.
(XLSX)

Table S5 Taxonomy of treatment burden with exemplar quotations. A taxonomy of treatment burden in stroke as shown in Table 2, with the addition of examples of quotations from included studies.
(DOC)

Text S1 Search strategy. Details of the strategies employed for searching Medline, Embase, PsycINFO, CINAHL, and Scopus databases.
(DOC)

Text S2 PRISMA statement.
(DOC)

Acknowledgments

The authors are members of the International Minimally Disruptive Medicine Workgroup (Frances S Mair, Carl R May, Victor M Montori, Katie Gallacher, Sara Macdonald, David T Eron, Nathan Shippee, Deborah Morrison, Bhautesh Jani, Susan Browne, David Blane, Nilay Shah, Patricia Erwin, Kathleen Yost, Alison Richardson, and Sara Demain) and would like to thank the other members for their conceptual assistance.

We would like to thank Jane Goodfellow for her assistance in the design of Figures 1 and 2, and the following for their assistance with the screening and data extraction process: Alastair Rankin, Jennifer Maxwell, Andrew Leitch, Louise Bradshaw, Nikole Runciman, Sylvia Kanya, Aishah Coyte, Yasmin Grant, Ahad Jan, Colette Kenman, Jamie Hooker, Megan Harwood, Patrick Collins.

Author Contributions

Conceived and designed the experiments: KG DM BJ SM CRM VMM PJE GDB DTE PL FSM. Analyzed the data: KG DM BJ SM CRM VMM FSM. Contributed reagents/materials/analysis tools: KG CRM VMM FSM. Wrote the first draft of the manuscript: KG FSM. Contributed to the writing of the manuscript: KG DM BJ SM CRM VMM PJE GDB DTE PL FSM. ICMJE criteria for authorship read and met: KG DM BJ SM CRM VMM PJE GDB DTE PL FSM. Agree with manuscript results and conclusions: KG DM BJ SM CRM VMM PJE GDB DTE PL FSM. Designed the search strategy: PJE.

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Editors' Summary

Background. Every year, 15 million people have a stroke. About 5 million of these people die within a few days, and another 5 million are left disabled. Stroke occurs when the blood supply of the brain is suddenly interrupted by a blood vessel in the brain being blocked by a blood clot (ischemic stroke) or bursting (hemorrhagic stroke). Deprived of the oxygen normally carried to them by the blood, the brain cells near the blockage die. The symptoms of stroke depend on which part of the brain is damaged but include sudden weakness or paralysis along one side of the body, vision loss in one or both eyes, and confusion or trouble speaking or understanding speech. Anyone experiencing these symptoms should seek immediate medical attention because prompt treatment can limit the damage to the brain. In the longer term, post-stroke rehabilitation can help individuals overcome the physical disabilities caused by stroke, and drugs that thin the blood, reduce blood pressure and reduce cholesterol (major risk factors for stroke) alongside behavioral counseling can reduce the risk of a second stroke.

Why Was This Study Done? Treatment for, and rehabilitation from, stroke is a lengthy process that requires considerable personal investment from the patient. The term "treatment burden" describes the self-care practices that patients with stroke and other chronic diseases must perform to follow the complicated management strategies that have been developed for these conditions. Unfortunately, treatment burden can overwhelm patients. They may be unable to cope with the multiple demands placed on them by health-care providers and systems for their self-care, a situation that leads to poor adherence to therapies and poor outcomes. For example, patients may find it hard to complete all the exercises designed to help them regain full movement of their limbs after a stroke. Treatment burden has been poorly examined in relation to stroke. Here, the researchers identify and describe the treatment burden in stroke by undertaking a systematic review (a study that uses predefined criteria to identify all the literature on a given topic) of qualitative studies on the patient experience of stroke management. Qualitative studies collect non-quantitative data so, for example, a qualitative study on stroke treatment might ask people how the treatment made them feel whereas a quantitative study might compare clinical outcomes between those receiving and not receiving the treatment.

What Did the Researchers Do and Find? The researchers identified 69 qualitative studies dealing with the experiences of stroke management of adult patients and analyzed the data in these papers using framework synthesis—an approach that divides data into thematic categories. Specifically, the researchers used a coding framework informed by normalization process theory, a sociological theory of the implementation, embedding and integration of tasks and practices; embedding is the process of making tasks and practices a routine part of everyday life and integration refers to sustaining these embedded practices. The researchers identified four main areas of treatment burden for stroke: making sense of stroke management and planning care; interacting with others, including health care professionals,

family and other patients with stroke; enacting management strategies (including enduring institutional admissions, managing stroke in the community, reintegrating into society and adjusting to life after stroke); and reflecting on management to make decisions about self-care. Moreover, they identified problems in all these areas, including inadequate provision of information, poor communication with health-care providers, and unsatisfactory inpatient care.

What Do These Findings Mean? These findings show that stroke management is extremely demanding for patients and is influenced by both the micro and macro organization of health services. At the micro organizational level, fragmented care and poor communication between patients and clinicians and between health-care providers can mean patients are ill equipped to organize their care and develop coping strategies, which makes adherence to management strategies less likely. At the macro organizational level, it can be hard for patients to obtain the practical and financial help they need to manage their stroke in the community. Overall, these findings suggest that care provision for stroke needs to be transformed so that the needs of patients rather than the needs of health-care systems are prioritized. Further work is required, however, to understand how the patient experience of treatment burden is affected by the clinical characteristics of stroke, by disability level, and by other co-existing diseases. By undertaking such work, it should be possible to generate a patient-reported outcome measure of treatment burden that, if used by policy makers and health-care providers, has the potential to improve the quality of stroke care.

Additional Information. Please access these Web sites via the online version of this summary at <http://dx.doi.org/10.1371/journal.pmed.1001473>.

- The US National Institute of Neurological Disorders and Stroke provides information about all aspects of stroke (in English and Spanish); its Know Stroke site provides educational materials about stroke prevention, treatment, and rehabilitation including personal stories (in English and Spanish); the US National Institutes of Health SeniorHealth website has additional information about stroke
- The Internet Stroke Center provides detailed information about stroke for patients, families, and health professionals (in English and Spanish)
- The UK National Health Service Choices website also provides information about stroke for patients and their families, including personal stories
- MedlinePlus has links to additional resources about stroke (in English and Spanish)
- The UK not-for-profit website Healthtalkonline provides personal stories about stroke
- Wikipedia provides information on the burden of treatment and on the normalization process theory (note: Wikipedia is a free online encyclopedia that anyone can edit; available in several languages)

Appendix 9 - Ethical approval for analysis of PCCIU data

NHS Grampian
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Research Ethics Committees

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Professor P Hannaford
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Dear Professor Hannaford

DATASETS HELD BY PRIMARY CARE CLINICAL INFORMATICS UNIT – RESEARCH

Thank you for your letter of 4th February 2005 in which you confirm that your dataset does not include the names nor addresses of patients. I also understand that it does not include their CHI number nor the day of the month of their birth, and their postcode is limited to sector level.

On that basis, I agree that ethics approval is not required for each use of the dataset.

If peculiar situations arise which makes you think that for a particular study our opinion would be useful, then we will happily oblige.

Kind regards

Yours sincerely

Irene Allan

Dr Melvin Morrison
Chair
Grampian Research Ethics Committee (1)

Appendix 10 - QOF business rule codeset

Code	Definition
G61	Intracerebral haemorrhage (excluding G617 intraventricular haemorrhage)
G63y0	Cerebral infarct/thrombosis/precerebral artery
G63y	Cerebral infarct /embolism/ precerebral artery
G66	Stroke/CVA unspecified (excluding G669 cerebral palsy non congenital/infant acquired)
G6	Cerebral arterial occlusion
G6760	Cerebral infarct/cerebral venous thrombosis ,nonpyogenic
G6W	Cerebral infarct ,unspecified occlusion or stenosis of precerebral artery
Gyu63	[X]Cerebral infarct, unspecified occlusion or stenosis of cerebral artery
Gyu64	[X]Other cerebral infarction
Gyu65	[X]Occlusion and stenosis of other precerebral arteries
Gyu66	[X] Occlusion and stenosis of other cerebral arteries
Gyu6F	[X]Intracerebral haemorrhage in hemisphere, unspecified
Gyu6G	[X] Cerebral infarct ,unspecified occlusion or stenosis of precerebral artery

Appendix 11 - Published paper from the observational study

Gallacher et al. *BMC Medicine* 2014, **12**:151
<http://www.biomedcentral.com/1741-7015/12/151>



RESEARCH ARTICLE

Open Access

Stroke, multimorbidity and polypharmacy in a nationally representative sample of 1,424,378 patients in Scotland: implications for treatment burden

Katie I Gallacher¹, G David Batty^{2,3}, Gary McLean¹, Stewart W Mercer¹, Bruce Guthrie⁴, Carl R May⁵, Peter Langhorne⁶ and Frances S Mair^{1*}

Abstract

Background: The prevalence of multimorbidity (the presence of two or more long-term conditions) is rising internationally. Multimorbidity affects patients by increasing their burden of symptoms, but is also likely to increase the self-care demands, or treatment burden, that they experience. Treatment burden refers to the effort expended in operationalising treatments, navigating healthcare systems and managing relations with healthcare providers. This is an important problem for people with chronic illness such as stroke. Polypharmacy is an important marker of both multimorbidity and burden of treatment. In this study, we examined the prevalence of multimorbidity and polypharmacy in a large, nationally representative population of primary care patients with and without stroke, adjusting for age, sex and deprivation.

Methods: A cross-sectional study of 1,424,378 participants aged 18 years and over, from 314 primary care practices in Scotland that were known to be demographically representative of the Scottish adult population. Data included information on the presence of stroke and another 39 long-term conditions, plus prescriptions for regular medications.

Results: In total, 35,690 people (2.5%) had a diagnosis of stroke. Of the 39 comorbidities examined, 35 were significantly more common in people with stroke. Of the people with a stroke, the proportion that had one or more additional morbidities present (94.2%) was almost twice that in the control group (48%) (odds ratio (OR) adjusted for age, sex and socioeconomic deprivation 5.18; 95% confidence interval (CI) 4.95 to 5.43). In the stroke group, 12.6% had a record of 11 or more repeat prescriptions compared with only 1.5% of the control group (OR adjusted for age, sex, deprivation and morbidity count 15.84; 95% CI 14.86 to 16.88). Limitations include the use of data collected for clinical rather than research purposes, a lack of consensus in the literature on the definition of certain long-term conditions, and the absence of statistical weighting in the measurement of multimorbidity, although the latter was deemed suitable for descriptive analyses.

Conclusions: Multimorbidity and polypharmacy were strikingly more common in those with a diagnosis of stroke compared with those without. This has important implications for clinical guidelines and the design of health services.

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Background

Multimorbidity, defined as the presence of two or more long-term conditions, is becoming a global challenge for policy-makers, clinicians, and patients [1-3]. Treatment advances and increasing sub-specialisation of health services have improved functional outcomes for those with long-term conditions, but such changes have resulted in an increasing burden of treatment demands on patients, particularly those with multimorbidity [3,4]. Treatment burden is defined as the workload of healthcare for patients and the impact of this on their wellbeing [5]. It includes information gathering, attending multiple appointments, taking medications, enacting self-care, and, in countries that lack a health service that is free at the point of care, organising finances to pay for treatments [5-8]. There is a risk that patients become overburdened by their treatments, which can mean failure to adhere to management plans, thus resulting in ineffective treatment and wasted resources [3,9-11].

One aspect of treatment burden described above is polypharmacy, which can contribute to other treatment burdens such as adverse drug events [12,13]. Polypharmacy is most commonly defined as the use of multiple (usually five or ten) prescribed medications [14-16]. Although there is no strong evidence to support the use of any particular threshold, the risk of drug-related problems seems to increase with each additional medication prescribed [17,18]. There is a known association between number of morbidities and polypharmacy [19-21], with a study using routine Scottish health records finding that of those with two clinical conditions, 20.8% were receiving four to nine medications, and 1.1% were receiving ten or more medications; for patients with six or more comorbidities, these values were 47.7% and 41.7%, respectively [19]. A systematic literature review investigating the relationship between the number of chronic conditions and healthcare utilisation outcomes found that about 60% of elderly respondents with zero or one condition reported taking prescription medications. This percentage went up to more than 90% for those with two or three conditions, and approached 100% for those with more than five conditions [20], supporting the premise that those with higher numbers of conditions to manage are more likely to experience higher levels of treatment burden [3]. Other aspects of treatment burden such as healthcare utilisation have also been shown to be associated with multimorbidity [20,22].

Stroke is a condition that can have a considerable impact on an individual's life. A recent systematic review of the qualitative literature revealed that people who have had a stroke experience four main areas of treatment burden: making sense of stroke management and planning care, interacting with others, enacting management strategies, and reflecting on management

[23]. Poor communication between patients and professionals was a common experience, exacerbated by fragmentation of health services and poor communication between healthcare providers themselves, aspects of stroke care likely to be exacerbated by multimorbidity [24-26]. Surprisingly, there has been limited exploration of multimorbidity or polypharmacy in people with stroke, the field being characterised by small-scale studies and a small number of conditions under examination [19,27-36]. Those studies that have examined stroke in relation to other long-term conditions have suggested that stroke is one of the diseases most significantly associated with polypharmacy [19,33], but there is a lack of large-scale studies examining a broad range of medications and comorbidities.

In the current study, using a large, nationally representative cross-sectional primary care dataset, we examined the prevalence of multimorbidity and polypharmacy in people with and without stroke.

Methods

Study design and participants

This was a cross-sectional study based on a nationally representative dataset managed by the Primary Care Clinical Informatics Unit at the University of Aberdeen in Scotland. This fully anonymised dataset contains clinical data on all people that were alive and permanently registered with 314 primary care practices in Scotland on 31 March 2007. Comprising approximately one-third of the Scottish adult population, this sample has been shown to be representative of this population [37]. In the UK, registration with a medical practice is required for an individual to access National Health Service (NHS) healthcare in the community. It is estimated that over 98% of the population are registered with a medical practice [38], which systematically records information on each patient in an electronic medical record, for the purposes of registration and subsequent everyday medical care. We examined data extracted from medical records and collated for a previous study of multimorbidity that had examined the presence of forty conditions [1]. The NHS National Research Ethics Service approved the use of these data for research purposes. Patient consent was not deemed necessary due to full anonymisation of the data.

Data collected and disease definition

The data examined consisted of the following variables: sex, age, socioeconomic deprivation (measured from patients' postcodes using the Carstairs score [39]), counts of regularly prescribed medications and the presence of 40 long-term conditions, including stroke.

There is no 'gold standard' method for the measurement of multimorbidity, therefore the forty long-term conditions included had been chosen and defined based on a recent systematic review [40] and expert consensus

[1]. Existing definitions for each long-term condition were used if possible, mainly those used in the Quality and Outcomes Framework (QOF) or by NHS Scotland [1,41,42]. If no standard definition was available, or there was concern about under-recording, then conditions were defined by the clinical members of the research team. For example, depression was defined as the presence of a QOF Read Code in the past year or receipt of four or more prescriptions for antidepressant drugs (excluding low-dose tricyclics, which are usually used for chronic pain) in the past year [1]. The definitions of all morbidities examined are given in supplementary material (see Additional file 1). Comorbidity was measured using a count of long-term conditions [43], with morbidities being noted as either mental health or physical morbidities. The original analysis measured the presence of a combined group of stroke or transient ischaemic attack (TIA), but for the purposes of this analysis, the presence of stroke alone was defined using the QOF Business Rules code set [41], and TIA was ignored.

As there are no standard definitions of regularly prescribed treatments or measure of polypharmacy, we utilised a count of current regular prescriptions, including tablets, inhalers, stoma care and topical therapies [17,18]. Regular ('repeat') prescriptions are clearly distinguished in UK general practice electronic medical records from one-off ('acute') prescriptions such as those for most antibiotics. For the purposes of this analysis, any regular prescription that was still active (that is, available for issue on request) on the date of extraction and that had been prescribed in the past 84 days was counted as current. This time frame was selected as this was the maximum length of a repeat prescription in Scotland at the time of data collection.

Statistical analysis

Analyses were predicated on a comparison of the characteristics of people with stroke (cases) and those without stroke (controls). First, the numbers of morbidities and prescribed medications in stroke cases and controls were calculated, and proportions within each group computed. Second, logistic regression, which produces ORs, was used to summarise the relationship between stroke and the presence of comorbidities and prescribed medications. ORs were initially unadjusted – for the purposes of comparison – then adjusted for the key confounding factors of age, sex and socioeconomic deprivation. Age and deprivation were used as continuous variables. Deprivation was measured using the Carstairs score, which is widely used in health research. The Carstairs score is based on four census indicators: low social class, lack of car ownership, overcrowding and male unemployment. The scores have been described as a measure that reflects access to 'those goods and services,

resources and amenities and of a physical environment which are customary in society' [39]. The scores therefore cannot be described as a measure of the extent of an individual's material wellbeing, but are rather a summary measure applied to populations contained within small geographic localities. Further adjustment for number of morbidities was made when polypharmacy was the characteristic of interest. Associations between numbers of morbidities and prescriptions were assessed using Spearman correlation coefficients. For the purposes of this analysis, a $P < 0.05$ was deemed statistically significant. All analyses were carried out using IBM Statistical Package for the Social Sciences (SPSS) Statistics software (V21).

Results

The analyses were based on 1,424,378 individuals (724,949 women) aged 18 years and over who were registered with a general practitioner. In total, 35,690 people (2.5%) had a diagnosis of stroke. As anticipated, the mean age of people in the stroke group (72.68 ± 12.21) was higher than that of the controls (47.36 ± 17.93). For the demographic characteristics for each group, see Additional file 2.

Comorbidities

Table 1 shows the number and percent of total morbidities, physical morbidities and mental health morbidities in the stroke and control groups, along with ORs for stroke in relation to these variables. Multimorbidity was common in stroke: of the study members with stroke, the percentage that had one or more additional morbidities present (94.2%) was almost twice that in the control group (48%) (OR adjusted for age, sex and deprivation 5.18; 95% CI 4.95 to 5.43). Disaggregating the data into type of morbidity revealed that physical morbidity was markedly more common in people with stroke (adjusted OR 4.50; 95% CI 4.31 to 4.68), and mental health morbidity was also more common but the relationship was less strong (adjusted OR 2.10; 95% CI 2.05 to 2.15). In terms of assessing whether these differences exist across different age groups, a sub-analysis for age groups 35–44 years and 75+ years was performed (see Additional file 3). This indicated that differences were larger for the younger age group, and increased with the number of conditions (a similar picture was found for number of repeat prescriptions). However, the skewed distribution of stroke prevalence towards the oldest age groups make any assessment of differences by age problematic, owing to the small sample sizes in the youngest age groups.

The ten most frequent comorbidities present in people with a diagnosis of stroke were: hypertension (60.9%), coronary heart disease (29.5%), painful condition (21.9%), depression (20.7%), diabetes (18.8%), chronic kidney disease (14.3%), constipation (13.8%), atrial fibrillation (13.0%), thyroid disorders (11.9%), and chronic obstructive pulmonary

Table 1 Stroke status and number of morbidities (N = 1,424,378)

	Stroke N (%) 35690 (100)	No stroke (%) 1388688 (100)	Unadjusted OR (95% CI) ^a	Age, gender and deprivation adjusted OR (95% CI) ^a
Total number of morbidities ^b				
None	2053 (5.8)	721430 (52.0)	1	1
One-three	17750 (49.7)	551295 (39.7)	11.31 (10.81 to 11.85)	4.35 (4.15 to 4.56)
Four-six	12300 (34.5)	100500 (7.2)	43.01 (41.03 to 45.09)	8.59 (8.17 to 9.04)
Seven or more	3587 (10.1)	15463 (1.1)	81.52 (77.04 to 86.26)	12.81 (12.05 to 13.61)
Number of physical morbidities ^b				
None	2769 (7.8)	800202 (57.6)	1	1
One-three	20716 (58.0)	510846 (36.8)	11.72 (11.26 to 12.20)	4.03 (3.86 to 4.20)
Four-six	10414 (29.2)	70709 (5.1)	42.56 (40.79 to 44.41)	7.32 (6.99 to 7.67)
Seven or more	1791 (5.0)	6931 (0.5)	74.68 (70.05 to 79.61)	10.33 (9.64 to 11.05)
Number of mental morbidities				
None	21961 (61.5)	1163095 (83.8)	1	1
One-three	13533 (37.9)	223739 (16.1)	3.20 (3.13 to 3.27)	2.08 (2.04 to 2.13)
Four or more	196 (0.5)	1854 (0.1)	5.60 (4.83 to 6.49)	3.56 (3.03 to 4.20)

^aall $p < 0.001$.^bexcluding stroke.

disease (11.9%). Prevalences of all morbidities are shown in supplementary material (see Additional files 4 and 5).

Figure 1 displays the ORs (adjusted for age, sex and deprivation) for stroke in relation to the thirty one physical morbidities examined. The supplementary material (see Additional file 4) elaborates on this by showing both the unadjusted and adjusted ORs along with the crude prevalence of all physical morbidities in the stroke and control groups. In all, twenty eight of the thirty one physical morbidities examined were significantly more common in the stroke group, this was twenty seven after adjustment for potential confounding factors. For instance, epilepsy (adjusted OR 4.43; 95% CI 4.14 to 4.74), hypertension (adjusted OR 2.67; 95% CI 2.61 to 2.73), peripheral vascular disease (adjusted OR 2.47; 95% CI 2.37 to 2.58), AF (adjusted OR 2.44; 95% CI 2.36 to 2.53) and CHD (adjusted OR 2.06; 95% CI 2.01 to 2.11) were all more common in people experiencing a cerebrovascular disease event. By contrast, dyspepsia was markedly less common in the stroke group (adjusted OR 0.63; 95% CI 0.60 to 0.66). Figure 2 shows the ORs (adjusted for age, sex and deprivation) for stroke in relation to eight mental health morbidities. The unadjusted and adjusted ORs, along with the crude prevalence of all mental health morbidities in the stroke and stroke-free groups, are shown in supplementary material (see Additional file 5). In all, six of the eight mental health morbidities examined were significantly more common in the stroke group, and following adjustments, all eight mental health morbidities were significantly more common. These included drug and medication use problems (adjusted OR 2.34; 95% CI 2.25 to 2.43),

depression (adjusted OR 2.09; 95% CI 2.03 to 2.15), alcohol problems (adjusted OR 2.05; 95% CI 1.96 to 2.15) and anxiety and stress (adjusted OR 1.61; 95% CI 1.55 to 1.66).

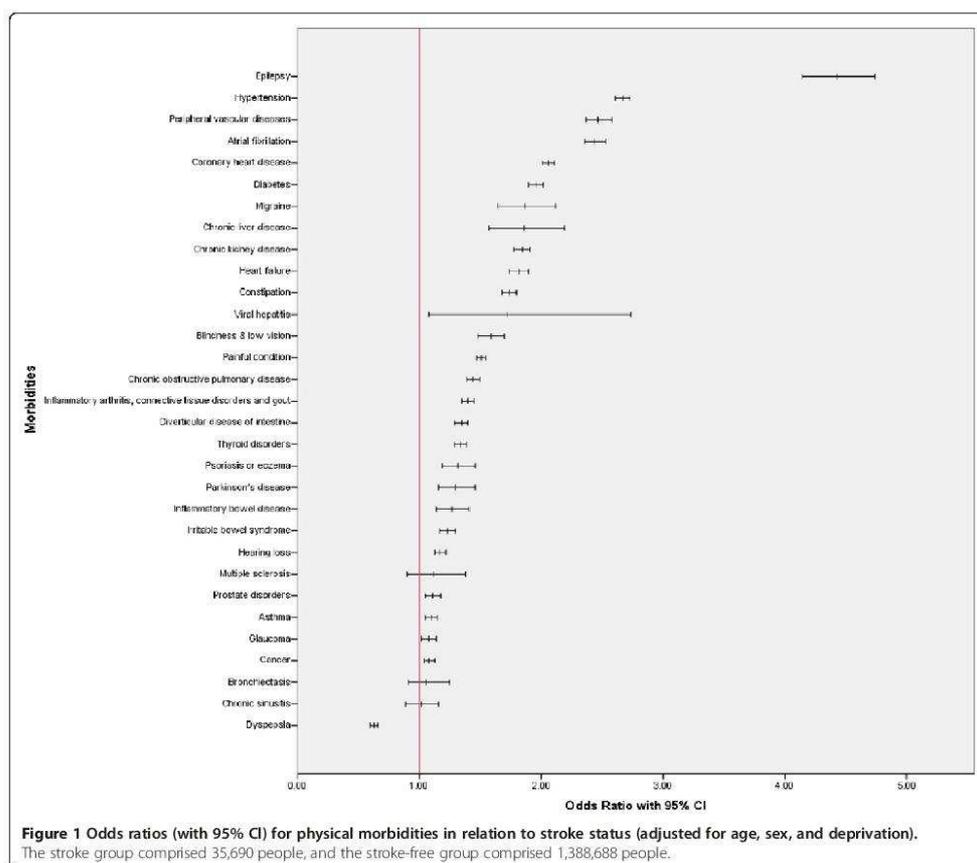
Regular prescriptions

As anticipated, the number of regular prescriptions was significantly correlated with number of morbidities in the stroke (Spearman's $\rho = 0.58$ $P < 0.001$) and control (Spearman's $\rho = 0.75$ $P < 0.001$) groups. Table 2 shows the number of repeat prescriptions in the stroke and control groups, and the ORs. Those with stroke were more likely than the controls to be on a repeat prescription (adjusted OR 4.53; 95% CI 4.33 to 4.74). In the stroke group, 12.6% had eleven or more repeat prescriptions compared with only 1.5% of the control group (OR adjusted for age, sex, deprivation and morbidity count 15.84; 95% CI 14.86 to 16.88).

Discussion

Summary of findings and implications

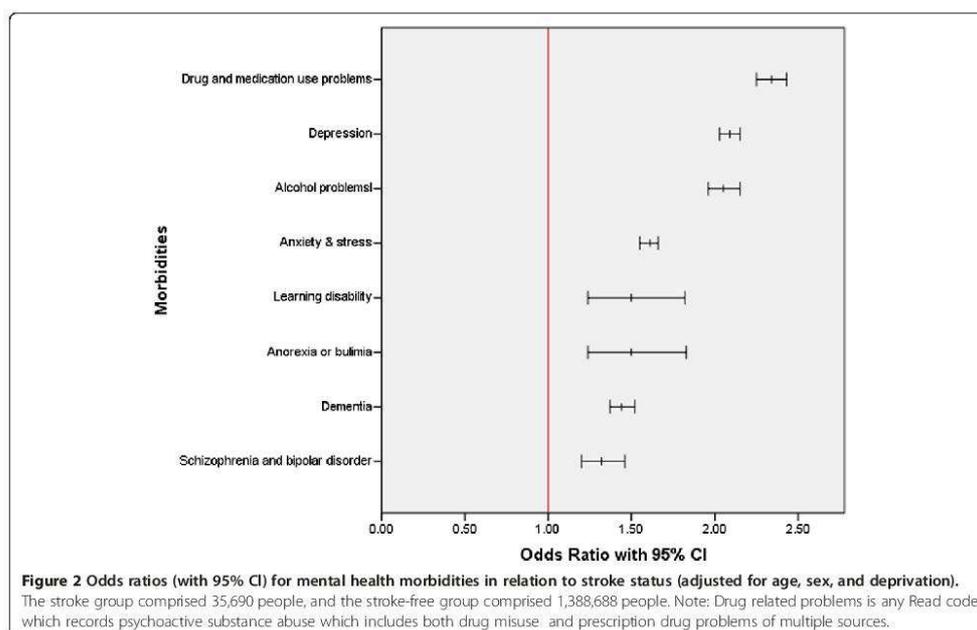
Analyses of a large, nationally representative sample of people in Scotland, a country with universal healthcare, showed that multimorbidity and polypharmacy were more common in people with a diagnosis of stroke. These findings are consistent with our knowledge that those with stroke are an elderly population with considerable cardiovascular disease risk [44], for whom effective treatments are increasingly available to alleviate symptoms and address underlying causal factors [45]. Diagnoses of most chronic conditions were more common in the stroke group, and this remained the case



after adjustment for age, sex and deprivation. In our preliminary analyses (see Additional file 2), both age and deprivation were associated with stroke in the expected directions. This gives us confidence in the novel results presented herein.

Polypharmacy represents only one aspect of treatment burden, but is directly measurable, and may be a proxy measure of wider aspects of burden [17,18]. Multimorbidity is likely to increase treatment burden in several ways. First, as this study and others have shown, the number of medications increases with number of conditions [20,21]. Second, treatments may interact, leading to side effects [5,7,46] and this has the potential to further increase the volume of work; for example, as new treatments are given to compensate for interactions [47]. Third, multimorbidity is likely to increase healthcare contacts and affect the capacity of the individual to follow therapeutic regimens [48];

for example, those with stroke and comorbid arthritis may find physiotherapy sessions more challenging [49,50]. Fourth, multimorbid patients who become overburdened, for example by complex medication regimens, may be less likely to adhere to therapies, leading to poor disease control and a further escalation of treatments by health professionals, further increasing treatment burden [3,9,51]. While many pharmacological therapies may be beneficial for those with stroke, a key question is whether people with stroke have made informed decisions regarding whether or not to take so many medications, given their modest benefits. Although perceived treatment burden and capacity to cope with any given treatment burden will vary, we would recommend that patients with stroke are made aware of the relative benefits of their drugs, and are empowered to make their own decision whether to take them.



Acknowledging and addressing treatment burden in stroke, particularly for those with multimorbidity, may improve the patient experience, adherence to therapies, and health outcomes [48]. Minimising unnecessary treatments, improving co-ordination of services and making care more patient-centred [23] are likely to lessen treatment burden, but will necessitate changes from policy level down to the individual consultation [3,48,52,53]. Most stroke management guidelines fail to mention multimorbidity, or merely acknowledge the more common comorbidities briefly with a lack of practical advice for clinicians [45,54-57]. We found only one stroke

guideline that acknowledged the issue of polypharmacy, and again, detailed practical help was lacking [56]. This issue has been gaining prominence [58,59]. Guidelines should be redesigned to take account of comorbidity and treatment burden; for example, by providing guidance on potential interactions from drug combinations commonly prescribed for those with stroke and multimorbidity and how to deal with the possible side effects or interactions that may arise [47]. In the current study, 21.9% of people with stroke had a painful condition, 20.7% had depression and 13.0% had atrial fibrillation, increasing the risk of being prescribed non-steroidal anti-inflammatory drugs (NSAIDs),

Table 2 Stroke status and number of repeat medications (N = 1,424,378)

	Stroke N (%) 35690 (100)	No stroke N (%) 1388688 (100)	Unadjusted OR (95% CI) ^a	Age, gender and deprivation adjusted OR (95% CI) ^a	Age, gender, deprivation and morbidity count adjusted OR (95% CI) ^a
Number of medications					
None	2447 (6.9%)	863688 (62.2%)	1	1	1
One-two	3038 (8.5%)	240721 (17.3%)	4.45 (4.22 to 4.70)	2.38 (2.26 to 2.52)	2.29 (2.17 to 2.42)
Three-four	6566 (18.4%)	122518 (8.8%)	18.92 (18.05 to 19.82)	6.25 (5.95 to 6.57)	5.78 (5.49 to 6.08)
Five-six	8185 (22.9%)	75512 (5.4%)	38.26 (36.55 to 40.05)	10.50 (9.99 to 11.03)	9.36 (8.89 to 9.86)
Seven-eight	6721 (18.8%)	43344 (3.1%)	54.73 (52.20 to 57.38)	13.90 (13.20 to 14.63)	11.94 (11.29 to 12.62)
Nine-ten	4219 (11.8%)	22536 (1.6%)	66.08 (62.76 to 69.57)	16.22 (15.34 to 17.15)	13.44 (12.65 to 14.29)
Eleven or more	4514 (12.6%)	20369 (1.5%)	78.22 (74.32 to 82.32)	20.13 (19.05 to 21.27)	15.84 (14.86 to 16.88)

^aall p < 0.001.

anti-depressants, anti-platelet therapies and anti-coagulants concomitantly, which increases risk of adverse events, such as bleeding. Care pathways should be structured around the patient themselves, rather than the individual conditions, using a more generalist approach that considers issues such as multimorbidity as well as the individual's support network and financial resources [9,60,61].

Strengths and limitations

This analysis was undertaken using data from a large, nationally representative, primary care sample, and as far as we are aware, this is the first study on such a scale to examine multimorbidity and polypharmacy in stroke. This sample is representative of the Scottish population [37]; however, it may not reflect experience in other countries and healthcare systems. The prevalence of stroke in this sample was similar to that shown in other studies [44,62], further validating the data; however, the data were collected for clinical rather than research purposes. No standard methods for measuring multimorbidity or polypharmacy exist, therefore a pragmatic approach was taken. We examined thirty nine long-term conditions, which is substantially more than in previous studies. The rationale for including the conditions examined and the rules for identifying the presence of each were described in detail by the team who previously collated the data [1]. In addition, any medications bought over the counter or given from secondary care were not included. However, at the time of the analysis, prescriptions to people over sixty five years of age and to many people with chronic conditions were all free, with others being able to cap their out-of-pocket costs, thus suggesting a financial incentive to obtain medication via the primary care practice.

As this is a cross-sectional study, the data we have were taken from one particular point in time, and therefore no conclusions about temporality or causation can be made. The measure of comorbidity was unweighted, as the aim was to be descriptive rather than to assess outcomes. This was deemed to be the most appropriate method, and is similar to that used by others investigating the prevalence of multimorbidity [1], but could be viewed as a limitation, especially as there may be a qualitative difference between the effects on perceived treatment burden of long-term conditions that produce regular symptoms (for example, heart failure) and those that are asymptomatic (for example, hypertension). We have no information about stroke severity, which is also a potential limitation. It should also be noted that due to the nature of the study, multiple analyses were carried out. Thus, the large numbers of cases and controls assessed in this study may have identified some associations that were statistically significant but not necessarily clinically significant; for example, for conditions such as cancer, glaucoma and asthma, which

had ORs between 1.08 and 1.10 but were statistically significant with $P < 0.001$.

Lastly, to explore treatment burden in stroke, this study examined multimorbidity and polypharmacy, however there are many more aspects of treatment burden still to be examined, such as clinic visits, continuity, coordination of care, and financial burden of therapies. The development of a patient-reported measure would enable a more detailed examination of treatment burden in stroke from the patient perspective.

Conclusion

In this study, we found that multimorbidity and polypharmacy were strikingly more common in those with stroke than those without. Polypharmacy can be thought of as a direct measure of one aspect of treatment burden, and we would suggest that people with stroke should be made aware of the relative benefits of their drugs so they can make informed decisions about therapeutic regimens. Both polypharmacy and multimorbidity are likely to be proxy markers for other aspects of treatment burden, as patients face the demands of managing multiple medications and conditions simultaneously. Clinical guidelines for stroke need to place greater emphasis on the management of multimorbidity, and further investigation of treatment burden in stroke is required to inform redesign of health services to improve patient outcomes.

Additional files

Additional file 1: Definitions of morbidities assessed.

Additional file 2: Stroke status in relation to demographic characteristics (n = 1,424,378).

Additional file 3: Stroke status and number of morbidities and repeat medications for two age groups.

Additional file 4: Stroke status and prevalence of physical morbidities (n = 1,424,378).

Additional file 5: Stroke status and prevalence of mental health morbidities (n = 1,424,378).

Abbreviations

AF: Atrial fibrillation; CHD: Coronary heart disease; NHS: National Health Service; PCQU: Primary Care Clinical Informatics Unit; QOF: Quality and Outcomes Framework

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KIG, GDB, CRM, PL and FSM were involved in conception and design of this study. SM and BG designed the original study for which the data was acquired, obtained the data and carried out the initial data management to define morbidities. KIG, GDB, GMcL, and FSM were involved in data analysis. KIG, GDB, GMcL, SWM, BG and FSM interpreted the data. KIG drafted the manuscript which was revised by all other authors. All authors approved the final version.

Acknowledgements

We thank the Chief Scientist Office of the Scottish Government Health Directorates (Applied Research Programme Grant ARPG/07/1); the Scottish School of Primary Care, which part-supported SWM's post and the development of the Applied Research Programme; and the Primary Care Clinical Informatics Unit at the University of Aberdeen, which provided the data. The views in this publication are not necessarily the views of the University of Aberdeen of University of Glasgow, their agents, or employees. We thank Katie Wilde and Fiona Chaloner of the University of Aberdeen, who performed the initial data extraction and management. GDB is a member of both the Alzheimer Scotland Dementia Research Centre funded by Alzheimer Scotland, and the University of Edinburgh Centre for Cognitive Ageing and Cognitive Epidemiology, and part of the cross-council Lifelong Health and Wellbeing Initiative (G0700704/ 84698). Funding from the BBSRC, EPSRC, ESRC, and MRC is gratefully acknowledged. We thank Jane Goodfellow for help with Figures 1 and 2. This study was funded by a CSO Clinical Academic Fellowship CAF/10/03 and the CSO 'Living Well with Multimorbidity' programme (ARPG/07/1). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Received: 24 April 2014 Accepted: 12 August 2014

Published online: 03 October 2014

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doi:10.1186/s12916-014-0151-0

Cite this article as: Gallacher et al.: Stroke, multimorbidity and polypharmacy in a nationally representative sample of 1,424,378 patients in Scotland: implications for treatment burden. *BMC Medicine* 2014, **12**:151.

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Appendix 12 - Correspondence with Research Ethics Committee

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow
and Clyde

West of Scotland REC 4

Ground Floor, Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT
www.nhsggc.org.uk

Dr Katie Gallacher
Clinical Academic Fellow
Department of Primary Care
University of Glasgow
1 Horselethill Road
Glasgow
G12 9LX

Date 24 May 2011
Direct line 0141-211-1722
Fax 0141-211-1847
e-mail evelyn.jackson@ggc.scot.nhs.uk

Dear Dr Gallacher

Study Title:	Understanding Treatment Burden in People with Stroke
REC reference number:	11/AL/0266

The Research Ethics Committee reviewed the above application at the meeting held on 17 May 2011.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
Covering Letter	-	18 April 2011
Investigator CV	-	-
Letter of invitation to participant	1	17 March 2011
Other: Prof F S Mair's CV	-	-
Other: Prof P Langhorne's CV	-	-
Other: Carl May's CV	-	-
Other: Dr G D Batty's CV	-	-
Other: Letter to GP Practice	1	17 March 2011
Other: Letter to Consultant (Stroke)	1	17 March 2011
Other: Letter re accessing demographic details, etc.	1	17 March 2011
Other: Letter re accessing demographic details, etc.	1	17 March 2011
Other: Letter from Anne Scoular	-	15 April 2011
Other: Letter from Judith Godden	-	11 March 2011
Other: E-mail from Isobel Brown on behalf of Caldicott Guardian	-	-
Participant Information Sheet	1	17 March 2011
Protocol	1	18 April 2011
REC application	-	12 April 2011

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Provisional opinion

The Committee reviewed the study. The Committee noted that it was only being asked to review the last part of the study which involved patient interviews as the earlier parts of the study, i.e. those relating to the extraction of the LES data, had already been deemed as not requiring ethical approval, as intimated in the e-mail written on behalf of the Caldicott Guardian. The Committee therefore did not review these parts of the study and gave no ethical opinion on them.

The Committee thanked you and Professor Frances Mair for attending the meeting and the following was discussed:

1. The Committee felt that it was not appropriate for the Consent Form to be sent out to potential participants and suggested that an expression of interest reply slip be sent out with the information about the study. Consent could then be taken face to face with the participant when they attend for their next appointment.

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to a meeting of the sub-committee of the REC.

Further information or clarification required

1. The Committee wondered if a more accurate title for the study would be "Understanding Treatment Burden in People with Stroke/Transient Ischaemic Attack (TIA)
2. Having been given the earlier part of the study to read, the Committee asked for information as to how the LES - Enhanced Stroke/Tia Care data will be extracted and asked for a letter from Mr Richard Copeland, Head of Data Protection giving assurance that the extraction of this data would not contravene any Data Protection restrictions. The responsibility for the ethics of the data extraction rests with the Caldicott Guardian as the Committee have no knowledge of the detail of this process.
3. In the Expression of Interest Form, the wrong study title is printed.
4. The participant's name should be not recorded on the interview guide and a Subject ID No. should be used instead.
5. In the Patient Information Sheet:
 - (a) The Committee felt that the wording used in the section headed "What is the purpose of the study?" is slightly leading and this should be changed.
 - (b) In the section headed "What will happen to me if I do not agree to take part?" remove the first sentence - "No further action will be taken."
 - (c) In the section headed "What are the possible disadvantages of taking part?", second sentence, remove ".....compared with the usual care you receive from your doctor."
 - (d) In the section headed "Expenses or payments" first sentence, change to read "If you wish the interview to take place at a location other than your home you will be reimbursed for any expenses incurred during travel to and from the interview.
 - (e) An independent contact should be named who can be contacted to discuss the study but is not involved in the study.
 - (f) Contact details to be printed at the top of the first page.

6. The Committee also seek assurance that consent will be taken face to face. A reply slip could be used to express interest to be returned to you.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Evelyn Jackson, Committee Co-ordinator.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers to respond fully to the above points. A response should be submitted by no later than given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you 23 September 2011.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet. Professor Chris Robertson submitted written comments.

I declared an interest in this study as I am involved in the LES - Enhanced Stroke/TIA Care network.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/AL/0266

Please quote this number on all correspondence

Yours sincerely



for **Dr Sue Langridge**
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Professor Frances Mair, University of Glasgow
Dr Erica Packard, R&D Office, Tennent Building, Western Infirmary

West of Scotland REC 2

Attendance at Committee meeting on 17 May 2011

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Sue Langridge (Chair)	General Practitioner	Yes	
Miss Lynda Brown	Public Health Adviser	Yes	
Dr A Crighton	Oral Medicine	Yes	
Rev Robert Currie	Clergy (Retired)	Yes	
Dr Jesse Dawson	Clinical Lecturer in Medicine	Yes	
Mrs Cairiona Donald	Senior Charge Nurse	Yes	
Dr Anja Guttlinger	Consultant in Sexual and Reproductive Health	No	
Dr Angela Jenkins	Specialist Trainee in Anaesthetist	Yes	
Mrs Mary Keenaghan	Independent Auditor	Yes	
Mrs Susan Knox	Physiotherapist	Yes	
Mr Steve McGlynn	Lead Pharmacist	Yes	
Mr J McHugh	Insurance	Yes	
Dr Stuart Milligan	Lecturer in Palliative Care	Yes	
Professor Chris Robertson	Professor	No	
Dr David Shaw	Lecturer in Ethics & Law	Yes	
Dr John Thorburn	Retired Constant Anaesthetist	Yes	
Mr James Timmons	Retired IT Manager	Yes	
Dr Andy Willis	Social Worker	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Judith Godden	Scientific Adviser/Manager
Ms Evelyn Jackson	Co-ordinator

Written comments received from:

<i>Name</i>	<i>Position</i>
Professor Chris Robertson	Professor

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Greater Glasgow
and Clyde

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Ground Floor, Tennent Building
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38 Church Street
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G11 6NT
www.nhs.gov.uk

Dr Katie Gallacher
53 Cecil Street
Hillhead
Glasgow
G12 8RW

Date 08 July 2011
Direct line 0141-211-1722
Fax 0141-211-1847
e-mail evelyn.jackson@ggc.scot.nhs.uk

Dear Dr Gallacher

Study title:	Understanding Treatment Burden in People with Stroke
REC reference:	11/AL/0266

Thank you for your letter of 2 June 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered, in correspondence by a sub-committee of the REC in correspondence. A list of the sub-committee members is attached.

Confirmation of ethical opinion

Following assurance from you the Sub-Committee are now satisfied that the data to be used in Phase 2b of the study is completely anonymous. The Sub-Committee are happy to approve the whole study as long as the data is anonymous and any linkage will be done within a safe haven.

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to

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the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter	-	18 April 2011
Interview Schedules/Topic Guides	2	02 June 2011
Investigator CV	-	-
Letter of invitation to participant	1	17 March 2011
Other: Prof F S Mair's CV	-	-
Other: Prof P Langhorne's CV	-	-
Other: Carl May's CV	-	-
Other: Dr G D Batty's CV	-	-
Other: Letter re accessing demographic details, etc.	1	17 March 2011
Other: Letter re accessing demographic details, etc.	1	17 March 2011
Other: Letter from Anne Scoular	-	15 April 2011
Other: Letter from Judith Godden	-	11 March 2011
Other: E-mail from Isobel Brown on behalf of Caldicott Guardian	-	-
Other: Letter to GP Practice	2	02 June 2011
Other: Expression of Interest Form - GP Practice	2	02 June 2011
Other: Letter from GP Practice to patient	2	02 June 2011
Other: Letter to Stroke Nurse	2	02 June 2011
Other: Expression of Interest - Stroke Nurse	2	02 June 2011
Participant Consent Form	2	02 June 2011
Participant Information Sheet	2	02 June 2011
Protocol	1	18 April 2011
REC application	-	12 April 2011
Response to Request for Further Information	-	02 June 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/AL/0266

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



for **Dr Sue Langridge**
Chair

Enclosures: List of names and professions of members who were present at the meeting
"After ethical review – guidance for researchers"

Copy to: Professor Frances Mair, University of Glasgow
Dr Erica Packard, NHS Greater Glasgow and Clyde

West of Scotland REC 2**Attendance at Sub-Committee of the REC meeting on 19 June 2011****Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Sue Langridge	General Practitioner	Yes	
Dr Stuart Milligan	Lecturer in Palliative Care	Yes	

Dear Katie and Elaine

I've checked my letter and the RED database and I have recorded the letter as being received. The documents I recorded as being received on 2 June 2011 were as follows:

Response to Request for Further Information	-	02 June 2011
Other: Letter to GP Practice	2	02 June 2011
Other: Expression of Interest Form - GP Practice	2	02 June 2011
Other: Letter from GP Practice to patient	2	02 June 2011
Other: Letter to Stroke Nurse	2	02 June 2011
Other: Expression of Interest - Stroke Nurse	2	02 June 2011
Participant Consent Form	2	02 June 2011
Participant Information Sheet	2	02 June 2011
Interview Schedules/Topic Guides	2	02 June 2011

I hope this will be enough for R&D to be able to process your application.

Best
Evelyn

Evelyn Jackson
Co-ordinator, West of Scotland Research Ethics Service
Ground Floor, Tennent Building
38 Church Street
Glasgow
G11 6NT
Tel No: 0141-211-1722
Fax No: 0141-211-1847
e-mail: evelyn.jackson@ggc.scot.nhs.uk



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Dr Katie Gallacher
 Clinical Academic Fellow
 University of Glasgow
 Department of Primary Care
 University of Glasgow
 1 Horselethill Road
 Glasgow
 G12 9LX

Date 02 August 2012

Direct line 0141 211 6294
 Fax 0141 211 1847
 E-mail Stephanie.keane@ggc.scot.nhs.uk

Dear Dr Gallacher,

Study title: Understanding Treatment Burden in People with Stroke
REC reference: 11/AL/0266
Amendment number: AM01
Amendment date: 02 August 2012

Thank you for your letter of 02 August 2012, notifying the Committee of the above amendment, namely, extension till November 2024.

The Committee does not consider this to be a “substantial amendment”, as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment		02 August 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/AL/0266:	Please quote this number on all correspondence
--------------------	---

Yours sincerely,



Stephani Keane
Committee Assistant Co-ordinator

Copy to: *Dr Erica Packard, NHS Greater Glasgow and Clyde*
Prof Frances Mair

Dr Katie Gallacher
Clinical Academic Fellow
University of Glasgow
Department of Primary Care
1 Horselehill Road
Glasgow
G12 9LX

West of Scotland REC 4

Ground Floor, Tennent Building
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38 Church Street
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www.nhs.gov.uk

Date 6 December 2013
Direct line 0141-211-1722
Fax 0141-211-1847
e-mail Wosrec4@ggc.scot.nhs.uk

Dear Dr Gallacher

Study title:	Understanding Treatment Burden in People with Stroke
REC reference:	11/AL/0266
Amendment number:	AM02
Amendment date:	04 December 2013
IRAS project ID:	55255

Thank you for your letter of 4 December 2013, notifying the Committee of the following amendment:

- Minor changes to interview schedule

The Committee does not consider this to be a "substantial amendment", as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment	AM02	04 December 2013
Interview Schedules/Topic Guides	3	21 October 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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--------------------	---

Yours sincerely



Ms Evelyn Jackson
Committee Co-ordinator

Copy to: *R&D Office, Tennent Building, Western Infirmary*

Appendix 13 - Correspondence to primary and secondary care

TO BE ON SPCRN HEADED NOTEPAPER

Date

Prof Frances mair
Department of General Practice and Primary Care
University of Glasgow
1 Horselethill Road
G12 9LX

Dear (GP)

Re- Understanding Treatment Burden in Stroke - CSO ref

I am writing to request your help with the above study being undertaken by the Academic Unit of General Practice at the University of Glasgow. The study is sponsored by NHS Greater Glasgow and Clyde and funded by the Chief Scientist Office Scotland and has ethical approval from the West of Scotland Research Ethics Committee.

The study aims to understand the ‘treatment burden’ or ‘workload’ that patients experience when managing their stroke. We propose that a high ‘treatment burden’ e.g. multiple medications, numerous appointments, can contribute to patient non adherence to treatments. The study aims to:

1. Understand how patients make sense of living with stroke, in terms of understanding investigations and treatments.
2. Understand what activities / work do stroke patients have to do to manage their condition.
3. Understand how stroke patients engage with others to manage their illness.
4. Understand how stroke patients appraise their management.

What we would ask the practice to do:

If your practice is willing to be involved, we would arrange for a member of the Scottish Primary Care Research Network (SPCRN) to run a search for study eligible patients and provide you with a list of potentially suitable individuals for screening in order to rule out anybody that you would feel would not be suitable to be approached to participate in the study (English language not good enough to be able to communicate in the interview, mental impairment suggesting they would not be able to give informed consent, a history of aggression or a co-existing terminal illness with a life expectancy of less than 6 months).

Please note that patients with communication difficulties due to stroke e.g. aphasic patients will be **included** and given the opportunity to communicate in another way such as writing, or their carers will be interviewed to gain insight into the patient’s experience. We will provide you with invitation packs and stamped envelopes to send to patients who you deem suitable. This will include a letter of invitation with written information about the

study, and a reply slip that the patient will return to us in a stamped addressed envelope provided.

We will inform you of any patients who agree to take part and ask you for permission to review their records in order to confirm contact details, current medications and co-morbidities.

The only additional workload to practices is the screening of patient lists and permission for access to the practice. We believe that this study will benefit patients in the future and improve patient adherence to therapies.

I would be very grateful if you can complete the enclosed 'Expression of Interest' Form and return it in the enclosed envelope to Dr Katie Gallacher, address above, within the next 7 days. If you have any questions, Dr Gallacher can be contacted on 330 8323.

Finally, the project has been granted ethics approval (West of Scotland Research Ethics Committee) and it has also been approved by the Research & Development Directorate in NHS Greater Glasgow and Clyde.

I look forward to hearing from you and hope very much that you will consider assisting with the research project.

Yours sincerely,

Prof Frances Mair

Expression of Interest Form

Understanding Treatment Burden in People with Stroke

Practice name

Address

Address

Address

Please cross one of the following boxes and return in the stamped addressed envelope

No, we do not want to hear more about the study

Yes, we would like to hear more about the study

If **yes**, would you prefer to receive more information by a telephone call from one of the researchers, or would you prefer for Dr Katie Gallacher to contact the practice to arrange a visit to the practice?

Telephone call from researcher

Call to arrange a visit

Best times to call.....

Practice manager name.....

Signature

Name (print)

Date

Tel number



Date

XXXXX
XXXXX
XXXXX
XXXXX
XXXX
XXXXX

Prof Frances Mair
Department of General Practic
and Primary Care
University of Glasgow
1 Horselethill Road
G12 9LX

Dear (GP)

**Re- Understanding Treatment Burden in Stroke - CSO ref
Patient -**

I am writing to you because the above patient has been recruited to our study through the Greater Glasgow and Clyde stroke service. The study is being undertaken by the Department of General Practice at the University of Glasgow. It is sponsored by NHS Greater Glasgow and Clyde, funded by the Chief Scientist Office Scotland, and has ethical approval from the West of Scotland Research Ethics Committee.

The study aims to understand the 'treatment burden' or 'workload' that patients experience when managing their stroke. We propose that a high 'treatment burden' e.g. multiple medications, numerous appointments, can contribute to patient non adherence to treatments. The study aims to:

1. Understand how patients make sense of living with stroke, in terms of understanding investigations and treatments.
2. Understand what activities / work stroke patients have to do to manage their condition.
3. Understand how stroke patients engage with others to manage their illness.
4. Understand how stroke patients appraise their management.

What we are asking you to do:

The above patient has been interviewed by our researchers and has given written consent for us to access their case notes to gain information about their demographic details, medical conditions and medications. We are therefore asking for your co-operation in allowing us access to this information. Enclosed is the consent form signed by your patient.

We will be phoning the practice within the next few weeks to discuss this, answer any queries and to hopefully arrange access to the case notes. This will be done, with your permission, by one of our researchers who has an honorary contract with the NHS, and access has been

granted approval by the West of Scotland Research Ethics Committee. We will require less than 30 minutes in the practice and this can be arranged at a time that suits you.

If you have any queries about this please contact Dr Katie Gallacher on 0141 330 8323.

We look forward to speaking with you. Thank you for your time.

Yours sincerely,

Prof Frances Mair



Date

XXXXX
XXXXX
XXXXX
XXXXX
XXXX
XXXXX

Prof Frances Mair
Department of General Practice
and Primary Care
University of Glasgow
1 Horselethill Road
G12 9LX

Dear (GP)

**Re- Understanding Treatment Burden in Stroke - CSO ref
Patient -**

I am writing to you because the above patient has been recruited to our study with your previous help. The study is being undertaken by the Department of General Practice at the University of Glasgow. It is sponsored by NHS Greater Glasgow and Clyde, funded by the Chief Scientist Office Scotland, and has ethical approval from the West of Scotland Research Ethics Committee.

The study aims to understand the 'treatment burden' or 'workload' that patients experience when managing their stroke. We propose that a high 'treatment burden' e.g. multiple medications, numerous appointments, can contribute to patient non adherence to treatments. The study aims to:

1. Understand how patients make sense of living with stroke, in terms of understanding investigations and treatments.
2. Understand what activities / work stroke patients have to do to manage their condition.
3. Understand how stroke patients engage with others to manage their illness.
4. Understand how stroke patients appraise their management.

What we are asking you to do:

The above patient has been interviewed by our researchers and has given written consent for us to access their case notes to gain information about their demographic details, medical conditions and medications. We are therefore asking for your co-operation in allowing us access to this information. Enclosed is the consent form signed by your patient.

We will be phoning the practice within the next few weeks to discuss this, answer any queries and to hopefully arrange access to the case notes. This will be done, with your permission, by one of our researchers who has an honorary contract with the NHS, and access has been granted approval by the West of Scotland Research Ethics Committee. We will require less than 30 minutes in the practice and this can be arranged at a time that suits you.

If you have any queries about this please contact Dr Katie Gallacher on 0141 330 8323.

We look forward to speaking with you. Thank you for your time.

Yours sincerely,

Prof Frances Mair



Date

Professor Frances Mair
 Department of General Practice and Primary Care
 University of Glasgow
 1 Horselethill Road
 G12 9LX

Dear (stroke research nurse)

Re- Understanding Treatment Burden in Stroke - CSO ref

I am writing to request your help with the above study being undertaken by the Department of General Practice and Primary Care at the University of Glasgow. The study is sponsored by NHS Greater Glasgow and Clyde and funded by the Chief Scientist Office Scotland and has ethical approval from the West of Scotland Research Ethics Committee.

The study aims to understand the 'treatment burden' or 'workload' that patients experience when managing their stroke. We believe that a high 'treatment burden' e.g. multiple medications, numerous appointments, can contribute to patient non adherence to treatments. This study aims to:

1. Understand how patients make sense of living with stroke, in terms of understanding investigations and treatments.
2. Understand what activities / work do stroke patients have to do to manage their condition.
3. Understand how stroke patients engage with others to manage their illness.
4. Understand how stroke patients appraise their management.

What we would ask you to do:

If you are willing to be involved, we would ask for you to screen your list of stroke patients who attend your clinic to assess who may be appropriate for the study.

Factors to consider that would make patients **not be suitable** to be approached to participate in the study would be: no previous diagnosis of stroke (cerebrovascular accident), ischaemic or haemorrhagic; English language not good enough to be able to communicate effectively (unfortunately we do not have translators); mental impairment suggesting the participant would not be able to give informed consent; a history of aggression; or a co-existing terminal illness with a life expectancy of less than 6 months. Ideally we would like to identify both recently diagnosed stroke patients and those who have had the illness for longer.

Patients with communication difficulties due to stroke e.g. aphasic patients will be **included** and given the opportunity to communicate in another way such as writing, or their carers will be interviewed to gain insight into the patient's experience.

We will provide you with invitation packs to give to or send to patients who you deem suitable (with stamped envelopes). This will include a letter of invitation with written information about the study, and a reply slip that the patient will return to us in a stamped addressed envelope provided.

The only additional workload to yourselves is the screening of patients and your work should be minimal. We believe that this study will benefit patients in the future and improve patient adherence to therapies.

I look forward to hearing from you and hope very much that you will consider assisting with the research project. If you have any questions, please contact Dr Katie Gallacher on 330 8323.

Yours sincerely,

Prof Frances Mair

Expression of Interest Form

Understanding Treatment Burden in People with Stroke

Practice name

Address

Address

Address

Please cross one of the following boxes and return in the stamped addressed envelope

No, we do not want to hear more about the study

Yes, we would like to hear more about the study

If **yes**, would you prefer to receive more information by a telephone call from one of the researchers, or would you prefer for Dr Katie Gallacher to contact the clinic to arrange a visit?

Telephone call from researcher

Call to arrange a visit

Best times to call.....

Name of contact.....

Signature

Name (print)

Date

Tel number

Appendix 14 - Patient information pack

PRACTICE HEADED NOTEPAPER.

DEAR PATIENT X

Our practice is helping with research being undertaken by the Academic Unit of General Practice at the University of Glasgow on the work patients have to do to manage their stroke condition and other chronic health problems. We are writing to you today to see if you would be willing to help with this research. The researchers merely wish to speak with you to explore your ideas and opinions.

Full details about the project and what you would need to do together with a reply slip are included with this letter. Please read this information carefully to decide whether you are willing to take part. If you have any queries please direct your questions to a member of the research team at the University of Glasgow on the following number: 0141 330 8323 (Dr Katie Gallacher).

Please send your reply to the research team in the stamped, addressed envelope included with this letter.

Many thanks

GP x or Y



Research Participant Information Sheet

The study is called '**Understanding Treatment Burden in Stroke**'

Introduction

You are being invited to take part in the above study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following carefully and discuss it with others. If there is anything not clear to you or you would like more information you can speak to Dr Katie Gallacher on telephone number 0141 330 8323 or Professor Frances Mair on 0141 330 8317 between 09.30 and 16.30 Monday to Friday. If we are not at our desks please leave a message and we will call you back.

Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of this study?

People with stroke may have to put time and effort into managing their condition, for example by taking medications and attending hospital and GP appointments, as well as other therapists. If people with stroke find these routines difficult and time consuming, it is possible that they may feel unable to follow their treatments, as they are overwhelmed by them. For example they may not take all their tablets as they feel they have too many to take or they may not be able to arrange transport to all their different appointments.

Research is needed to better understand the time and efforts that people put into managing their condition. If we understand this better then we can try to help people by making their treatments easier to follow.

Why have I been chosen?

Your doctor or stroke nurse has identified you and other people who have had a stroke. A stroke occurs when the blood supply to the brain is disrupted, which can happen due to a blood clot or small leak occurring in the blood vessels in the brain. A stroke is also sometimes called a 'brain attack'. This is a common condition - around one million people living in the UK today have had a stroke. It affects people in many different ways.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to send us a reply slip or to contact us by

telephone. If you decide to take part you are still free to withdraw at any time. A decision not to take part will not affect the medical care you receive in any way.

What will happen to me if I do not agree to take part?

Your medical care will be unaffected.

What will happen to me if I agree to take part?

If you decide to take part you should fill out the reply slip and send it to us in the stamped addressed envelope provided, or alternatively contact us by telephone on one of the above numbers.

If you send us the reply slip through the post, we will phone you to arrange an interview with one of our researchers.

This interview can take place either at your GP practice or home. You can choose which location suits you best. It will last approximately one hour fifteen minutes. This will involve the interviewer asking you questions about your health and treatments, and we will fill in a questionnaire about how your life is affected by stroke. There will be an opportunity for you to add any extra comments you would like to make about your treatments.

The interview will be recorded using an audio recording device such as a tape recorder, recordings will be stored confidentially.

We will also require to know the following information: your date of birth; address; telephone number; medications and other chronic conditions you have which we will find out from your GP or stroke nurse, only with your permission. All information will be kept secure and confidential.

Your normal treatments will be continued as usual and are unaffected by this study.

What will happen if I do not want to continue with this study?

If you change your mind after signing the consent form for the study and wish to withdraw from the study, this will not affect your medical care. We will need to use the data collected up to your withdrawal but will not trouble you any further with the study. If, after giving consent, you become unwell so that you are no longer considered able to give your own consent, you will not be asked to participate any further. We will, however, keep the data collected up to this point.

How long will the study last?

The study will run for 3 years but we will only need to talk to you on one occasion for the interview itself, unless you wish to speak to us at other times to ask us questions about the study.

What are the possible benefits of taking part?

The information gained from this work may help to improve the future care of people who have had a stroke. There may be no direct benefits to you for taking part, however, some people find talking to someone about their condition and its treatment helpful, although please note that no changes can be made to treatments by the research team.

What are the possible disadvantages of taking part?

This study requires approximately one hour, fifteen minutes of your time. There are no identifiable risks to you taking part in this study.

Expenses or payments

If you wish the interview to take place at a location other than your home, you will be reimbursed for any expenses incurred during travel to and from the interview. There will be no other costs involved. No payments are available for taking part in this study.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of research will be kept strictly confidential.

Any information about you, including medications and medical history, will have your name, date of birth, address and telephone number removed from it so that you cannot be recognised from it. This information will also be removed from information gathered from the interview (tapes, written information) so that you cannot be recognised from it.

Your details will be kept in a secure, locked cabinet at the University of Glasgow and will be stored for up to 10 years. Only authorised persons such as members of the research team, representatives of the sponsor (NHS Greater Glasgow and Clyde - see below), or regulatory authorities (e.g. for monitoring the quality of the research) will have access to this information, including identifiable data (name, address, phone number, date of birth). Such authorised persons will have a duty of confidentiality to you as a research participant.

Anonymous information from the interviews may be kept for up to 10 years and this may be used in future research or teaching. This will be completely anonymous so that you will not be able to be identified from this information.

What will happen to the results of the research study?

We plan to publish the results of the study in relevant medical journals. This is because the subject is important for health professionals. All information published including direct quotations from the interviews will be anonymised and so any report or papers that are written or published about the study will not identify you or any other patient taking part.

Who is organising and paying for this study?

The study is being sponsored by NHS Greater Glasgow and Clyde and is funded by the Chief Scientist Office Scotland. There is no commercial sponsorship of any description e.g. from the pharmaceutical industry.

Involvement of the General Practitioner / Family doctor (GP)

We will notify your GP that you are taking part in the study, because it is useful for them to know this information. This will not affect your care in any way. This also means that we can access information about your medications and other chronic illnesses, if any, from your practice. We will also check with your GP if you have any history of violence or aggression that may put our researchers at risk when carrying out the interview. This is simply to

protect our researchers from any potential harm and any information gained will be kept completely confidential.

Who has reviewed this research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by West of Scotland Research Ethics Committee.

Who should I contact if I have any complaints about the study?

There is a standard complaints procedure which can be followed if you have any complaints related to this study. Please contact - Professor Graham Watt, Department of General Practice and Primary Care, 1 Horselethill Road, University of Glasgow, G12 8RW, telephone no 0141 330 8345. This contact is independent to our study team.

Further information and contact details

If you wish to obtain further information about this research, please do not hesitate to call Dr Katie Gallacher on telephone number 0141 330 8323 or Professor Frances Mair on 0141 330 8317 between 09.30 and 16.30 Monday to Friday.

Thank you for taking the time to read this information.



Reply Slip

I would like a member of the research team to contact me by telephone to discuss the project and / or to arrange a time for interview.

Please enter details of your address and telephone number:

Address:

Telephone number:

Please enter details of your GP's name and address:

Name of Participant (print)

Date

Signature

Please send this back to us in the stamped addressed envelope provided. Alternatively you can call Dr Katie Gallacher for more information on 0141 330 8323.

Appendix 15 - Consent form



University
of Glasgow



Centre: Glasgow

Study Number:

Participation Identification Number for this trial:

CONSENT FORM

Title of Study: Understanding Treatment Burden in Stroke

Name of Researcher: Dr Katie Gallacher

Please initial each box

1	I confirm that I have read and understand the information sheet dated xxxx (version x) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered to my satisfaction.	<input type="checkbox"/>
2	I understand that my participation is voluntary and that I am free to withdraw at any time without having to give a reason. I am aware that this will not affect my medical care or legal rights.	<input type="checkbox"/>
3	I understand that individuals from the research team will have access to my name, address, date of birth, and telephone number, details of my current medical conditions and medications. I also understand that representatives from the sponsor (NHS Greater Glasgow and Clyde) and regulatory bodies auditing the conduct of this research may also have access to this information, for up to 5 years after the study has finished. I understand that this information will be stored securely and treated confidentially. I give permission for these individuals to have access to this information.	<input type="checkbox"/>
4	I understand that my interview will be recorded by an audio device such as a tape recorder and give permission for this.	<input type="checkbox"/>
5	I understand that information or quotes from the interview may be used in publications / reports, but that this will be completely anonymous so that I cannot be identified.	<input type="checkbox"/>
6	I understand that anonymous information from the interview may be used for future research or teaching, but that this will be completely anonymous so that I cannot be identified.	<input type="checkbox"/>

7	I understand that my GP will be informed of my participation in the study, and that they will be asked if I have any history of violence or aggression that would prevent me from being included in this study, and give permission for this.	<input type="checkbox"/>
8	I understand that if, after giving consent, I become unwell so that I am no longer considered able to give consent, I will not be asked to participate any further. The researchers will, however, keep the data collected up to that point.	<input type="checkbox"/>
9	I agree to take part in the study above.	<input type="checkbox"/>

Name of Participant (print)

Date

Signature

Person taking consent Date

-----Signature -----Name of

Appendix 16 - Interview schedules



University
of Glasgow



INTERVIEW GUIDE: PATIENTS' PERCEPTIONS OF TREATMENT BURDEN

Background Information for the Interviewer

In situations where there is a lack of knowledge, questions will be posed in a manner which takes account of such a limitation.

The interview will be semi-structured in format, and thus the exact wording and prompts used may vary between patients to encourage the patient to share their views and allow them and opportunity to talk at length about their views about their illness and particularly their treatment and management.

Introduction Procedure with Patients

1. Give complete name.
2. Identify self as a researcher from the Department of General Practice and Primary Care at the University of Glasgow.
3. State that the doctors at the surgery know about the study.
4. Give short explanation of the purpose of the study:

'I would like you to help me understand what you feel about your stroke. I really just want to find out your views on how you have learnt to live and deal with your condition, the treatments and advice you have been given. Please feel assured that no one will be able to identify you from what you say when talking to me and everything you tell me will be treated in the strictest confidence.'

'We think it is important to know not only how the illness affects your body, but also how you think the management of your condition, for example the medications you have to take and the appointments you have to attend affect your everyday life, and if so in what ways?'

If at any time you want to stop, or have a break, please feel free to let me know.

'I will be recording the interview, so I can remember all that you have said to me.'

PATIENT PROFILE

Subject ID:

Age:

Gender: Male () Female ()

Length of Time Registered with Current Practice:

Less than 5 years ()
 6 to 15 years ()
 16 to 24 years ()
 25 years + ()

Have you been in hospital for the condition you are taking _____ to treat?

Yes ()

No ()

Have you seen a specialist regarding your condition?

Yes ()

No ()

Marital Status:

Single ()

Married / Civil Partnership ()

Living with partner ()

Separated ()

Divorced ()

Widowed ()

Have you any Children?

Yes ()

No ()

Can I ask how many?	1	()
	2	()
	3	()
	4	()
	5+	()

Can you tell me whether you went on to any further education after secondary school? Yes/No

If yes, please describe.

Date and Time of Interview:

COHERENCE

The initial questions will explore how patients make sense of stroke that is, how do they come to develop an understanding of what it means to have had a stroke and the treatment required, in terms of implications for one's future and learning to manage their condition (coherence)?

The interviewer will therefore explore the following general areas in an open fashion:

- 1) How the participant found out about their stroke?
- 2) What investigations they have had and why?
- 3) What treatments they have been given for what?
- 4) What they were first told about their treatments and by whom?
- 5) What they have been told since about treatments and by whom?
- 6) How else they have found out about their treatments? (Have they asked friends and family, read leaflets or books, watched television, looked on the internet?)
- 7) Whether they have received lifestyle or other advice? From whom? And what is their understanding of this advice?
- 8) What they have been told about risk factors and their management?
- 9) What they have been told to do if they have symptoms suggestive of another stroke? Or when they should seek help?

Cognitive Participation

The interviewer will explore how stroke patients engage with others in terms of communicating about their illness and involving others in their care (*cognitive participation*)?

The interviewer will therefore explore the following general areas in an open fashion:

- 1) When participants would ask the doctor for help, for example, make an emergency appointment? And arrangements with doctors or nurses about contacting them in an emergency?
- 2) How friends and family feel about their illness and its treatments?
- 3) Do they experience difficulty with communication due to their stroke? And what do they have to do to overcome/deal with this?
- 4) Whether they ask friends and family to help you with treatments and lifestyle changes or instead do everything themselves?
- 5) How participants organise getting prescriptions?
- 6) How participants organise getting to appointments?

Collective Action

The interviewer will explore what activities/work do stroke patients have to undertake to help them manage their condition in practice and what challenges, if any, do their personal circumstances such as co-morbidities or social situation pose (collective action)?

- 1) The interviewer will explore how difficult participants' find it is to remember how or when to take your medicine, and what strategies, if any, participants adopt to promote medication adherence?
- 2) The interviewer will explore how many different types of clinics or therapists they need to attend and how they manage this? For example, how often do they go to the GP or hospital each week or month?
- 3) The interviewer will explore issues of access to health care? How difficult or easy it is to get appointments, access advice?
- 4) Participant's confidence in their general practitioner and other health professionals will be explored and in particular their perspectives on the co-ordination of care and adequacy of communication between professionals and professionals and themselves?
- 5) Participants' views on the importance, or not, of continuity of care.
- 6) The interviewer will explore how patients integrate their illness and its management into their social circumstances. How does it affect their life at home, leisure and social activities, or work (if relevant). For example, how, if at all, have they modified daily and social activities; or financial implications of their illness; or challenges in accessing social services support. Does it affect their diet or ability to eat or drink?

- 7) Have they had to get any adaptations for their home (such as a chair lift or rails), or aids to get out of the house (such as a stick)?

Reflexive Monitoring

The interviewer will explore how stroke patients appraise the value of the advice provided and the therapies prescribed and does this lead them to modify their treatment regimens, if so, how and why? (reflexive monitoring)

- 1) The interviewer will explore how if at all, they have adapted or modified treatments or adherence to advice and the reasons for this?
- 2) Participants' thoughts/ideas about their treatments and management, including worries, will be explored. For example, whether they experience side effects or keep all their appointments and what has influenced their adherence or non adherence?
- 3) Whether participants discuss concerns or review their management plans with their doctor and how this has modified, if at all, how treatments will be explored? For example, are medications ever changed by the doctor or nurse and why?
- 4) Whether the participant's doctor has ever made changes to their treatment regime to make it easier for them to follow?
- 5) Finally, what strategies, if any, participants adopt to help them keep up to date with new treatments or the latest information on their condition?

At close of Interview

The interviewer will ask the participant if there are any issues they would like to mention which haven't been covered.

And thank the participant, and reiterate that all they have discussed is confidential.



INTERVIEW GUIDE 2: PATIENTS' PERCEPTIONS OF TREATMENT BURDEN

Background Information for the Interviewer

In situations where there is a lack of knowledge, questions will be posed in a manner which takes account of such a limitation.

The interview will be semi-structured in format, and thus the exact wording and prompts used may vary between patients to encourage the patient to share their views and allow them and opportunity to talk at length about their views about their illness and particularly their treatment and management.

Introduction Procedure with Patients

1. Give complete name.
2. Identify self as a researcher from the Department of General Practice and Primary Care at the University of Glasgow.
3. State that the doctors at the surgery know about the study.
4. Give short explanation of the purpose of the study:

'I would like you to help me understand what you feel about your stroke. I really just want to find out your views on how you have learnt to live and deal with your condition, the treatments and advice you have been given. Please feel assured that no one will be able to identify you from what you say when talking to me and everything you tell me will be treated in the strictest confidence.'

'We think it is important to know not only how the illness affects your body, but also how you think the management of your condition, for example the medications you have to take and the appointments you have to attend affect your everyday life, and if so in what ways?'

If at any time you want to stop, or have a break, please feel free to let me know.

'I will be recording the interview, so I can remember all that you have said to me.'

PATIENT PROFILE

Subject ID:

Age:

Gender: Male () Female ()

Length of Time Registered with Current Practice:

Less than 5 years ()

6 to 15 years ()

16 to 24 years ()

25 years + ()

Have you been in hospital for the condition you are taking _____ to treat?

Yes ()

No ()

Have you seen a specialist regarding your condition?

Yes ()

No ()

Marital Status:

Single ()

Married / Civil Partnership ()

Living with partner ()

Separated ()

Divorced ()

Widowed ()

Have you any Children?

Yes ()

No ()

Can I ask how many?	1	()
	2	()
	3	()
	4	()
	5+	()

Can you tell me whether you went on to any further education after secondary school? Yes/No

If yes, please describe.

Date and Time of Interview:

The interviewer will first of all explain:

We have done some previous interviews with people who have had a stroke and also looked at previous research done in this area, and would like to ask you about your thoughts on what we have found, and your own experiences.

COHERENCE

Based on results from previous interviews, patients will be asked about any positive and negative experiences of learning about / making sense of their stroke, the reasons for experiences being good or bad, and any improvements that could have been made by health services.

Interviewer will explain:

Some people who have had a stroke describe finding it difficult to gain information about their stroke, and in making sense of this information. Others feel overwhelmed by too much information. Different people prefer information being given in different forms. Some describe spending a lot of time thinking about and planning for the future, such as setting goals for their recovery.

The interviewer will therefore explore the following general areas in an open fashion:

- *Reaching a diagnosis of stroke*
- *Gaining info from health professionals*

2) *How did you do the following and what could have been done to make this easier?*

- *Making sense of what a diagnosis of stroke means*

- *Understanding the roles of different health professionals involved in your care*
 - *Understanding investigations and treatments that have been done / given to you*
 - *Self directed research on stroke and its management (books / leaflets / internet / media/ friends and family / life experience / stroke groups)*
- 3) *Do you find that receiving information makes your life harder or easier? What affects this, for example, does it make a difference if the information is written or verbal?*
- 4) *Did you ever receive conflicting information from different sources?*
- 5) *Do you think about the future with regards to the following and is there any way that health services could make this easier for you:*
- *The possibility of another stroke*
 - *How to prevent another stroke*
 - *What you would do if you thought you were having another stroke*
 - *Motivation to recover / prevent another stroke*
 - *Goal setting*
 - *The effect of stroke on your life*
 - *Coping strategies*

Cognitive Participation

Based on results from previous interviews, patients will be asked about positive and negative experiences of engaging with others and organizing their stroke care, the reasons for these experiences being good or bad, and any improvements that could have been made by health services.

Interviewer will explain:

People who have had a stroke describe seeking psychological and practical help from friends, family and other patients, and the difficulties they have with this. They also describe the difficulties they have interacting with health professionals for example speaking to doctors in the hospital, and booking appointments with their GP.

The interviewer will therefore explore the following general areas in an open fashion:

- 1) *Have your family helped with psychological and practical support such as transport, prescriptions, finances, help with therapies, aiding communication? Were there any areas of difficulty with this? Could health services help with this process in any way?*
- 2) *How have you found the experience of contacting your GP or the out of hours service for help or making an appointment? How could this be made easier?*

- 3) *How have you found the experience of contacting secondary care directly for help?
How could this experience have been made easier?*
- 4) *Do you have difficulty using the phone?*
- 5) *How do you get to your appointments at your GP or at the hospital? How could this be made easier?*
- 6) *Did you think that health professionals spent adequate time with you in hospital? Do you have any suggestions for how this may be improved?*
- 7) *How do you feel you have been treated by health professionals involved in your care? Do you have confidence in these health professionals?*
- 8) *Is it important to you to see the same health professional i.e. is continuity important to you? What is more important: seeing a health professional quickly or seeing someone that you have seen before?*

Collective Action

Based on results from previous interviews, patients will be asked about positive and negative experiences of carrying out activities involved in stroke management, the reasons for these experiences being good or bad, and any improvements that could have been made by health services.

Interviewer will explain:

People who have had a stroke sometimes describe negative experiences during their hospital stay. Some describe the time of discharge from hospital as very difficult. Once home they can find it challenging to take medications, see therapists, attend stroke groups, manage their stroke on a day to day basis. They may have to adapt their homes, move house or arrange their finances. They often find the time that they stop seeing therapists at home very difficult. Many also have other illnesses to manage at the same time.

The interviewer will therefore explore the following general areas in an open fashion:

- 1) *What was your experience of the following in hospital and how could these experiences have been improved?*
 - *Attending hospital / emergency department at the time of having your stroke?*
 - *Being an inpatient on the ward and receiving personal care?*
 - *Undertaking therapies as an inpatient?*
 - *Discharge from hospital?*

- 2) *What was your experience of the following at home and how could these experiences have been improved / what would have made your life easier?*
 - *Seeing therapists either at home or in the clinic?*
 - *Practicing therapies at home on your own?*
 - *Discharge from therapists in community?*
 - *Adapting your home or moving to a suitable house?*
 - *Obtaining walking aids or braces?*
 - *Arranging social care eg carers / home helps?*
 - *Returning to driving?*
 - *Returning to work?*
 - *Finding / attending a support group?*
 - *Arranging finances / dealing with the benefits system?*
 - *Taking medications and arranging prescriptions?*

- 3) *Have you had to buy any of your own healthcare, social care or equipment or pay for anything else yourself?*

- 4) *Has there been any significant delays in your care? Why do you think this happened?*

- 5) *Do you feel you received adequate psychological support during recovery?*

- 6) *Do you find contact with health professionals/ therapists helpful? Do you find it hard work, and if so, do you feel the work is worth it? What affects this? Overall, would you rather have seen therapists / health professionals more or less?*

- 7) *Do you find having several different health professionals looking after you a good or bad thing? Do you feel they communicate? How could this be improved?*
- 8) *Have you used technology at all during recovery e.g. an app on a smart phone? If so how did you find this?*
- 9) *Have you used any alternative therapies, if so, why, and how did you find the experience?*
- 10) *Have you made any changes to your lifestyle since your stroke and did you experience any difficulties with this? If so, what would have made your life easier?*
- 11) *Have you developed any coping strategies to deal with new disabilities and is there anything that would make this easier?*
- 12) *Do you have other illnesses to manage along with your stroke? If so, do you have any difficulties managing more than one illness? What would make your life easier?*
- 13) *Have you taken part in other research projects? Have you had any difficulties, and if so, what would make this easier (including this project)?*

Reflexive Monitoring

Based on results from previous interviews, patients will be asked about their experiences of reflecting on their stroke management, any difficulties they have had with this, and any improvements that could have been made by health services.

Interviewer will explain: People who have had a stroke describe spending time reviewing their stroke care on their own and with health professionals. They make decisions about their healthcare based on their own judgments, and on advice from others.

The interviewer will therefore explore the following general areas in an open fashion:

- 6) *How often do you see a health professional to review your stroke care? Is this too often / not often enough? Do you have any difficulties with this?*
- 7) *How often did you see a doctor in the hospital to review your stroke care? Was this too often / not often enough? Do you have any difficulties with this?*
- 8) *Do you try and keep up to date with new treatments available and if so, how, and do you have any difficulties with this?*
- 9) *Do you use the internet to look up information about your stroke?*
- 10) *Do you feel involved in decisions about your healthcare?*

- 11) *Are frequent changes made to your medications? How do you feel about this? What would make your life easier?*
- 12) *Do you monitor your own health at home in any way? What would make this easier?*
- 13) *How do you feel about your treatments / therapies? Have you ever stopped taking them / doing them against medical advice?*
- 14) *How do you feel about the progress you have made in recovering from your stroke? What could have improved this?*
- 15) *How have you found psychological adjustment after your stroke? Have you altered your expectations of recovery since diagnosis?*

At close of Interview

The interviewer will ask the participant if there are any issues they would like to mention which haven't been covered.

And thank the participant, and reiterate that all they have discussed is confidential.

Appendix 17 - Modified Rankin Scale

MODIFIED RANKIN SCALE (MRS)

Patient Name: _____

Rater Name: _____

Date: _____

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

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