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Exploring Rapid Evidence Synthesis Methods for Policy: A Case Study of Healthcare Regionalisation

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of Philosophy (PhD)

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Abstract

Policymakers' need for evidence generation is becoming increasingly complex, and multifactorial, driven by the diverse, interconnected challenges within health systems and the dynamic context in which decisions are made. Evidence-based medicine (EBM) has developed a range of evidence synthesis methods to support decision-making, but it is unclear how fully these methods meet the specific requirements of evidence-informed policy (EIP), particularly in terms of timeliness, contextual relevance, and usability for policymakers. To address these issues, evidence synthesis must be conducted efficiently within available resources while providing insights that are accessible and actionable for policy stakeholders.

New and emerging synthesis approaches, such as rapid realist reviews and umbrella reviews, have the potential to enhance EIP by producing timely, context-sensitive evidence that aligns with policymakers' needs. This thesis will investigate the application of rapid evidence synthesis methods to EIP. By investigating whether methods such as rapid realist reviews and umbrella reviews can provide timely, relevant, and context-sensitive evidence, the thesis seeks to explore their potential for improving decision-making processes. This thesis aims to evaluate the strengths and limitations of these methods in the context of real-world policy research, using healthcare regionalisation as a case study. The overall goal is to provide insights into how these methods might enhance the capacity of policy research groups to deliver robust, actionable evidence efficiently, thereby contributing to more effective policy development and implementation in complex and dynamic environments.

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Author's Declaration

I declare that I am the sole author of this thesis and was responsible for leading all aspects of this research, under guidance from my supervisors. A number of colleagues collaborated at various stages and they are formally acknowledged below.

Umbrella review

I acted as first reviewer during all stages of the review including paper screening, data extraction, quality appraisal and analysis. Neil Hawkins and Hilary Thomson acted as second reviewers for screening and supported my thinking in relation to the analysis.

Rapid-realist review

The search strategy for the realist review was developed after discussion with Paul Cannon from the University of Glasgow Library. I acted as first reviewer during all stages of the review including paper screening, data extraction, quality appraisal and analysis. Neil Hawkins, Emma Reece and Kate O'Donnell acted as second reviewers for screening and data extraction and supported my thinking in relation to the analysis.

Publications & Presentations

Publications

- Regionalisation of healthcare systems: an umbrella review, under review at Health Policy Open

Presentations

- A scoping review of definitions of patient-centred care, poster presentation, Structured Population health, Policy and Health-services Research Education (SPHeRE) conference 2023, poster presentation
- Healthcare regionalisation and patient-centred care: a rapid-realist review and implications for HTA, SPHeRE conference 2024, poster presentation
- Regionalisation and patient-centred care: a rapid-realist review. HTAi conference 2024, oral presentation

Abbreviations

CMO	Context mechanism outcome
CMOC	Context mechanism outcome configuration
EBM	Evidence-based medicine
EBP	Evidence-based policy
EIP	Evidence-informed policy
HRB	Health Research Board
IPPOSI	Irish platform for patient organisations, science and industry
OECD	Organisation for Economic Co-operation and Development
PCC	Patient-centred care
PRIOR	Preferred reporting items for overviews of reviews
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
PRISMA-ScR	Preferred reporting items for systematic reviews and meta-analyses extension for scoping reviews
RCT	Randomised controlled trial
RHA	Regional health area
RHO	Regional health organisation

Chapter 1 Introduction

To meet policymakers' needs, evidence synthesis must be conducted rapidly, presented in an accessible way, and produced within significant resource and time constraints. Policymakers are rarely in a position to engage with the full complexity of relevant primary studies and require concise, credible overviews that can directly inform decision-making (Langlois et al., 2019; Tricco et al., 2017, 2015). Yet, the demand for timely and usable evidence poses challenges: conventional systematic reviews are often resource-intensive and time-consuming, and their emphasis on predefined protocols and narrowly specified questions can limit responsiveness to contextual, political, and implementation factors that are central to policy decision-making. These challenges are particularly pronounced in the context of evidence-informed policymaking (EIP), where decisions must often be made under time constraints and in settings characterised by uncertainty, competing values, and varying local contexts. EIP is an approach to policy decisions that aims to ensure that decision-making is well-informed by the best available research evidence. It is characterised by the systematic and transparent access to, and appraisal of, evidence as an input into the policy-making process, even though the overall process of policy development may not itself be systematised or fully transparent (Oxman et al., 2009). This thesis will explore which methods for evidence synthesis might best meet the needs of policymakers working under an EIP framework.

In terms of intellectual foundations, the movement towards using research in decision-making has developed along several strands. Evidence-based medicine (EBM) emerged in the 1980s, emphasising the use of rigorous scientific research, particularly randomised controlled trials (RCTs), to improve clinical decision-making (Guyatt, 1991; Sackett, 1981). In the 1990s, evidence-based policy (EBP) gained traction as an offshoot of EBM, motivated by the need for empirical data in public policymaking more broadly (Cairney, 2016; Parkhurst, 2017). Unlike EBM, RCTs are rare in primary policy research; instead, a broader range of study designs and data sources is typically used.

Both EBM and EBP have been critiqued for overemphasising supposedly “gold-standard” evidence such as systematic reviews of comparative trials while overlooking political, social, and contextual realities (Head, 2010). In response, EIP was developed as a more inclusive framework. EIP integrates evidence synthesis as a central component, but also explicitly recognises the importance of stakeholder input, political feasibility, and local knowledge in shaping policy decisions (Boaz et al., 2019).

Central to both EBP and EIP is evidence synthesis, which identifies, reviews, and integrates findings from multiple studies to reduce bias, clarify complex issues, and inform policy decisions (Gough et al., 2020; Petticrew and Roberts, 2006). This approach strengthens the legitimacy and practicality of policies by ensuring they are grounded in the best available evidence, understood as evidence that is both methodologically sound and relevant to the policy question, context, and decision-making constraints. This includes quantitative evidence on effectiveness where available, qualitative and mixed-methods research that provides insight into implementation, acceptability, and mechanisms of change, as well as contextual and system-level evidence relevant to feasibility and transferability. The relative value of different forms of evidence is therefore contingent on the nature of the policy problem, the decision context, and the time available for decision-making. EIP and evidence synthesis are essential for developing effective, credible, and context-sensitive public policies.

However, evidence synthesis for EIP presents several challenges due to the complex and context-dependent nature of policymaking, which differs significantly from the controlled settings typical of clinical research with well-defined interventions. Traditional methods from EBM, like systematic reviews and quantitative meta-analyses may be limited in fully capturing the complexities of policy environments, where political, social, and economic factors heavily influence outcomes (Cairney and Oliver, 2017; Petticrew and Roberts, 2006). These methods also prioritise quantitative data, which may fail to capture the nuanced, qualitative aspects of policy impacts, particularly in fields such as public health or social care (Head, 2010). Additionally, interventions shown to be effective in one

context may not translate well to others due to differences in local governance, resources, or culture (Greenhalgh et al., 2014). Beyond methodological issues, the uptake of evidence in policymaking is influenced by political dynamics and timing; research must align with policy windows and be acted upon by decision-makers to drive change (Davis and Howden-Chapman, 1996; Kingdon, 2013). Moreover, the time required to conduct rigorous evidence synthesis can conflict with policymakers' need for timely decisions, creating a disconnect between research and practice. To address this, initiatives such as rapid response teams and dedicated evidence synthesis units, like those of the Canadian Institutes of Health Research's (CIHR) Best Brains Exchanges, the UK's National Institute for Health and Care Research (NIHR) Policy Innovation and Evaluation Policy Research Unit, and Ireland's Health Research Board's Evidence Centre have emerged to deliver timely, relevant evidence, though ensuring the availability and adaptability of suitable methods remains a key challenge (Government of Canada, 2011; "HRB Evidence Centre," 2025; NIHR Policy Research Unit, 2025).

1.1 Motivation for this thesis

Between 2018 and 2019, as part of my role at the Health Research Board (HRB) in the Republic of Ireland, I carried out research to inform the Irish Department of Health's approach to healthcare regionalisation. Healthcare regionalisation refers to the transfer of responsibility for healthcare services from centralised authorities or government bodies to regional entities, thus creating an intermediary level of governance (Church and Barker, 1998). The HRB research project aligned with implementation of the Irish government's 2016 initiative to reform healthcare, culminating in the 2017 *Sláintecare Report*, which mandated significant system changes, including the introduction of healthcare regions with regional responsibility for the delivery of healthcare and management of regional healthcare budgets. The Irish Department of Health commissioned the HRB to conduct an evidence review, within a timeframe of approximately 16 months, to inform the rollout of regionalisation in Ireland. While regionalisation of the healthcare system was strongly supported by Sláintecare, the HRB project aimed to inform the best design for healthcare regionalisation. My role in leading a

systematic review of the impact of healthcare regionalisation, including both quantitative and qualitative data, sparked the motivation for this PhD. I worked on the HRB project with two other researchers and a librarian. We performed a systematic review of published empirical evaluations to inform the decisions of policymakers; quantitative data were extracted on the impact of regionalisation and qualitative data were extracted on the barriers to and facilitators of effective regionalisation. Quantitative and qualitative findings were initially analysed separately before results were then integrated through a logic model. While this research was utilised by policymakers in implementing the regional health areas, the research was confounded by issues with context and compromised by the need for speed in research delivery. The HRB Evidence Centre, which was responsible for the review, has a small team of researchers, comprising five information specialists and eight researchers, some of whom work part-time (“Evidence Centre Team,” 2025), who work to deliver evidence reviews within a six-to-twelve-month timeframe (“Evidence Centre Team,” 2025). The project team for the review of healthcare regionalisation was comprised of three researchers supported by an information specialist. The HRB review found that regionalisation was typically introduced alongside broader healthcare reforms, often motivated by cost-containment or local autonomy, and its effects were highly context-dependent. Across countries, acute care resource utilisation generally decreased after regionalisation, but this was influenced by concurrent budget cuts. Mortality and most care indicators stayed the same or improved, though waiting times sometimes lengthened, however, it was difficult to determine if this was due to regionalisation alone, or improvements in healthcare more generally. Efficiency gains were reported in some settings, but cost savings were inconsistent, while some regions saw reduced expenditure, others experienced increases due to factors like staff costs or structural changes. Evidence on equity was mixed: regionalisation did not worsen income-related equity, but geographical disparities (for example rural versus urban) often persisted. Implementation barriers included tensions between regional organisations and central governments, inadequate funding formulas, unclear governance roles, and lack of capacity or training for regional boards. Facilitators included clear national strategies, supportive health

ministries, effective information systems, and strong engagement with staff and communities.

The Department of Health explicitly acknowledged the limitations of the HRB review, particularly those related to the contextual nature of its findings. In feedback received they acknowledged that regionalisation does not guarantee clear or consistent outcomes, since results were often shaped by local priorities, such as hospital cost-containment measures. Nonetheless, the Department of Health confirmed that the report had adequately addressed the research questions, providing a balanced assessment of both the positive and negative impacts of regionalisation, alongside the barriers and facilitators to implementation. The HRB review played a formative role in informing the Department of Health's approach to regionalisation in Ireland. Its findings supported the drawing of geographical boundaries for the Irish regional health areas and provided a foundation for ongoing discussions on the design, governance, and monitoring of Ireland's regionalised healthcare system. Crucially, the Department of Health's acknowledgement of the review's contextual limitations also underlined the need to reflect more deeply on the choice of evidence synthesis method. In addition, given that the review was resource-intensive, it raises questions about whether alternative approaches might have produced similarly useful insights in a more timely and efficient way, both issues explored in the following chapters. The issues encountered as part of the HRB research project motivated me to explore whether newer methods of evidence synthesis could provide better information for decision making for policymakers working in evidence-informed health policy.

Research groups engaged in generating and synthesising evidence to inform policy require techniques that can deliver robust findings quickly without requiring significant resource investments, but which also acknowledge and incorporate the context in which research findings will be implemented. It is hypothesised that newer synthesis methods could be beneficial for policymakers, presenting them with nuanced findings that more fully account for local and national contexts. The

objective of this thesis is to assess the applicability of these methods to EIP. This thesis will use healthcare regionalisation as a case study, allowing for the direct comparison of various evidence synthesis methods on the same topic.

1.2 Aims and research questions

The primary aim of this thesis is to assess the applicability and effectiveness of newer evidence synthesis methods in supporting policymakers and policy research groups working with limited time and resources. Umbrella reviews and rapid realist reviews were considered as methods that might be used to generate timely, relevant and context-sensitive evidence, this thesis explores their potential to strengthen evidence-informed decision-making in complex policy contexts.

To support this aim, the thesis draws on the evidence synthesis selection framework developed by Wickremasinghe et al. (2016), which provides a structured approach for comparing synthesis methods across dimensions such as utility, technical characteristics and resource requirements. While the framework was originally developed to guide the selection of evidence synthesis approaches, it has not previously been empirically tested through application to a real-world policy case study. The origins and applicability of this framework are outlined Chapter 2.

Using healthcare regionalisation in Ireland as a case study, this thesis applies and evaluates selected evidence synthesis methods in practice. In doing so, it examines the strengths and limitations of these approaches in the context of real-world policy research and considers how the Wickremasinghe et al. framework may be further refined based on insights generated through the application of these synthesis methods. In doing so, the thesis also seeks to generate empirically grounded insights to inform the refinement of the Wickremasinghe et al. framework for selecting evidence synthesis methods in policy-relevant research.

The thesis research questions are grouped into a priori methodological questions, which shaped the initial design and analytical framework of the thesis, and applied

case-study questions, which guided the subsequent empirical chapters focused on healthcare regionalisation.

A. *A priori* methodological questions

These questions were established at the outset of the research and relate directly to the thesis's central focus on identifying and evaluating appropriate evidence synthesis methods for policy-relevant questions:

1. Which evidence synthesis methods are most suitable for addressing evidence-informed policy questions?
2. What methodological challenges were identified in the Health Research Board's review of healthcare regionalisation?
3. Based on the methods identified as most suitable in Question 1, how do these approaches compare in their ability to provide timely, relevant, and context-sensitive evidence to support decision-making in healthcare policy?

These questions underpin the methodological orientation of the thesis and informed the subsequent selection and application of specific evidence synthesis approaches.

B. Applied case-study questions: healthcare regionalisation

Building on the above, and to enable the selected methods to be tested in a real-world policy context, the following questions were developed to guide the applied and empirical elements of the thesis:

4. How do umbrella reviews, rapid realist reviews, and traditional systematic reviews compare in terms of their ability to generate timely, relevant, and context-sensitive evidence, when assessed using the Wickremasinghe et al. (2016) evidence synthesis selection framework, and how can that framework be expanded with new considerations arising from this thesis?

Part 1:

5. What are the health system impacts and patient impacts of healthcare regionalisation according to existing review-level evidence? (umbrella review)

Part 2:

Three research questions were developed to support a rapid-realist review.

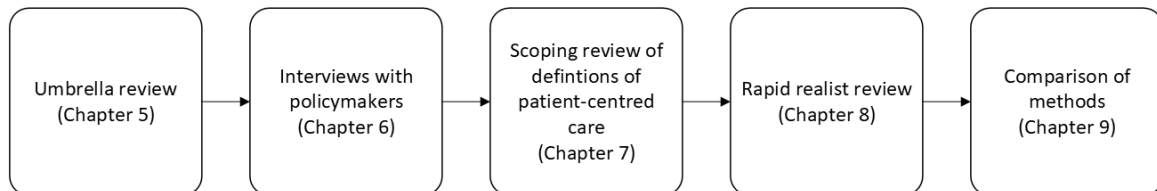
Question 6 was the overarching research question for part 2 of the thesis, however Research Questions 6a and 6b were prerequisite steps to inform the rapid realist review

6. Under what circumstances, and through what mechanisms, can healthcare regionalisation contribute to an increase or improvement in patient-centred care? (rapid realist review)
 - a) What are the specific goals of the introduction of regionalisation in Ireland, and what are the specific requirements for an evidence synthesis in this context? (Interviews with policymakers)
 - b) What is patient-centred care and what is the most appropriate definition for use in the context of healthcare regionalisation, specifically in Ireland? (scoping review)

Together, these research questions reflect the dual focus of the thesis: first, on critically examining the methodological suitability of evidence synthesis approaches for policy-relevant questions, and second, on applying and testing those approaches through an in-depth case study of healthcare regionalisation. The findings also provide an opportunity to reflect on how existing evidence synthesis selection frameworks, such as that proposed by Wickremasinghe et al., may be refined based on empirical application.

The research questions are addressed over five chapters as outlined in Figure 1-1.

Figure 1-1 Overview of thesis



1.3 Thesis structure

The material covered within each chapter of this thesis is now briefly outlined.

- Chapter 2 provides a background overview of evidence synthesis methodologies for evidence-informed policy. The chapter also examines existing approaches for selecting evidence synthesis methods and identifies the framework developed by Wickremasinghe et al. as a suitable tool for comparing synthesis methods in policy contexts.
- Chapter 3 provides an overview of the Health Research Board's evidence review and the case study intervention, regionalisation.
- Chapter 4 describes the methods used in this thesis. In particular, the rationale for the choice of methods to answer the research questions are presented.
- Results Part 1
 - Chapter 5 is an umbrella review of healthcare regionalisation.
- Results Part 2
 - Chapter 6 describes interviews that were conducted for the understanding of policymakers plans for healthcare regionalisation in Ireland.

- Chapter 7 is a scoping review of definitions of patient-centred care.
- Chapter 8 is a rapid realist review of healthcare regionalisation and patient centred care.
- Chapter 9 is the discussion chapter, drawing upon the findings from the four results chapters to compare and contrast methods of evidence synthesis in evidence-informed policy. The chapter reflects on the applicability of the Wickremasinghe framework, considers how insights from the case study may inform its further development, and discusses implications for policy, practice and future research.

Chapter 2 Evidence-synthesis methods for evidence-informed policymaking: a literature review

2.1 Overview

This chapter establishes the conceptual and methodological foundation for addressing Research Question 1: Which evidence synthesis methods are most suitable for addressing evidence-informed policy questions? It begins by introducing the principles of evidence-informed policy and the role of research evidence in policymaking. It then examines the critical function of evidence synthesis in supporting policy decisions, alongside the key limitations of traditional synthesis approaches when applied to complex, system-level interventions.

The chapter goes on to describe core concepts and approaches to evidence synthesis, before comparing traditional and emerging synthesis methods in terms of their relevance, strengths, and applicability to policy-oriented questions. Consideration is given not only to methodological characteristics, but also to the practical realities of conducting these reviews, such as resource requirements, time constraints, and the skills required of review teams. The chapter also explores the role of stakeholder engagement in strengthening both the relevance and impact of evidence synthesis for policy.

Drawing on this literature, the chapter identifies existing frameworks for selecting and comparing evidence synthesis methods. In particular, the evidence synthesis selection framework developed by Wickremasinghe et al. is examined as a structured approach for evaluating synthesis methods across a range of methodological and practical dimensions. This framework is subsequently used within the thesis to guide the comparison of synthesis approaches and to support the selection of methods for the healthcare regionalisation case study.

Together, these sections provide a structured basis for identifying which synthesis approaches are most appropriate for complex, real-world policy challenges such as

healthcare regionalisation. To inform this chapter, a targeted literature review was conducted, focusing on seminal and influential publications in the fields of evidence-informed policy and evidence synthesis. Seminal literature was identified through a combination of citation frequency, repeated reference across key policy and methodological texts, and prominence within established frameworks and typologies of evidence synthesis. Where appropriate, snowballing techniques were also employed to identify additional relevant literature cited within these seminal sources. Priority was given to peer-reviewed journal articles, foundational books, and widely cited methodological guidance that have shaped conceptual and practical debates in the field. This approach allowed for the identification of key concepts, methodological frameworks, and comparative evaluations of synthesis methods most relevant to complex policy questions, while ensuring that the review remained focused on literature with established influence and relevance to evidence-informed policy.

2.2 Evidence-informed policy

Evidence-based medicine (EBM) originated in the early 1980s as a response to the growing need for more rigorous, scientific approaches to clinical decision-making. The EBM movement started with David Sackett and colleagues based at McMaster University in Canada. In 1981, they published the first of a series of articles advising physicians how to appraise the medical literature (Sackett, 1981). The actual term ‘evidence-based medicine’ was first coined by Gordon Guyatt, as the Internal Medicine residency coordinator, at McMaster University in 1991 (Guyatt, 1991). EBM began as a movement to improve clinical decision-making by integrating the best available research evidence with clinical expertise and patient values (Guyatt, 1991; Sackett et al., 1996). Initially, EBM focused on applying the best available research to clinical practices to improve patient outcomes (Sackett et al., 1996). It was defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al., 1996, p. 71). At its core, EBM aims to promote clinical effectiveness by applying robust evidence from systematic research to practice, while also recognising the importance of individual patient perspectives,

preferences, and circumstances in guiding care decisions (Guyatt, 1991). Over time, EBM has come to be seen as a key framework for supporting more systematic and transparent approaches to healthcare decision-making.

Evidence-based policy (EBP) has developed as a new field, with roots in EBM, as policymakers and healthcare practitioners recognised the need for rigorous, empirical data to inform decision-making processes across a wider range of sectors (Florin, 1996; Soumerai et al., 1997). Over time, this approach extended beyond the clinical setting to encompass health policy and broader public policy, where it aimed to ensure that policies were grounded in robust evidence of effectiveness (Cairney, 2016). Evidence-based policy refers to policymaking that systematically draws on the best available empirical evidence (quantitative and qualitative), alongside theoretical insight, stakeholder perspectives, and contextual factors, to inform decisions. It involves institutional structures and norms that promote transparency, accountability, and balanced consideration of evidence in order to improve policy effectiveness and legitimacy (Cookson, 2005). The election of the UK Labour government in 1997 is often seen as a milestone for EBP - this government were elected on a platform of 'what matters is what works' (Blair and Cunningham, 1999; Davies et al., 1999; Demir, 2020). The transition to EBP was facilitated by the growing demand for transparency, accountability, and the need to address complex-health and social challenges with evidence that could guide interventions and allocate resources effectively (Nutley et al., 2007).

While the rise of EBP has brought greater transparency, accountability, and methodological rigour to policymaking, it has also revealed important advantages and limitations. On the one hand, EBP promotes the systematic use of research evidence to improve the effectiveness and efficiency of public policies, enabling decisions to be grounded in empirical data rather than intuition, ideology, or political expediency (Mays et al., 2005; Muir Gray, 2004). This approach can enhance policy legitimacy and resource allocation by linking interventions to demonstrable outcomes and encouraging continuous learning and evaluation (Nutley et al., 2007; Sheldon, 2005). However, the translation of evidence into policy is rarely straightforward. Policy processes are inherently political and value-

laden, shaped by institutional constraints, stakeholder interests, and contextual factors that may outweigh or reinterpret empirical evidence (Kingdon, 2013; Walt, 1994; Weiss, 1982). While Weiss (1982) first described the conceptual use of research as a means of shaping policy thinking rather than prescribing decisions, subsequent scholars have shown that evidence is also used strategically to legitimise or justify existing policy positions (Cairney, 2016; Parkhurst, 2017). Consequently, while EBP aspires to rational, evidence-based decision-making, in practice, evidence is only one of several competing influences on policy. These limitations have prompted calls for a more nuanced understanding of how evidence interacts with context, power, and values in policymaking.

Over the past two decades, there has been another notable conceptual and practical shift from EBP to evidence-informed policy (EIP). While EBP emphasised the importance of scientific evidence such as randomised controlled trials and systematic review, as the basis for policy decisions, this approach was increasingly critiqued for its technocratic assumptions and limited responsiveness to political, contextual, and experiential factors (Head, 2010). In response, EIP emerged as a more inclusive and pragmatic model, recognising that while high-quality evidence is essential, policy decisions must also consider values, stakeholder input, feasibility, and local context (Boaz et al., 2019). EIP thus represents a more considered and negotiated use of evidence, better suited to the complexity of real-world governance. The fundamental understanding of EIP is that rather than seeking to dictate policy through scientific findings, evidence supports policymakers in integrating a broader range of knowledge types, enhancing both the legitimacy and practicality of policy interventions (Head, 2010; Parkhurst, 2017).

EIP relies on a range of evidence and evidence synthesis methods to ensure that public policies are both effective and efficient in achieving desired outcomes. Evidence synthesis is the review of what is known from existing research, using systematic and explicit methods, in order to clarify the evidence base (Gough et al., 2020). Within EIP, evidence synthesis is used to integrate and summarise findings across diverse bodies of research, including quantitative, qualitative, and

mixed-methods studies. This enables policymakers to assess the overall body of knowledge on a particular issue, particularly in complex policy areas where evidence is heterogeneous and no single study or review provides definitive answers. By combining results from multiple studies and perspectives, evidence synthesis can help reduce bias, strengthen the robustness of conclusions, and support judgement in situations characterised by uncertainty and contextual variation (Gough et al., 2017). By synthesising diverse sources of evidence, evidence synthesis ensures that policies are informed by a thorough analysis of the available data, increasing their effectiveness and credibility (Petticrew and Roberts, 2006).

Most commonly used evidence synthesis methods such as systematic review have origins in EBM. However, using methods developed for EBM in EIP presents several challenges due to the distinct nature of policy decision-making compared to clinical practice. First, EBM methods, such as systematic reviews and meta-analyses, are primarily designed to evaluate the effectiveness of interventions in clinical settings, where variables can be isolated and controlled (Cairney and Oliver, 2017). However, policy interventions operate in more complex, multifaceted environments where multiple contextual factors—such as political, social, and economic influences—affect outcomes, making it difficult to generalise findings from clinical trials to real-world policy settings (Petticrew and Roberts, 2006). Additionally, EBM prioritises quantitative data, which may not be sufficient for capturing the complexities and nuances of policy outcomes, especially in areas like social care or public health (Head, 2010). There are also areas of health policy for which it is either very difficult or inappropriate to conduct randomised controlled trials, particularly in relation to patient-centred outcomes such as equity (Buse et al., 2024). Another challenge is the context-specific nature of policy, where interventions that work in one setting may not be effective or feasible in another, due to differences in local governance, resources, or cultural factors (Greenhalgh et al., 2014). The growing recognition of these challenges has led to calls for the adaptation of evidence synthesis methods to better suit the unique needs of policymakers.

Additionally, as indicated in section 2.2, it is not just evidence alone that makes policy change. Evidence must be acted on by policymakers (Kingdon, 2013). Kingdon's multiple streams framework illustrates how research evidence represents only one component of policy change, alongside problem recognition and political considerations (Kingdon, 2013). While a detailed examination of agenda-setting and policymaking processes falls outside the scope of this chapter, this literature is relevant insofar as it underscores the limits of assuming a linear relationship between evidence and policy action. Empirical analyses of health system reform similarly suggest that major policy shifts have often been driven by fiscal pressures, ideological currents, and political feasibility rather than by comprehensive assessments of research evidence alone (Davis and Howden-Chapman, 1996). This reinforces the importance of evidence synthesis approaches that are sensitive to context, complexity, and policy realities, an issue taken up in later sections of this chapter.

While evidence synthesis provides a more time-efficient way to compile and analyse a large body of existing research than conducting new primary studies, it can still face challenges in delivering findings quickly enough to meet urgent policy needs. Policymakers may be forced to make decisions in the absence of evidence when decisions need to be taken before research can be completed; evidence synthesis misses the window of opportunity for impact in these cases (Buse et al., 2024). Policymakers frequently face pressing timelines and other pressures that traditional academic research processes are ill equipped to address, resulting in a disconnect between evidence production and policy needs (Oliver et al., 2014). To address this, many governments and health systems have established dedicated evidence synthesis teams or rapid response units linked to health ministries. These teams, such as the Canadian Institutes of Health Research's (CIHR) *Best Brains Exchanges*, the UK's National Institute for Health and Care Research (NIHR) *Policy Innovation and Evaluation Policy Research Unit* or Ireland's Health Research Board's *Evidence Centre*, are designed to provide timely, policy-relevant evidence tailored to specific decision-making contexts (Government of Canada, 2011; "HRB Evidence Centre," 2025; NIHR Policy Research Unit, 2025). By streamlining access to existing research, conducting rapid evidence synthesis, and fostering sustained

researcher-policymaker relationships, these initiatives aim to improve the speed and relevance of evidence use. However, the availability and practicality of suitable evidence synthesis methods for policy for these teams to ensure timeliness is a persistent issue.

2.3 Concepts and methods of evidence synthesis

Evidence synthesis refers to the systematic process of gathering, evaluating, and combining findings from multiple studies to provide a comprehensive understanding of a particular research question or policy issue. This process aims to aggregate diverse research findings in a transparent and reproducible way, using methods such as systematic reviews, meta-analyses, realist reviews, and scoping reviews (Gough et al., 2017; Petticrew and Roberts, 2006). By synthesising evidence, researchers can identify patterns, assess the quality of existing studies, and generate more robust conclusions than individual studies alone. Evidence synthesis is particularly valuable in informing EIP, as it provides policymakers with an aggregated view of the best available evidence on complex issues (Greenhalgh et al., 2014). This approach enhances the reliability and relevance of the evidence used in decision-making, ensuring that policies are based on a thorough evaluation of existing research rather than on isolated or anecdotal information (Cairney and Oliver, 2017).

Systematic review has been the staple of evidence synthesis for policy since the advent of EBP. A systematic review seeks to systematically search for, appraise and synthesis research evidence, typically following standard guidelines (Grant and Booth, 2009). Systematic review is often combined with meta-analysis which is a technique that statistically combines the results of quantitative studies to provide a more precise effect by combining results from multiple studies (Grant and Booth, 2009). There are now many variations on this basic formula for systematic review, from incorporating alternative types of evidence to getting to results more rapidly. A comprehensive typology of review types was published Sutton et al. in 2019 (Sutton et al., 2019). Sutton et al. identified 48 review types, and these review types were categorised into seven broad review ‘families’: traditional reviews, systematic reviews, review of reviews, rapid reviews, qualitative reviews, mixed

method reviews, and purpose specific reviews. However, a persistent issue identified is that there are frequently inconsistencies or overlaps between the descriptions of nominally different review types. This can lead to confusion when trying to select the most appropriate evidence synthesis method.

Newer methods in evidence synthesis have evolved to address the growing need for more flexible, efficient, and context-sensitive approaches to synthesising research findings. One such method is the rapid review, which streamlines the traditional systematic review process by shortening timelines and reducing the scope of data extraction and analysis, making it suitable for time-sensitive policy decisions (Khangura et al., 2012). Another innovative approach is the realist review, which focuses on understanding *how* and *why* interventions work in specific contexts, providing insights into the mechanisms of change and contextual factors that influence outcomes (Pawson, 2006). Additionally, umbrella reviews, which synthesise findings from multiple systematic reviews and meta-analyses, are gaining popularity as they allow for high-level, comprehensive summaries of existing evidence on broader topics (Grant and Booth, 2009). These methods cater to the evolving needs of policymakers and practitioners by offering timelier, relevant, and nuanced evidence synthesis to inform decision-making in complex and rapidly changing environments.

As the field of evidence synthesis continues to mature, the selection of an appropriate synthesis approach is increasingly recognised as contingent upon the purpose of the review, the characteristics of the available evidence, and the practical constraints under which the review must be undertaken. Within the context of EIP, traditional systematic reviews, while methodologically robust, have been critiqued for their limited responsiveness to the urgent and contextually complex questions faced by policymakers (Greenhalgh et al., 2011a; Tricco et al., 2015). This has prompted the development of alternative and adaptive review types that seek to balance rigour with responsiveness. Rapid-realist review has emerged from this evolution, combining the explanatory focus of realist synthesis, which seeks to understand how, why, and in what contexts interventions work—with the pragmatic, time-efficient features of the rapid review (Saul et al., 2013;

Wong et al., 2013a). In parallel, umbrella reviews have gained prominence as integrative syntheses of existing systematic reviews and meta-analyses, offering policymakers high-level summaries of the available evidence on broad and complex topics (Grant and Booth, 2009).

Accordingly, the remainder of this chapter focuses on three key evidence synthesis methods, systematic review, umbrella review, and rapid realist review, to enable a structured comparison of their respective utility, methodological characteristics, and resource implications. Because rapid-realist review is a relatively new and less well-documented approach, insights from the broader rapid review and realist-review literatures are also incorporated to provide methodological context and strengthen the discussion. This focus provides a coherent framework for examining how these synthesis methods differ in their capacity to address the multifaceted and contextualised evidence needs that characterise contemporary policy challenges.

Given the complexity of the policy questions addressed in this thesis, relating both to the design and expected impacts of healthcare regionalisation, and to the suitability of different evidence synthesis approaches for informing such policy decisions, these three synthesis methods were selected because they can integrate diverse forms of evidence while accounting for contextual variation and underlying mechanisms. Together, they represent a continuum from aggregative to explanatory approaches, allowing for a comprehensive exploration of how evidence synthesis can best inform policymaking in complex health system reforms. Given this predetermined selection, the purpose of this chapter is twofold: to provide a descriptive comparison of these methods, highlighting their methodological characteristics, utility, and resource implications, and to offer further justification for their selection in the context of this thesis.

2.4 Comparison of emerging synthesis methods to traditional synthesis methods

To provide a structured and transparent comparison of the three review methods, this chapter applies the evidence synthesis framework developed by Wickremasinghe et al. (2016). While this framework is often used to guide method selection, in this context it is applied descriptively, to evaluate how each review type performs across four domains: key features, utility, technical characteristics, and resources required.

2.4.1 Wickremasinghe et al. framework

The Wickremasinghe et al. (2016) framework provided the structural basis for this descriptive comparison, as it accommodates quantitative, qualitative, and mixed-methods synthesis—key for evaluating systematic reviews, umbrella reviews, and rapid-realist reviews that integrate diverse forms of evidence. To ensure a comprehensive and nuanced analysis, this framework was supplemented with extensive additional literature, drawing on methodological studies, seminal texts, and recent evaluations of evidence synthesis approaches. The Wickremasinghe et al. (2016) framework explicitly considers the needs of evidence users, aligning with the thesis focus on EIP, and allows the comparison to reflect not only methodological rigour but also factors such as timeliness, applicability, and accessibility for policymakers. By including practical considerations such as time, personnel, and expertise, the framework supports a realistic assessment of feasibility for different synthesis approaches, which is critical in applied health policy contexts. While Sutton et al.'s (2019) typology is used in this chapter to classify and describe different review types, including the recognition of rapid realist review as a distinct approach, the Wickremasinghe et al. framework was selected as the primary analytical tool because it was the only identified framework that simultaneously (a) supports comparison across diverse synthesis traditions, (b) integrates mixed-methods approaches, and (c) is explicitly designed to inform decision-making in policy-relevant contexts.

The Wickremasinghe et al. (2016) framework was developed through a structured exploratory review of literature on evidence synthesis methods and their use in

policymaking, combined with consultation with experts involved in knowledge translation and evidence synthesis. The authors conducted a multi-strand literature search including bibliographic databases of peer-reviewed literature, hand searching of key methodological journals, and targeted searches of grey literature from organisations involved in evidence synthesis for policy. This was complemented by a snowballing approach to identify additional relevant sources. Insights from this literature were then refined through consultation with a purposively selected panel of experts with experience in producing evidence syntheses for policy audiences. Through iterative discussion and synthesis of the literature and expert insights, Wickremasinghe et al. developed a framework designed to guide the selection of evidence synthesis approaches according to both methodological characteristics and the practical needs of policymakers.

Building on this development process, the Wickremasinghe et al. framework was not empirically tested at the time of its publication, but was instead derived from a synthesis of the literature and informed by expert consultation and consensus. As such, it was conceived as a conceptual tool to guide the selection of evidence synthesis approaches based on both methodological characteristics and the needs of evidence users. Targeted searches of the methodological literature conducted as part of this thesis did not identify studies that had empirically applied the framework to compare multiple synthesis methods within a single research programme. However, the framework has been cited in the literature in discussions of evidence synthesis for policymaking and has been used to support the justification for selecting particular review approaches in applied research contexts, including scoping reviews and other policy-oriented syntheses. This thesis therefore provides an opportunity to apply the framework in practice by comparing systematic review, umbrella review, and rapid realist review within the context of a single policy case study. Through this application, the thesis not only uses the framework to guide a descriptive comparison of synthesis methods but also generates insights into its practical strengths and limitations when used to support evidence-informed policymaking.

In this chapter, three principal synthesis methods, systematic review (with or without meta-analysis), umbrella review, and rapid-realist review, are compared using the Wickremasinghe et al. framework. These methods were chosen because they represent the principal synthesis approaches applied within this thesis to explore regionalisation and are among the most relevant for addressing complex policy questions that require the integration of varied evidence types and consideration of contextual mechanisms. As rapid realist review is a relatively new and evolving method, reflections on realist synthesis and rapid review are also incorporated to supplement published evaluations and strengthen the analysis.

The comparison is structured under the domains of utility, technical characteristics, resources required, and skills of the team, reflecting the practical considerations faced by researchers and policymakers when selecting an appropriate synthesis method. The framework comprises four domains: key features, utility, technical characteristics, and resources, however, this chapter also considers the skills of the team that would be required to undertake the synthesis as an additional domain, as suggested by Tricco et al. (2016).

In addition to these methodological domains, the framework highlights the importance of aligning review design with the needs of the evidence users. Wickremasinghe et al. propose four key dimensions, collectively referred to as the 4 Rs, which ensure that reviews are not only methodologically robust but also relevant and accessible for policymakers. These dimensions are:

1. **Rigour** - The transparency, reproducibility, and systematic documentation of decisions and analytical steps in the synthesis. High rigour ensures credibility and confidence in the findings.
2. **Relevance** - The degree to which the review addresses the context and questions of interest to policymakers, including the timeliness of the review and its applicability to specific settings.

3. **Readability** - The clarity and accessibility of the review report, including the use of plain language, logical structure, and clear explanation of how conclusions were reached. Readable reviews enhance comprehension and uptake by non-specialist audiences.
4. **Resources** - The time, personnel, and funding available to conduct the review. Resource considerations influence the feasibility of completing the review to a given standard within policy timelines.

Sutton et al's (2019) typology of different review types was used to classify evidence synthesis types as it is recent and recognises rapid-realist review as a distinct method (Table 2-1). Information has also been extracted from the Wickremasinghe to inform the comparisons (Wickremasinghe et al., 2016).

Table 2-1 Definitions of synthesis methods compared in this section

Synthesis type	Definition
Systematic review	All review types in the systematic review family employ a comprehensive search approach as a defining feature.
Umbrella review	Specifically refers to reviews compiling evidence from multiple reviews into one accessible and usable document.
Realist Synthesis Also known as: Realist Review	Answers the question “What works for whom under what circumstances?” rather than “What works?”. Specifically, it seeks to ‘unpack the mechanism’ of how complex programmes work (or why they fail) in particular contexts and settings.
Rapid review	Knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a short period of time.
Rapid Realist Synthesis Also known as: Rapid Realist Review	Applies a realist approach to knowledge synthesis (“What works for whom under what circumstances?”) to produce a product that is useful to policymakers in responding to time-sensitive and/or emerging issues within limited time and

Synthesis type	Definition
	resources. Can be purposive and opportunistic in their approach to sampling, drawing on expert advice or readily available local documents as a basis for theories

Source: (Sutton et al., 2019)

This descriptive application of the Wickremasinghe et al. framework provides a coherent basis for comparing systematic, umbrella, and rapid realist reviews in terms of their methodological characteristics, utility, and resource implications. It also sets the stage for Chapter 9, where the framework is further expanded and updated to incorporate insights from the empirical evaluation of these three reviews. In that chapter, the framework is used to assess how each method performed in practice, including their capacity to address context, explanatory depth, and timeliness, and to provide additional considerations for selecting and adapting evidence synthesis methods in policy-relevant settings. This linkage ensures continuity between the conceptual foundation established here and the applied evaluation, highlighting both the descriptive and analytic value of the framework within the thesis.

2.4.2 Key features

The key features of the evidence synthesis methods are outlined in Table 2-2.

Table 2-2 key features of evidence synthesis methods

Method	Key features	References
Systematic review	• Protocol driven • Explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies • Can incorporate peer-reviewed and grey literature • Draws a clear scientific conclusion • Adheres to published guidelines • Systematic search	(Grant and Booth, 2009; Schick-Makaroff et al., 2016; Wickremasinghe et al., 2016)

	• Can include meta-analysis, if appropriate	
Rapid review	• A quick review of key, easily accessible evidence, from research and other sources, on a particular (constrained) topic • Often produced for a specific, time bound purpose • Components of the systematic review process are simplified or omitted to produce information in a short period of time • Can be proposed as an intermediary step to be followed by a more comprehensive review • No consistent definition	(Haby et al., 2016; Schick-Makaroff et al., 2016; Tricco et al., 2015; Wickremasinghe et al., 2016)
Umbrella review	• A review compiling evidence from multiple reviews into one accessible and usable document • An umbrella review focuses on a broad condition or problem for which there are two or more potential interventions and highlights reviews that address these potential interventions and their results • Explore consistency of findings across reviews, and to summarise, integrate, synthesise and compile evidence from multiple systematic reviews into one • Uses systematic and explicit methods similar to systematic reviews	(Grant and Booth, 2009; Hartling et al., 2012)
Realist review	• Answers the question “What works for whom under what circumstances?” rather than “What works?”. Specifically, it seeks to ‘unpack the mechanism’ of how complex programmes work (or why they fail) in particular contexts and settings • Theory-driven approach • Beginning with the theory that (apparently) underlies a particular programme or intervention, it seeks evidence in many forms, including formal study reports (both qualitative and quantitative) as well as case studies, media reports and other diverse sources, and integrates them by using them as forms of proof or refutation of theory	(Booth, 2016; Dixon-Woods et al., 2005; Petticrew et al., 2013)

	Highly iterative approach	
Rapid-realist review	Applies a realist approach to knowledge synthesis to produce a product that is useful to policymakers in responding to time-sensitive and/or emerging issues within limited time and resources.	(Booth, 2016; Saul et al., 2013)

2.4.3 Utility of different forms of evidence synthesis

2.4.3.1 Traditional systematic review

Wickremasinghe et al. (2016) suggest the primary audience for systematic reviews are administrative and managerial professionals. When time and resources are available, systematic review provides the most comprehensive and commanding summary of a body of evidence at a particular point in time, to inform policy decisions or programme designs (Wickremasinghe et al., 2016). Although effectiveness-focused systematic reviews remain common, methodological studies have documented growing recognition that systematic reviews can incorporate quantitative, qualitative, and mixed-methods evidence when addressing complex or policy-relevant questions (Grant and Booth, 2009; Mallidou, 2014; Schick-Makaroff et al., 2016).

An additional benefit of meta-analysis, which can accompany systematic review, is the facility to take individual studies, often without statistical significance, and not in themselves sufficient to impact on practice, and to assimilate them into a composite evidence base which shows a strong direction of effect useful for decision-making (Grant and Booth, 2009).

2.4.3.2 Rapid review

Wickremasinghe et al. (2016) suggests that policymakers are the primary audience for rapid reviews. The purpose of a rapid review is to produce a fast review of the literature, within a defined and usually limited time frame, on a question of immediate importance to a stakeholder group, overcoming the barrier of lack of timely and relevant research (Haby et al., 2016; Schick-Makaroff et al., 2016).

They may also be used to help identify key issues and/ or questions for more in-depth reviews (Wickremasinghe et al., 2016).

Rapid reviews aim to be rigorous and explicit in method, and therefore systematic, but must make concessions to the breadth or depth of the process by limiting particular aspects of the systematic review process (Grant and Booth, 2009). Aspects of the review which may be limited include breadth of research question, sources searched, variables extracted, quality and relevance assurance measures, and depth of analysis (Gough et al., 2012; Grant and Booth, 2009).

2.4.3.3 Umbrella review

The framework of Wickremasinghe et al. (2016) suggests the primary audience for umbrella reviews are researchers and academics. However, Caird et al. (2015) suggests umbrella reviews are also suitable for policymakers.

Umbrella reviews are undertaken where multiple systematic reviews already exist within a given topic area and are designed to synthesise findings across these reviews rather than return to primary studies (Wickremasinghe et al., 2016). As such, their feasibility is contingent on the maturity of the evidence base. Caird et al. (2015) suggest that umbrella reviews may be particularly useful in contexts where policy timelines are constrained, as they allow decision-makers to draw on existing syntheses rather than commissioning new primary systematic reviews.

Grant and Booth (2009) report that umbrella reviews were initially conceived to be part of the Cochrane Library, providing a quick overview (and an exhaustive list) of reviews relevant to the decision at hand. More broadly, they frame umbrella reviews as a methodological response to a recurring tension in evidence synthesis: whether to undertake broad reviews spanning multiple interventions, potentially at the expense of depth and specificity, or to rely on multiple narrowly focused reviews, which may fragment understanding across a policy domain. In this context, umbrella reviews are presented as one approach to mediating this trade-off by integrating findings across existing reviews.

Caird et al. (2015) further suggest that when broad research questions co-occur with urgent policy deadlines and budgets prohibiting the employment of extremely large research teams, reviewing all relevant primary research may represent an insurmountable challenge and as such umbrella reviews may sometimes be the only means by which research evidence for broad policy questions may be mediated at speed.

2.4.3.4 Realist review

When the surrounding context or multiple mechanisms could be influencing outcomes, theory driven methods such as realist review may be appropriate (Viswanathan et al., 2017). The explicit purpose of a realist review is to guide programme and policy development by providing decision makers with programme theory or hypotheses that identifies potential policy or practice levers for change (Kastner et al., 2016; Schick-Makaroff et al., 2016; Tricco et al., 2016). Realist review is used to investigate complex questions to inform what works, for whom, under what circumstances, and why (Kastner et al., 2016). By taking the theory of the programme or intervention as the unit of analysis, realist review has the potential to maximise learning across policy, disciplinary and organisational boundaries (Tricco et al., 2016). Engagement of stakeholders is a built in part of realist synthesis, with policymakers and practitioners involved in the process to define the research questions, and interpret and disseminate the findings (Kastner et al., 2016; Schick-Makaroff et al., 2016). Realist review can generate theories that are generalisable across contexts (Tricco et al., 2016). The emphasis on an explanatory approach is inherently attractive to both researchers and policymakers who want to take an approach from one country or setting and apply it to another (Sheldon, 2005).

In realist review, the assumption is that all forms of data have something to contribute to knowledge and theory in a topic area, and evidence will be assessed in terms of its contribution rather than according to some pre-set criteria based on quality. The approach therefore differs from the predominantly a priori strategy used in traditional systematic review (Gough et al., 2012). Realist review includes a range of data types such as both quantitative and qualitative studies, theoretical

work, case studies, evaluations, epidemiological studies, trials, and policy documents (Schick-Makaroff et al., 2016; Tricco et al., 2016). With this method small studies that might be individually perceived as of poor quality, can be combined as data to support or refute the propositions developed (Tricco et al., 2016). Emerging methods such as realist review all have a defined but flexible process, in recognition that the methods may need to shift as knowledge develops through the process (Schick-Makaroff et al., 2016). Realist review is widely acknowledged as a method that can provide a deeper understanding of how and why interventions work in particular contexts (Kastner et al., 2016; Sheldon, 2005; Tricco et al., 2016)

Realist review is applicable to both policy and clinical questions, and the finding of realist review can directly inform policy, public health or clinical decisions (Kastner et al., 2016; Wong et al., 2013b). However, realist synthesis is less suitable than other review methods for certain topics and questions; for example, those which seek primarily to determine the average effect size of a simple intervention administered in a single or limited range of conditions (Wong et al., 2013b).

2.4.3.5 Rapid-realist review

Brownson et al. (2022) suggest that to advance policy implementation research, the pace of evidence development needs to be sped up; policymakers often need information in a much shorter time frame than researchers can deliver and this calls for the use of tools such as rapid-realist reviews. Saul et al. (2013) suggest that rapid-realist review is a useful tool for addressing time-sensitive policy decisions on system-level programmes or initiatives. They outline methodology that they suggest is scalable with respect to involvement of external experts based on the time and resources available. The rapid-realist review methodology can work well in contexts where there is limited evidence due to its incorporation of practice evidence via expert panels.

2.4.4 Technical characteristics of different forms of evidence synthesis outputs

2.4.4.1 Quality appraisal

Quality appraisal can be a time-consuming step in the evidence synthesis process especially when required to be completed in duplicate. Quality appraisal is definitively linked to resource requirements. Therefore, if a method dictates that full quality appraisal must be undertaken this method may not be appropriate when resources are restrained (Wickremasinghe et al., 2016). Quality appraisal of all included studies in a key component of systematic review methods (Boutron et al., 2019). Formal quality assessment of systematic reviews included in umbrella reviews is also required (Mallidou, 2014; Wickremasinghe et al., 2016). For rapid-realist reviews, there is no guidance on whether quality appraisal should be considered (Saul et al., 2013). Quality appraisal of primary studies included in full realist review depends on judgement and reflexivity on the part of the person/persons undertaking the review (Mallidou, 2014; Tricco et al., 2016). According Schick-Makaroff et al. (2016) realist review supports the principle that high quality evidence should be used but takes a different position than in systematic reviews on how the evidence is to be judged; quality appraisal is seen as occurring in stages with a focus on the relevance of the study to the theory under consideration, and the extent to which there is rigour in an inference to make a credible contribution to the test of a particular intervention theory. Realist review will assess the value of evidence in terms of its contribution rather than according to pre-set criteria (Gough et al., 2012). Quality appraisal in rapid reviews is limited, in some cases no appraisal is conducted and in others an abridged assessment is carried out (Mallidou, 2014; Schick-Makaroff et al., 2016; Wickremasinghe et al., 2016).

2.4.4.2 Evidence presentation

According to Wickremasinghe et al. (2016), each potential audience has different knowledge needs and the evidence may need to be presented in different ways to enhance its utility. All evidence-synthesis methods typically use some combination of narrative description, tables and graphics to present evidence (Wickremasinghe et al., 2016).

Emerging evidence-synthesis approaches, such as realist reviews and rapid realist reviews, pose unique challenges when attempting to translate findings into policy-relevant outputs. While these methods, by emphasising context, mechanism, and outcome configurations, offer deeper explanatory insight into *how* and *why* interventions succeed or fail in specific settings (Pawson et al., 2005; Saul et al., 2013), these same strengths contribute to difficulties in communicating results to policymakers, who require clear, concise, generalisable, and actionable messages (Greenhalgh et al., 2011b). Realist reviews tend to be philosophically and theoretically dense, involving iterative search strategies and theory development, which may not align well with the pragmatic demands of policy decision-makers (Rycroft-Malone et al., 2012).

Rapid-realist review methods were developed partly to address time constraints in policymaking, maintaining fidelity to realist reasoning while accelerating output, but they nevertheless require significant expertise, stakeholder engagement, and iterative refinement to ensure that complexity is not lost (Jagosh, 2019; Saul et al., 2013). Moreover, findings from realist reviews are often context-dependent, whereas policymakers may prefer recommendations that appear universally applicable. The nuanced and conditional nature of realist findings may therefore be harder for non-academic audiences to interpret or to translate into policy without supplementary framing (Greenhalgh et al., 2011b).

Given these issues, there is a clear need for further methodological guidance on how to present realist and rapid realist review findings in ways that are both rigorous and accessible to policymakers. This includes simplifying complex theoretical constructs without misrepresenting them, framing findings in policy-relevant language, providing executive summaries or policy briefs, and involving stakeholders in interpretation and dissemination (Greenhalgh et al., 2011b; Rycroft-Malone et al., 2012).

2.4.4.3 Systematic documentation and replicability

According to Wickremasinghe et al. umbrella reviews, systematic reviews and rapid reviews require a systematic documentation of evidence for a particular research

question through systematic and transparent identification of studies.

Wickremasinghe et al. also consider realist reviews (as part of mixed-methods research synthesis) to require comprehensive systematic documentation, however, others have indicated this may be less stringent than a traditional systematic review (Tricco et al., 2016).

According to Wickremasinghe et al. only systematic reviews have a high degree of replicability; umbrella reviews, rapid reviews, and mixed methods review (including realist review) have a medium degree of replicability (Wickremasinghe et al., 2016). This characterisation reflects the more iterative and interpretive elements often involved in these methods. However, it should be noted that replicability can be enhanced in umbrella and rapid reviews when a detailed, transparent protocol is followed, and in realist or mixed-methods reviews when methodological standards such as RAMESES (Realist And Meta-narrative Evidence Syntheses: Evolving Standards) (Wong et al., 2013a) are applied. Thus, the medium replicability rating should be interpreted as a practical tendency rather than an intrinsic limitation of the method. Reporting guidelines such as the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement, and its adaptations for different review types, and RAMESES for realist review have meant that most evidence synthesis methods are required to be systematically reported (Page et al., 2021; Wong et al., 2013a). All the methods covered in this chapter required systematic methods for searching.

2.4.4.4 Periodic update

A major limitation of systematic reviews, meta-analyses and umbrella reviews is that they rapidly go out of date (Schick-Makaroff et al., 2016; Wickremasinghe et al., 2016). While this might be true for evidence synthesis of quantitative data Schick-Makaroff et al. (2016) indicated that those synthesis that produce theory might be less likely to go out of date.

2.4.5 Limitations

Although this sits within technical characteristics in the Wickremasinghe evidence synthesis framework, there is a significant amount of data related to this domain and so it is presented separately here.

2.4.5.1 Systematic review

There are several widely acknowledged limitations of traditional systematic reviews. Systematic reviews are resource intensive, as are most non-rapid synthesis methods (Wickremasinghe et al., 2016). Typically, systematic reviews focus on randomised controlled trials, or quantitative comparative studies excluding qualitative studies, theoretical work, and epidemiological studies (Grant and Booth, 2009; Schick-Makaroff et al., 2016). This restriction limits what can be learned in a topic area providing only insights about effectiveness, rather than seeking answers on why a particular intervention is effective (Grant and Booth, 2009; Schick-Makaroff et al., 2016). Traditional systematic reviews may have a narrow, well-defined, clinical question or set of questions and the method does not lend itself to complex interventions (Mallidou, 2014; Schick-Makaroff et al., 2016; Wickremasinghe et al., 2016).

2.4.5.2 Rapid review

According to Grant and Booth (2009) by curtailing the duration of the review process, rapid reviews are at a greater risk of introducing bias. While all evidence syntheses are at risk of bias, this risk is accentuated when measures are fast-tracked or even sidestepped. Limiting the time taken to search may result in publication and selection bias (Grant and Booth, 2009; Wickremasinghe et al., 2016). As rapid reviews are selective and incomplete by design they should (and often do) include appropriate caveats about likely missing data (Littell, 2018; Mallidou, 2014; Wickremasinghe et al., 2016).

Rapid reviews carry out limited quality assessment which may place a disproportionate emphasis on poorer quality research (Grant and Booth, 2009). Grant and Booth (2009) suggest that rapid reviews may not focus on synthesis which could lead to overlooking inconsistencies or contradictions in evidence.

There is a risk that if researchers pay inadequate attention to the question to be addressed or the quantity and quality of literature that exists in a topic it may result in a very precise answer to the wrong question or increase the risk of generating inconclusive findings that provide a weak answer to the original question (Grant and Booth, 2009; Wickremasinghe et al., 2016). Gough et al. (2012) highlighted there is a risk that the limited scope (and limited contribution to the broader research agenda) is not understood by funders and users of the review.

2.4.5.3 Umbrella review

Each review included as part of an umbrella review needs to be assessed for quality (Wickremasinghe et al., 2016). This may lead to challenges for resources and synthesis. Caird et al. (2015) suggested that quality assessment for umbrella reviews encompasses two dimensions, including both a) an assessment of the quality of each included review, and b) an assessment of the quality of evidence in included reviews (Caird et al., 2015). If quality assessment of the primary research provided by reviews is variable, this aspect of quality assessment in umbrella review is often far more problematic than assessment at the review level, particularly when the time and resources are limited (Caird et al., 2015). Deciding how to handle mixed quality systematic reviews can also be challenging in an umbrella review; including lower quality reviews may introduce uncertainty but excluding low quality reviews (or those containing weak primary research) may result in a biased overview of the evidence (Caird et al., 2015).

Umbrella reviews are not always feasible, as there must be pre-existing narrower component reviews (Grant and Booth, 2009; Mallidou, 2014). When synthesising and extracting data from multiple systematic reviews, there is a reliance on the data and explanation provided by the authors of the included systematic reviews, or researchers may decide time consuming additional data extraction of primary studies will be necessary (Caird et al., 2015). Due to the volume and diversity of the primary research they contain, umbrella reviews are likely to pose a greater challenge than standard systematic reviews when determining which data to select

for synthesis. There are also limitations of this previously extracted data (Caird et al., 2015). Due to their reliance on existing systematic reviews, umbrella reviews have the potential to be susceptible to bias introduced in the process of selecting which data to include. Also relying on review-level evidence introduces the potential to fall susceptible to the interpretive and conceptual biases of previous reviewers.

Results of an umbrella review may more quickly be out of date due to long intervals between conducting primary research, its incorporation into a review, and subsequently, an umbrella review (Caird et al., 2015). Additionally, umbrella reviews cannot capture emerging concepts in a field. As systematic reviews of complex interventions are limited umbrella reviews on the efficacy of complex or non-health related interventions may also be limited (Caird et al., 2015).

2.4.5.4 Realist review

Although realist review has been established since the mid-2000s (Pawson et al., 2005), it continues to evolve in its application across diverse policy and practice contexts. Much of the methodological guidance has been developed by a relatively small group of researchers, which may have limited broader methodological innovation and diversity of application. There may be also be fewer published applications by researchers other than the developers of the methods, and limited methodology guidance, so new users often struggle with its application (Schick-Makaroff et al., 2016; Tricco et al., 2016). The RAMESES project, which produced quality and publication standards and training materials for realist research has helped to bridge this gap (Wong et al., 2013a).

Often lauded as a benefit of realist review, the inclusion of a diverse range of data types can lead to issues when applying this method. Problems include the tendency to treat all forms of evidence as equally authoritative, the lack of explicit guidance on how to deal with contradictory evidence, and lack of transparency regarding choice of evidence to synthesise (Dixon-Woods et al., 2005; Tricco et al., 2016). There can be difficulties in defining appropriate search terms and in

operationalising the inclusion/exclusion criteria in full realist review (Tricco et al., 2016).

It has also been suggested that realist reviews may be particularly challenging for inexperienced teams, partly due to the interpretive terminology used and the shift from the structured, stepwise logic of traditional systematic reviews to the more iterative, theory-driven processes of realist review (Petticrew et al., 2013). A particular challenge is the ability to clearly define mechanisms, and distinguish between what is a mechanism and what is context (Tricco et al., 2016). Moreover, realist reviews can be labour and resource intensive, particularly due to the iterative nature of synthesis and the potentially large scope of relevant literature (Petticrew et al., 2013; Sheldon, 2005; Tricco et al., 2016; Wickremasinghe et al., 2016). Resources required are outlined in section 2.4.6.4.

The realist-review method is focus on collecting explanatory information; however, primary studies do not always provide the information needed. There may be a lack of more informal and contextualised information about practical and relational elements of the intervention (Dixon-Woods et al., 2005; Tricco et al., 2016). These gaps in the evidence could be too great to allow explanatory propositions (Tricco et al., 2016). If realist review is undertaken, additional primary research methods such as interviews and focus groups can be utilised to support the development of the review and its interpretation (Petticrew et al., 2013).

The interpretive and context-dependent nature of realist review means that its findings are shaped by judgement and may be best understood as contextually situated rather than universally generalizable (Mallidou, 2014; Tricco et al., 2016). Some scholars have suggested that the purposive and iterative nature of the approach may create scope for reviewers' assumptions to influence interpretation, potentially making aspects of the review process less transparent to readers (Sheldon, 2005). In addition, because realist review relies on flexible and adaptive procedures rather than a fixed protocol, and is iterative, it is argued that

achieving full reproducibility may be more challenging than in more standardised systematic approaches (Mallidou, 2014; Tricco et al., 2016).

Realist synthesis combines quantitative and qualitative research, and it can be challenging to identify data as there is a lack of detailed indexed terms (e.g. MeSH terms) for qualitative research or for specific qualitative methods, non-informative titles and abstracts, diffuse terminology, and poor indexing (Moser and Korstjens, 2023). Supplemental searching may be required. Despite these methodological challenges, realist review remains an influential and evolving approach for synthesising complex evidence in policy-relevant contexts. The adaptation of realist principles to more time-sensitive policy processes has given rise to the rapid-realist review. While grounded in the same explanatory logic as the full realist review, rapid-realist review aims to produce timely insights to inform decision-making under practical constraints. Consequently, many of the broader limitations identified for realist review, such as the need for interpretive expertise, iterative synthesis, and transparent reasoning, remain relevant to its rapid counterpart. However, rapid-realist review introduces additional challenges linked to the expedited nature of its processes, as outlined in the following section.

2.4.5.5 Rapid-realist review

There is little written in the literature on the limitations of rapid-realist review. However, as it is an emerging method, the limitations related to emerging synthesis methods may be considered relevant (Moser and Korstjens, 2023). According to Moser and Korstjens (2023) all team members should be well-informed about the review methodology and the team should include an analysis specialist. This may be difficult to achieve for new and emerging synthesis methods.

As for full realist review rapid-realist review may require supplemental searches to address issues in identifying diverse types of data through database searches (Moser and Korstjens, 2023). Saul et al. formally defined rapid-realist review methodology and also outline several limitations of the methodology (Saul et al.,

2013). The rapid-realist review method explicitly uses an expedited search process, while advantageous with respect to the faster turnaround time for the finished review, it may also result in certain resources/references being missed, potentially introducing a source of bias. Saul et al. attempt to mitigate the risk associated with the rapid method by using two groups to inform and comment on the developing review: an expert panel and a reference group. The expert panel is made up of researchers and practitioners, actively engaged in conducting work in the area under review, with knowledge of research, practice and policy in the topic; the reference group includes the target audience for the findings of the review, including funders (Saul et al., 2013). However, convening and maintaining reference groups and expert panels is challenging and providing honoraria may be required.

Rapid-realist reviews are described as requiring substantial resources in a short time frame, due to the iterative nature of the synthesis process and the expectation to convene expert panels (Saul et al., 2013). While this may limit feasibility for some government agencies or departments with limited in-house capacity, the method can be successfully implemented with targeted use of external expertise. Saul et al. (2013) note that engaging expert methodologists at key stages can be a cost-effective strategy, allowing resources to be focused strategically on addressing specific questions. In the context of this thesis, the rapid-realist review was feasible within available resources, demonstrating that these constraints can be mitigated through careful planning and team composition.

A further limitation arises from the expectation that all members of the review team possess a strong understanding of realist methodology. In practice, policymakers and other stakeholders involved in the review process may not share the same level of methodological expertise or appreciation of the realist approach and its potential value for policy. To address this Saul et al. (2013) recommend maintaining a clear focus on the links between interventions and outcomes, and using programme theories to explain why particular interventions may work well in specific contexts or for certain populations.

2.4.6 Resources required for different evidence synthesis types

According to Wickremasinghe consideration of resources can help to determine what is a feasible and relevant scope for the synthesis output within the time available (Wickremasinghe et al., 2016). Consideration of production time and other resource issues will likely affect various aspects of an output, including its rigour, depth, quality appraisal and scope. Resources can influence the number of reviewers who can be employed to work on a synthesis in the time available (Wickremasinghe et al., 2016). There was significant variability in the typical amount of time indicated in the literature for each type of synthesis.

2.4.6.1 Systematic review

A traditional systematic review is considered one of the most time-consuming evidence synthesis methods. They can take up to 18 months to complete (Wickremasinghe et al., 2016). Systematic reviews addressing broad questions are likely to take longer to complete than reviews with a narrow focus; narrowly focused systematic reviews typically take approximately 12 months to complete (Caird et al., 2015).

2.4.6.2 Rapid review

There was a wide range in timeframes considered typical for a rapid review reflecting the variety of options that can be selected to make a review rapid. Estimates ranged from one to nine months (Mallidou, 2014; Schick-Makaroff et al., 2016; Wickremasinghe et al., 2016).

2.4.6.3 Umbrella

Caird et al. (2015) suggest that an umbrella review can be completed within twelve months, while Wickremasinghe et al. (2016) suggest three months is the average production time for an umbrella review.

2.4.6.4 Realist review

Realist synthesis is time-consuming and human resource intensive, and for those reasons a potentially expensive endeavour (Rycroft-Malone et al., 2012). It may take up to 24 months to complete a full realist review (Saul et al., 2013).

2.4.6.5 Rapid-realist review

Saul et al. (2013) reported that a rapid-realist review will take three to six months compared to 12 to 24-month turnaround for realist review. Saul et al. also describe the cost implications of a rapid-realist review compared with a full realist review; they suggest that while the shorter length of time for a rapid-realist review will decrease costs overall, project management costs per month are likely to be greater for rapid-realist reviews than for longer realist reviews, given the necessity to interact frequently with the reference group and expert panel, and the need to obtain timely responses from them.

2.4.7 Skills of the team

Tricco et al. (2016) described the make-up of the team required to undertake a realist review - the characteristics of the team should include people with a nursing background, and sociology background, and the team should have a broad range of skills and experiences. Saul et al. (2013) note that for a rapid realist review it is a requirement that all members of the review team be well versed in realist review methodology (Saul et al., 2013).

Moser and Korstjens (2023) outlined the composition of the review team for emerging syntheses such as rapid-realist review; the review team should minimally comprise experienced reviewers, information specialists, analysis specialists (qualitative analysis experts and/or statisticians) and content experts. Depending on the synthesis method used other stakeholders such as policymakers, patient representatives and practitioners might be essential members too.

2.5 Involving stakeholders in evidence-informed policy

Involving lay participants and co-creation of evidence can increase wider evidence literacy and demand for policy-relevant research increasing evidence-informed policymaking (Buse et al., 2024). Emerging synthesis methods in research increasingly involve policymakers to ensure that research is both relevant and actionable in real-world settings. By engaging policymakers in the research process, these methods aim to bridge the gap between academic findings and policy implementation, enhancing the impact of research on decision-making.

Participatory research is a collaborative approach to research that actively involves all stakeholders, particularly those affected by the issue being studied, in the research process. This method emphasises the co-creation of knowledge, where researchers and participants work together to identify problems, develop research questions, collect data, and analyse results (Cargo and Mercer, 2008). Participatory research prioritises co-constructing research through partnerships between researchers and stakeholders, community members, or others with insider knowledge and lived expertise (Jagosh et al., 2012).

This collaborative approach helps to align research priorities with pressing policy issues, ensuring that the resulting evidence addresses the needs and concerns of policymakers. Moreover, it fosters a two-way flow of information, where researchers can better understand the practical challenges faced by policymakers, and policymakers gain access to the latest evidence to inform their decisions. As a result, the integration of policymakers in research synthesis not only improves the salience and applicability of research findings but also contributes to more effective and informed policy development (Boaz et al., 2018; Oliver and Boaz, 2019).

However, issues with participatory research are also common. For example, incorporating stakeholder involvement can lead to increased time and resources to incorporate these elements into a research process. Tensions between researchers and end-users in decision-making can also mean sacrificing scientific rigor for end-user preferences and concerns regarding study design (Jagosh et al., 2012).

2.6 Conclusion

There are a range of evidence synthesis options to consider when synthesising research to address complex policy interventions. Emerging evidence synthesis methods such as rapid-realist reviews and umbrella reviews could offer advantages for evidence-informed policy, especially in complex and evolving topics like healthcare regionalisation. Rapid-realist reviews are particularly valuable because they focus on understanding *how* and *why* interventions work in specific contexts, which is crucial when exploring health system changes, as the effectiveness of

policies may vary based on local conditions and institutional settings. On the other hand, umbrella reviews aggregate findings from multiple systematic reviews and meta-analyses, offering a comprehensive overview of existing high-quality evidence, which is vital in evidence-informed policy research where various interventions and models of care are constantly being tested and refined. The use of umbrella reviews can help policymakers synthesise evidence from different strategies across multiple settings, allowing for a broader comparison and identification of best practices. These methods, due to their ability to provide timely, context-sensitive insights, are well suited to evaluate the dynamic nature of healthcare regionalisation and will be tested further in this thesis.

Building on the discussion of evidence synthesis methods in Chapter 2, the next chapter focuses on healthcare regionalisation in Ireland as a case study for exploring the application of these methods in practice. It reflects on previous Irish evidence synthesis work on regionalisation, identifies methodological and practical issues encountered in that work, and provides a foundation for examining alternative approaches. By highlighting these challenges, the chapter sets the stage for subsequent chapters, which test different evidence synthesis methods on regionalisation research questions, allowing for a critical appraisal of the suitability of various research methods for the generation of policy-relevant evidence.

Chapter 3 Case study: healthcare regionalisation

3.1 Overview

This chapter examines the Health Research Board's (HRB) review of healthcare regionalisation as a case study for exploring the challenges of applying evidence synthesis in the policy domain. Building on Chapter 2, which considered which evidence-synthesis methods are most suitable for addressing evidence-informed policy questions, this chapter shifts the focus to a concrete example of how such methods are used in practice. The central research question guiding this chapter is: what methodological challenges were identified in the Health Research Board's review of healthcare regionalisation? The HRB review was commissioned to inform the Department of Health of the Republic of Ireland as part of the Sláintecare reforms and represents a substantial effort to synthesise international evidence on regionalisation. While the review generated findings that contributed directly to policymaking in Ireland, it also raised important methodological considerations. To situate the HRB review, the chapter also outlines the structure and reform trajectory of the Irish healthcare system. The HRB review was a key motivator for the present thesis. Its findings highlighted not only the relevance of evidence synthesis for health policy, but also the complexity of selecting and applying methods suited to policy questions. Reflecting on the HRB's experience therefore provides a foundation for examining how methodological choices influence the role of evidence in policymaking.

3.2 Introduction

Healthcare regionalisation represents a significant restructuring of health systems. Aims might include optimising the distribution of services, improving efficiency, and enhancing access to care across diverse populations (Council of Europe Parliamentary Assembly, 2007; Houses of the Oireachtas and Committee on the Future of Healthcare, 2017). At its core, regionalisation involves reorganising the administration of healthcare services, organising them into defined geographical regions that can better respond to the specific needs of local populations (Ramos et al., 2020). However, the complexities of implementing and assessing healthcare

regionalisation go beyond mere organisational change. These systems encompass a range of interacting components, including governance structures, resource allocation, service integration, and population health management (Exley et al., 2024; Matos et al., 2025). As such, healthcare regionalisation is a complex intervention, which requires careful consideration and evaluation to understand its effectiveness, potential unintended consequences, and the conditions under which it succeeds or fails (Schulmann et al., 2024).

Given its multifaceted nature, healthcare regionalisation presents several challenges for evidence-informed policy. The interactions between regional governance, health professionals, patients, and local communities create a dynamic and context-dependent environment that influences how healthcare is delivered and experienced. The outcomes of such interventions are often not linear or predictable, making it difficult to evaluate using standard systematic review synthesis methods, which were designed for the synthesis of straightforward interventions measured through randomised controlled trials (Chapter 2). This complexity makes it an ideal case study for evidence-based policy as the complexity is representative of the issues that arise when attempting to synthesise health system intervention studies for evidence-informed policy.

3.3 Healthcare regionalisation

Healthcare regionalisation refers to the transfer of responsibility for healthcare services from centralised authorities or government bodies to regional entities, thus creating an intermediary level of governance (Church and Barker, 1998). This restructuring may involve decentralisation (moving power down from central governments to regional bodies) or, in some instances, centralisation (moving authority from local authorities upwards to a regional level). In practice, healthcare regionalisation generally involves decentralising responsibility from national government agencies to regional bodies, with some level of centralisation at the local level to consolidate services and ensure coordination (Quigley et al., 2019). This shift has been implemented in a range of countries, including both high-income and low-income contexts, such as Australia, Brazil, Canada, Italy,

Spain, the Netherlands, Uganda and Zambia in response to the challenges of managing healthcare systems effectively and equitably (Ramos et al., 2020).

3.3.1 Theoretical Foundations of Regionalisation and Decentralisation

The theoretical foundation for regionalisation and decentralisation is rooted in various economic and political frameworks that explore the balance between central and local governance (Arends, 2017; Nelson, 1997; Rotulo et al., 2023). One widely cited theoretical framework in the literature is the theory of *fiscal federalism*. Fiscal federalism focuses primarily on the allocation of expenditure and revenue-raising powers across different levels of government, suggesting that regional or local authorities with some degree of fiscal autonomy may be better able to align public services with the preferences and needs of their populations. By tailoring spending and investment decisions to local priorities, decentralised governments can, in principle, provide public goods and services that are more responsive to regional demands (Oates, 1999, 1972). This is particularly relevant in the context of healthcare regionalisation, as it posits that regions can respond more effectively to the specific healthcare needs of their populations compared to a centralised national government (Oates, 1999, 1972). However, critics of this framework have noted potential downsides, including the risk that decentralisation may exacerbate regional inequalities, undermine economies of scale, and lead to inefficiencies when local administrative capacity is weak (Prud'Homme, 1995; Rotulo et al., 2023).

3.3.2 Historical Background and International Experience

Healthcare regionalisation, a global phenomenon implemented in a range of countries, gained momentum from the 1980s onwards as governments sought to improve efficiency, equity, and responsiveness by reallocating responsibilities from centralised authorities to regional structures (Church and Barker, 1998; Cobos Muñoz et al., 2017). The rationale was that intermediate governance levels could better tailor healthcare delivery to the needs of defined populations while still operating within a nationally coordinated system.

In Canada, beginning in the 1980s and expanding through the 1990s, provinces introduced Regional Health Authorities (RHAs), which were tasked with overseeing healthcare delivery for defined geographic areas within provinces. These RHAs assumed responsibility for healthcare planning, budgeting, and service delivery at the regional level (Church and Barker, 1998; Marchildon, 2015). The reforms emerged amid fiscal pressures, with aims including greater local responsiveness, improved coordination, and potential cost containment. However, evidence on outcomes is mixed: while some improvements in local service alignment were observed, anticipated system-wide gains in efficiency, cost control, and equity have not been consistently realised (Hutchison et al., 2011; Marchildon, 2015).

In Europe, healthcare regionalisation has been explored with varying results. For example, Spain and Italy have undergone decentralisation reforms creating regional healthcare systems with greater autonomy for regional bodies. In Spain, decentralisation began in Catalonia in 1981 and extended gradually, culminating in full transfer of healthcare authority to all 17 autonomous communities by 2002. The objective was to improve access and responsiveness while reducing regional disparities. Research suggests that decentralisation did not systematically worsen inequities in expenditure or outcomes, but differences in service quality and efficiency remain across communities (Costa-Font and Rico, 2006; García-Armesto et al., 2010).

In Italy, healthcare regionalisation accelerated with constitutional reform in 2001, which transferred full responsibility for healthcare financing, planning, and delivery to regions. While some convergence in outcomes such as infant mortality has been observed, persistent north-south inequalities in resources, efficiency, and patient mobility highlight how regional capacity and governance can mediate the impact of decentralisation (France et al., 2005; Landi et al., 2021).

In Scotland, regionalisation has been in place since the early 1970s, with 14 territorial NHS Health Boards responsible for planning, funding, and delivering services to defined populations within their geographical boundaries. This

structure was reinforced in the 2014 reforms that requires councils and NHS boards to work together to form new partnerships, known as integration authorities (Audit Scotland, 2018). Scotland's experience highlights that regionalisation can be pursued not only for fiscal and equity reasons, but also to support population-based planning and integration across services. Similarly, in England, the establishment of Integrated Care Boards (ICBs) under the Health and Care Act 2022 represents a form of regionalisation. It brings together NHS organisations and local authorities to coordinate planning and service delivery at a regional level, highlighting a broader trend toward regional governance in healthcare (NHS England, 2022).

Brazil provides a particularly important non-Organisation for Economic Co-operation and Development example. With the creation of the Unified Health System (SUS) in 1988, the country embedded decentralisation into its constitution, granting municipalities and states responsibility for managing healthcare within a nationally defined framework. From the 1990s, successive reforms promoted regional health planning, requiring municipal and state actors to collaborate in delivering services, with federal coordination and funding mechanisms (Paim et al., 2011; Viana et al., 2018). Regionalisation in Brazil has expanded access dramatically, contributing to reductions in infant mortality and improvements in primary care coverage. However, persistent challenges include fragmentation, weak regional governance capacity, and significant inequalities across regions, especially between wealthier southern states and poorer northern areas (Paim et al., 2011; Viana et al., 2018).

International experience with healthcare regionalisation indicates that while regionalisation can offer potential benefits, such as better alignment with local needs, increased citizen participation, and improved coordination, it also presents significant challenges. These challenges include the risk of exacerbating regional inequalities and the complexity of ensuring that regionalisation does not lead to fragmentation or inefficiency. An important contextual factor in understanding these potential benefits and risks is the model of funding allocation, as the impact

of regionalisation can vary considerably depending on whether resources are sourced primarily through regional revenues, central transfers, or equalisation mechanisms.

3.3.3 Funding Allocation in Regional Healthcare Systems

In regionalised healthcare systems, funding for healthcare delivery can come from a mix of regional revenue sources and transfers from the central government. The structure of these financial arrangements plays a crucial role in determining the efficiency, equity, and sustainability of healthcare systems in decentralised settings, as different funding mechanisms shape local capacity to deliver services, influence the distribution of resources across populations, and affect long-term fiscal stability. There are three main types of financial arrangements: regional revenue sources, central government transfers and equalisation grants.

3.3.3.1 Regional revenue sources

Regional governments often generate a portion of their healthcare funding through taxes collected within their own jurisdiction. These can include local or regional taxes such as property taxes, income taxes, or specific healthcare-related levies. In some cases, regions also participate in state-wide tax systems, contributing to a shared pool of resources that is later redistributed based on regional needs (Costa-Font and Turati, 2018). The reliance on regional taxes gives local governments some degree of financial autonomy, allowing them to respond to local priorities and needs more directly. This system is common in federalised countries, however, healthcare regions set up on an administrative basis alone will not have the ability to raise their own funds, they will rely instead on central government transfers.

3.3.3.2 Central government transfers

All healthcare regions receive substantial funding through transfers from the central government. These transfers often take the form of block grants, which are amounts of money transferred to the regions based on certain pre-determined criteria. Block grants can be allocated based on population size, regional healthcare needs, or historical funding levels (Hewitt, 1991). This system allows

for some flexibility in how funds are spent, but it can also lead to disparities between regions with differing financial needs and capacities.

3.3.3.3 Equalisation Grants

To mitigate disparities in wealth and ensure more equitable healthcare provision across regions, central governments often allocate equalisation grants. These grants are designed to redistribute resources from wealthier to poorer regions, taking into account fiscal capacity, which refers to the ability of a region to raise funds locally. Regions with lower local revenue potential—often those with lower income levels or smaller populations—receive a higher share of central government transfers. The goal is to ensure that all regions can provide a minimum standard of healthcare, regardless of their local economic conditions (Costa-Font and Turati, 2018). Both Spain and Italy have a form of equalisation grant in place. In Spain, autonomous communities receive advance equalisation grants based on forecasts in the draft state budget. These advance payments are reconciled two years later against the final budget, and any overpayments must be returned (Kölling and Herrero-Alcalde, 2025). Italy operates two separate equalisation systems: one for regions and another for municipalities. Regions with fiscal capacities below the national average are entitled to equalising grants based on their fiscal capacity. These grants are generally annual and are intended to ensure that all regions can provide a minimum standard of healthcare services, regardless of their local economic conditions (Brosio, 2018).

Effective funding allocation in regional healthcare systems requires careful design to balance the financial autonomy of regions with the need for equitable healthcare delivery. The combination of local taxes, central transfers, and equalisation grants aims to ensure that regional governments can meet the healthcare needs of their populations while addressing disparities in resources.

3.4 Irish health-system context

The Republic of Ireland has a population of just over 5 million people, with a high concentration in urban centres (such as Dublin, Cork, Limerick, and Galway), while much of the country remains sparsely populated and rural. This urban-rural divide

creates distinct challenges for healthcare delivery, including access to specialist services in rural areas and pressure on acute services in cities. Ireland's relatively small population and geographic distribution mean that health reforms must balance efficiency in centralised services with equitable access across dispersed communities.

The Irish healthcare system has long been criticised and subjected to multiple reform attempts (Wren and Connolly, 2019). Initially, healthcare was regionalised through the establishment of Health Boards in 1971 following the 1970 Health Act, transferring responsibility from Local Health Authorities to the Health Boards (Health Service Executive, 2014). Eight health boards were established with responsibility for provision of largely medicine/surgery and institutional care (acute hospitals and mental health hospitals and elderly hospitals) (Health Service Executive, 2014). Primary and community care were outside the remit of these health boards. However, this regional system led to unintended regional disparities in service delivery, with disjointed and siloed systems and varying service quality (Health Service Executive, 2014). In 2005, responsibility for healthcare in Ireland was centralised under the Health Service Executive (HSE) to address these issues and promote a more equitable and integrated national healthcare system. Once established the HSE faced intense political and public scrutiny, and in 2016, the government established the Houses of the Oireachtas (Irish Government) Committee on the Future of Healthcare to develop a cross-party consensus and a ten-year reform plan, resulting in the Sláintecare Report (Barry et al., 2021). This plan, described as the 'largest level of reform' in Ireland's healthcare history by former Health Minister Simon Harris, mandated extensive changes in healthcare delivery, infrastructure development, improved access, and accountability (Department of Health, 2018a; Houses of the Oireachtas and Committee on the Future of Healthcare, 2017).

3.4.1 Rationale for healthcare regionalisation in Ireland

The rationale for the current cycle of regionalisation in Ireland reflects a combination of systemic challenges and reform ambitions. Like many European health systems, Ireland faces demographic and epidemiological pressures,

including an ageing population and a rising burden of chronic diseases and multimorbidity (OECD/European Observatory on Health Systems and Policies, 2023). These trends underscore the need for care models that go beyond episodic treatment and instead support ongoing, community-based, and multidisciplinary approaches, which are objectives that regionalisation was designed to support.

Persistent criticisms of the HSE have centred on fragmented service delivery, weak coordination between acute, primary, and community services, and limited responsiveness to local needs. These issues have contributed to inefficiencies, poor value for money, and inequitable access to care, reflected in long waiting lists and widespread public dissatisfaction (Burke et al., 2018; Department of Health, 2018b). The complex and often contested relationship between the State and voluntary hospitals (privately governed but largely publicly funded) has further complicated cohesive service planning (Day et al., 2018; HMI, 2015).

In response to these challenges, the *Sláintecare Report*, produced by the Committee on the Future of Healthcare, explicitly links regionalisation to broader goals of health system strengthening, community network building, and service coordination, which are considered strategies central to integrated care models internationally (Houses of the Oireachtas and Committee on the Future of Healthcare, 2017; World Health Assembly, 2016). Regional Health Areas (RHAs) were proposed as decentralised governance structures capable of aligning hospital, primary, and community services, while creating clearer lines of accountability at sub-national level. Regionalisation was framed not only as a response to fragmentation but also as a mechanism to improve cost-effectiveness and responsiveness:

‘Enabling integrated care to develop... will create an efficient and cost-effective health service which meets patients’ needs in a timely manner’ (Houses of the Oireachtas and Committee on the Future of Healthcare, 2017, p. 12).

The Committee also wanted RHAs with direct accountability for service planning and coordination at local level. This recommendation reflected frustration with the HSE's centralised governance model, which was seen as ill-suited to managing local variation or ensuring equitable access.

The subsequent *Sláintecare Implementation Strategy* (2018b), developed by the Department of Health, diagnosed the Irish health system as highly fragmented, with limited formal coordination between acute hospitals, primary care, and community services. The strategy recognised that where integration did occur, it was often due to individual initiative rather than systemic design:

‘Our system is highly fragmented and does not deliver care that is coordinated and integrated... Where coordination does exist, it is down to hardworking individuals on the front line who have built relationships across organisational and institutional lines’ (Department of Health, 2018b, p. 8).

Improving governance and accountability was another key rationale. The *Sláintecare Report* called for clearer lines of managerial and clinical accountability from the Minister for Health down to service providers, while the implementation strategy emphasised the need for robust governance and quality assurance frameworks, particularly in community-based care (Department of Health, 2018b; Houses of the Oireachtas and Committee on the Future of Healthcare, 2017).

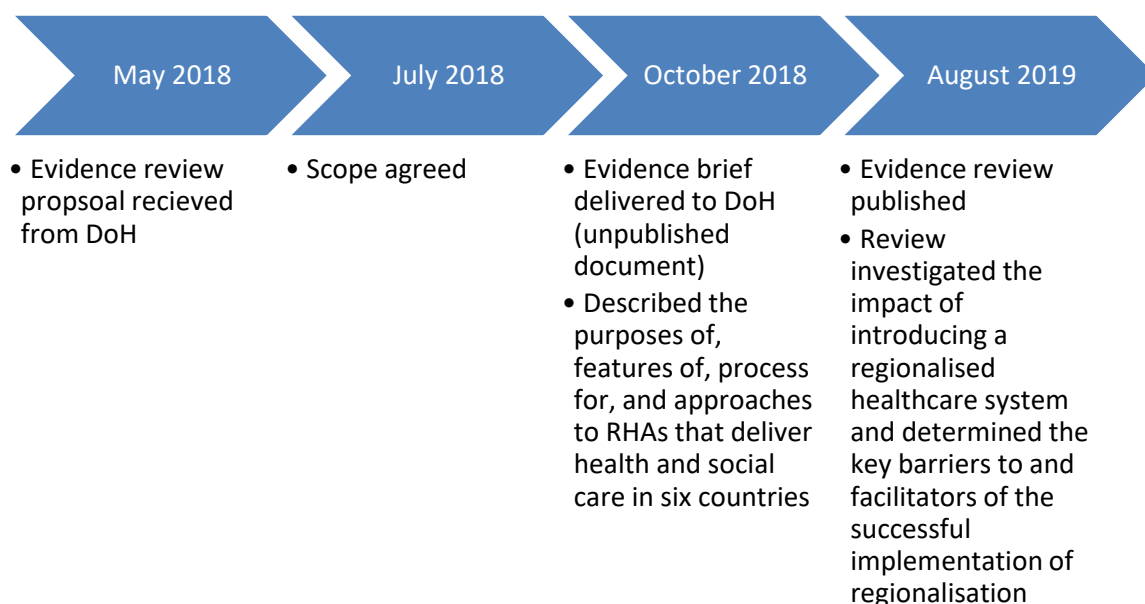
In summary, the rationale for regionalisation under *Sláintecare* reflects multiple drivers: the need to address demographic and chronic disease pressures, longstanding inefficiencies and fragmentation in the centralised HSE model, and the demand for stronger governance and accountability, and the challenge of integrating voluntary hospitals into a unified system. RHAs were therefore positioned as the structural reform necessary to deliver integrated, community-based, and cost-effective care.

3.4.2 Role of research from the Health Research Board in informing Irish healthcare regionalisation

The HRB Evidence Centre in Ireland plays a crucial role in supporting the country's health system by producing high-quality evidence to inform policy and practice. It conducts systematic reviews, evidence synthesis, and research that addresses key health and social care issues, with a focus on improving healthcare outcomes. The HRB Evidence Centre collaborates with policymakers, healthcare professionals, and researchers to ensure that evidence is accessible and actionable. By gathering, analysing, and synthesising data from various sources, the HRB helps guide decision-making in healthcare, ensuring that policies are based on the best available evidence. Additionally, it contributes to capacity-building in health research and promotes the integration of evidence into health policy and practice. The Evidence Centre can be classified as a policy research and knowledge translation centre that plays a central role in bridging the gap between research findings and their practical application in healthcare decision-making. The Centre has been in existence since 2011.

The Irish Department of Health asked the Evidence Centre of the Health Research Board to undertake a research project to inform their implementation of the regionalisation policy. The Department of Health posed a wide range of research questions to the HRB. These questions were discussed and consensus on the scope, questions, and methodological approach was agreed through several face-to-face meetings. The project began in summer 2018, and the project milestones are outlined in Figure 3-1. The project took 16 months to complete. There were three researchers assigned to work fulltime on the project and they were supported by a librarian for relevant parts of the project.

Figure 3-1 Timeline of the HRB regionalisation project



Key: DoH – Department of Health

There were two deliverables as part of this project:

- An evidence brief: this involved writing high-level country case studies on regional health organisations in various countries, addressing the question: "What are the purposes, features, processes, and approaches to regional health organisations delivering health and social care?" (Quigley et al., 2018). This part was not published, as it was to be used internally by the Department of Health.
- An evidence review: this mixed-methods review employed convergent parallel design, as such qualitative and quantitative findings were analysed separately in the initial stage of synthesis. Thematic analysis was used to synthesise the results of included qualitative studies. For the included quantitative studies, a narrative synthesis and meta-analysis were used to combine findings where feasible and appropriate. The results from the qualitative and quantitative syntheses were integrated in the final stage of the synthesis, in accordance with convergent parallel design (Quigley et al.,

2019). This evidence review underwent international peer-reviewed before publication.

3.4.2.1 Issues with the HRB review

In the evidence review the HRB reviewed the impacts of regionalised healthcare and identified barriers and facilitators to implementation. However, despite the significant investment of effort, the findings were ultimately highly context-dependent and lacked clear policy direction. The systematic review of 33 articles on the impact of regionalisation reported variable outcomes across settings, while the review of barriers and facilitators drew only broad conclusions around government influence, competing interests, and internal organisational processes. The findings of the evidence review were used by the Department of Health in planning the geographical boundaries of the regional health areas in Ireland. However, while the Department confirmed that the evidence adequately addressed the research questions, providing a thorough review of both the positive and negative impacts of regionalisation and the barriers and facilitators to its success, several methodological issues were identified.

A central limitation lay in the inability of standard systematic review methods to meaningfully incorporate context. The HRB evidence review did not formally incorporate context into the synthesis which is typical with standard systematic-review methods. Contextual data related to external factors such as socioeconomic conditions and institutional arrangements were identified from sources beyond the systematic review references and were incorporated into the discussion section of the evidence review. These external data sources included non-comparative administrative reports typically excluded from systematic reviews due to a question of quality of evidence. This piecemeal approach left important contextual influences underexplored and undermined the usefulness of the conclusions for Irish health policy. Moreover, because systematic reviews typically exclude external data sources such as national statistics or historical performance indicators, the HRB was unable to situate study findings within a fuller system-wide picture. The result was a body of evidence that described variability but

offered little explanation for why outcomes differed across contexts or how lessons could be transferred.

The time demands of the project further compounded these issues. The HRB review took 16 months to complete, a timeframe that significantly limits the relevance of findings in fast-moving policy environments. By the time such a review is finalised, political priorities, organisational structures, or external pressures may already have shifted. Policymakers therefore receive evidence that risks being outdated before it can inform decisions. In contrast, alternative synthesis approaches such as rapid reviews or umbrella reviews can deliver timely, if more targeted, outputs, while methods like realist reviews explicitly address context by examining how and why interventions work differently in different settings. These approaches may not only be faster but also better aligned with the realities of policy decision-making.

The Department of Health's feedback also reflected these shortcomings, noting the inconsistent findings and context-dependent nature of the evidence, particularly around waiting lists and efficiency outcomes. While the HRB review did contribute to shaping Sláintecare's regional boundaries, this impact reflects the necessity of using available evidence rather than the adequacy of the synthesis itself.

3.5 Conclusion

In conclusion, the HRB report illustrates the limitations of relying solely on traditional systematic review methods in complex health system reforms. Its protracted 16-month timeline and failure to systematically incorporate context meant that the findings, while thorough in description, were slow to emerge and of limited practical value for policymakers. These weaknesses underline the need to consider alternative evidence synthesis methods. Rapid and umbrella reviews can provide more timely assessments, while realist reviews explicitly integrate contextual factors into the analysis. This thesis will therefore explore how such approaches might generate more policy-relevant evidence, using healthcare

regionalisation as a case study to demonstrate their potential advantages over standard systematic review methodologies.

Chapter 4 Methodological and theoretical considerations

4.1 Overview

This chapter outlines the methodological and theoretical considerations that informs how the umbrella review and rapid realist review are conducted in this thesis. As described in Chapters 1 and 2, these methods were identified as suitable approaches for addressing the research questions and were therefore selected prior to the work reported here. The purpose of this chapter is not to compare review types, this is addressed in Chapter 2, but to describe how the literature recommends each method should be undertaken and how these recommendations were operationalised within the thesis.

While the detailed methodological procedures are reported in each results chapter, this chapter provides a unifying methodological narrative. It explains the principles guiding each method, the adaptations made to ensure their suitability for evidence-informed policy (EIP), and the preparatory steps undertaken, particularly for the realist component, to ensure that the methods were applied rigorously and appropriately within a policy-relevant context.

4.2 Introduction

This chapter summarises the methodological guidance from the literature on how each method should be conducted and to explain how this guidance was operationalised in the context of this thesis. For the umbrella review, the focus is on the methodological standards that underpin reviews of reviews, such as the rationale for this approach, expectations around protocol development, quality appraisal, overlap assessment, and synthesis. Section 4.3 outlines how these principles were interpreted and applied in analysing the evidence base on healthcare regionalisation.

In contrast, the rapid-realist review required additional preparatory steps to ensure that the review reflected policy priorities and that key concepts were

sufficiently well-defined to support theory development. Two preliminary activities were undertaken: interviews with policymakers to identify priority outcomes and contextual considerations, and a scoping review to refine the definition of patient-centred care, which emerged as a core outcome of interest. The first step in a rapid-realist review involves developing the project scope, which requires collaborating with knowledge users to define the content area of interest for the review, ensuring that the process is feasible given the timeline. The next step is to refine the research questions, ensuring they are specific and answerable with the available evidence. Interviews with relevant stakeholders were used to define the area of interest – patient-centred care. The scoping review presented in this thesis was not part of the formal rapid realist review process as described in the methodological literature. Instead, it was conducted as a preparatory step unique to this thesis. Because policymakers' interviews revealed a lack of consensus on the definition of patient-centred care, and because the realist review required a stable, clearly defined outcome, this scoping review was undertaken to establish conceptual clarity before proceeding with theory elicitation and evidence synthesis. The methodological considerations for interviews with policymakers, scoping review, and rapid-realist review are described in sections 4.4 to 4.6.

Taken together, these sections outline the methodological foundations of the thesis and describe how established guidance on umbrella review and rapid-realist review was adapted to meet the aims of advancing evidence synthesis for evidence-informed policy.

4.3 Umbrella review

Section 4.3 presents the methodological considerations for conducting the umbrella review. For each component of the method, the section first summarises the guidance available in the literature and then explains how this guidance was interpreted and applied in the umbrella review undertaken for this thesis. This structure ensures a clear distinction between established methodological standards and the specific decisions made in this study.

Umbrella reviews, also known as overviews of reviews or reviews of reviews, have emerged as an important method for synthesising evidence across multiple systematic reviews on a specific topic. They serve to provide a comprehensive understanding of a research area by examining the findings from a range of systematic reviews and (if appropriate) meta-analyses, thus offering a higher level of evidence aggregation (Belbasis et al., 2022). As a methodological approach, umbrella reviews differ from traditional systematic reviews by focusing on summarising and evaluating the results of existing reviews rather than conducting new primary research (Grant and Booth, 2009).

4.3.1 Rationale

Umbrella reviews are increasingly valuable for policymakers due to their ability to provide a comprehensive overview of existing evidence across diverse studies. These reviews consolidate findings from various sources, offering policymakers a high-level summary of the effectiveness, safety, and cost effectiveness of interventions, treatments, or health policies. This broad perspective helps decision-makers identify trends and make evidence-based decisions in complex areas where individual studies may be insufficient or conflicting (Belbasis et al., 2022). Furthermore, umbrella reviews can highlight gaps in research, guiding future studies and resource allocation (Belbasis et al., 2022). An umbrella review can also be used to quickly assess a large amount of evidence (Joo-Choi and Kang, 2022). By reducing the time and effort required to analyse multiple systematic reviews, umbrella reviews are an evidence synthesis method which could speed up delivery of evidence for policy.

4.3.2 Definition and purpose

An umbrella review is a method that can bring together a large amount of scientific evidence for dissemination to policymakers; an umbrella review is a review of systematic reviews and is considered appropriate when multiple systematic reviews on a topic exist (Belbasis et al., 2022). They are considered particularly useful when the focus is on a broad problem, such as regionalisation, and where there are competing interventions (Grant and Booth, 2009; Sutton et al., 2019). By summarising the available evidence from multiple reviews, umbrella

reviews can provide clarity and help resolve contradictions across the evidence base (Fusar-Poli and Radua, 2018).

The main purpose of umbrella reviews is to aggregate and critically appraise the evidence from multiple reviews to offer a more comprehensive perspective on a research question (Joo-Choi and Kang, 2022). They help policymakers, healthcare professionals, and researchers navigate large bodies of evidence by distilling key findings and offering insights that are derived from the collective body of reviews. Furthermore, umbrella reviews can highlight gaps in evidence, identify methodological limitations and suggest areas where further research is needed (Belbasis et al., 2022).

4.3.3 Theoretical considerations of umbrella reviews

The theoretical foundations of umbrella reviews are rooted in the principles of evidence synthesis and the hierarchy of evidence in research. Umbrella reviews aim to provide a higher-level synthesis by aggregating findings from multiple systematic reviews and meta-analyses positioning them as a tool for distilling complex and diverse evidence across a research area (Fernandez et al., 2025). From a theoretical standpoint, umbrella reviews can be viewed as a form of meta-synthesis where the focus is not on primary data but on synthesising findings from existing reviews to offer an overarching perspective on a topic (Grant and Booth, 2009). The process assumes that such higher-level evidence synthesis can be more reliable than individual primary studies due to the reduced potential for bias and increased rigour of systematic review methodologies (Fernandez et al., 2025). However, theoretical challenges arise when attempting to reconcile conflicting conclusions across reviews, especially when differences in inclusion criteria, study designs, and methodological approaches exist. The theoretical underpinning of consistency and coherence within evidence synthesis is often tested by these discrepancies, as umbrella reviews must navigate the complexity of synthesising results from varied review types (Caird et al., 2015). Additionally, the quality of the underlying systematic reviews plays a crucial role in shaping the conclusions of an umbrella review, as weak methodological foundations in the included reviews

can undermine the validity of the synthesis (Caird et al., 2015). Therefore, theoretical considerations in umbrella reviews must account for the epistemological implications of aggregating findings from reviews that are themselves prone to certain biases or limitations.

4.3.4 Defining the research question

The process of conducting an umbrella review closely resembles that of a systematic review, with the primary distinction being the unit of analysis. In an umbrella review the unit of analysis is a systematic review itself, whereas in a systematic review it is the individual primary study (Fernandez et al., 2025). Step one is to define the research question.

The research question to be answered by the umbrella review in this thesis was:

- What are the health system impacts and patient impacts of healthcare regionalisation according to existing review-level evidence?

Given the extent of primary research on regionalisation, the prior existence of the HRB systematic review, and the thesis aim of testing the utility of different review and synthesis methods, an umbrella review was identified as an appropriate approach to test.

4.3.5 Protocol

4.3.5.1 What the literature recommends

A prespecified protocol is crucial for an umbrella review as it ensures a systematic, transparent, and reproducible approach to the review process. By outlining the review's objectives, eligibility criteria, search strategy, data extraction methods, quality appraisal, and analysis plan in advance, a prespecified protocol minimises biases and enhances the validity of the findings (Fernandez et al., 2025; Fusar-Poli and Radua, 2018). Frameworks such as PICO (population, intervention, comparison, and outcomes) can be used to help structure the eligibility criteria for umbrella reviews of interventions (Belbasis et al., 2022; Fernandez et al., 2025).

Transparency can be further increased by registering the protocol in advance (Cant et al., 2022).

Reporting guidelines for systematic reviews and umbrella reviews are essential tools that ensure transparency, consistency, and rigour in the conduct and reporting of evidence synthesis (Page et al., 2021). For umbrella reviews the Preferred Reporting Items for Overviews of Reviews (PRIOR) are specifically designed to address the unique challenges posed by synthesising findings from multiple systematic reviews (Gates et al., 2022). These guidelines ensure that key aspects such as the search strategy, inclusion criteria, data synthesis methods, and risk of bias are transparently reported, promoting consistency across reviews and improving the reliability of findings. Adhering to these guidelines helps maintain the integrity of the review process and enhances the credibility and reproducibility of the results.

4.3.5.2 Application in this thesis

A protocol for this umbrella review was developed and uploaded to the OSF registry (<https://doi.org/10.17605/OSF.IO/DH4ES>). The PRIOR statement was adhered to in reporting this umbrella review (Gates et al., 2022).

4.3.6 Literature search strategy

4.3.6.1 What the literature recommends

In general, MEDLINE and Embase index most systematic reviews of health service organisation interventions according to Hartling et al.(2016). More recently Epistemonikos, has also been considered a useful database for identifying systematic reviews, however, it relies on data scraped from other databases and the internet (Goossen et al., 2020). Supplemental searching for grey literature is also recommended to avoid publication bias (Fernandez et al., 2025).

4.3.6.2 Application in this thesis

Searches of MEDLINE, Embase, the Cochrane database of systematic reviews, and the archived DARE database of systematic reviews were conducted. Previous work

on regionalisation has shown that grey literature is particularly important for this topic and so grey literature searching was also conducted in search engines Google and Google Scholar (Quigley et al., 2019).

4.3.7 Screening and data extraction

Screening and data extraction should be carried out independently by two researchers as is the case for standard systematic reviews (Belbasis et al., 2022). Screening of potentially relevant studies was carried out by two independent researchers. However, as part of this thesis it was not feasible to conduct data extraction in duplicate.

4.3.8 Quality assessment of included reviews

4.3.8.1 What the literature recommends

The quality of an umbrella review's findings depends on the quality of the eligible systematic reviews, making quality assessment an essential step in the process (Belbasis et al., 2022). To assess the methodological quality or risk of bias in systematic reviews, authors can use tools like AMSTAR, AMSTAR 2, ROBIS, and the Joanna Briggs Institute umbrella review methodology working group appraisal tool. AMSTAR (Shea et al., 2007) is widely used for evaluating systematic reviews of randomised controlled trials and is known for its practical application for health professionals and policymakers. AMSTAR 2 (Shea et al., 2017) is an updated version that can evaluate systematic reviews of both randomised and non-randomised studies helping to assess factors such as protocol registration, literature search adequacy, and risk of bias. The ROBIS tool (Whiting et al., 2016) was developed for authors of Cochrane overview of systematic reviews, covering four broad categories of reviews: interventions, diagnosis, prognosis, and aetiology. The Joanna Briggs Institute umbrella review methodology working group have also developed a methodology quality checklist for systematic reviews (Aromataris et al., 2015).

4.3.8.2 Application in this thesis

While the Cochrane Handbook does not endorse one tool over another due to a lack of empirical evidence, AMSTAR 2 was chosen in this umbrella review for its

flexibility in evaluating a broad range of study types (Pollock et al., 2020; Shea et al., 2017).

4.3.9 Synthesis of findings

4.3.9.1 What the literature recommends

In some cases, a quantitative approach to synthesis can be undertaken, whereas in other cases a narrative approach may be taken (Fernandez et al., 2025). A quantitative analysis, such as a meta-analysis of meta-analyses, can be challenging due to the overlap of primary studies across multiple meta-analyses. Using the same data from individual studies more than once could artificially inflate statistical power, potentially leading to misleading and overly precise estimates. To address this, each included study in the original review would need to be individually separated and their results recombined. This process is complex and time-consuming, making it crucial to carefully consider the value and necessity of conducting a systematic review of reviews before proceeding (Pieper et al., 2014; Smith et al., 2011).

Narrative synthesis can be defined as “an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis. Whilst narrative synthesis can involve the manipulation of statistical data, the defining characteristic is that it adopts a textual approach to the process of synthesis to ‘tell the story’ of the findings from the included studies” (Popay et al., 2006). A narrative synthesis involves arranging data into standard tables, highlighting the context and characteristics of each study, with similarities and differences compared across studies (Barnett-Page and Thomas, 2009). This method is appropriate for the pooling of different types of data, e.g. qualitative and quantitative (Dixon-Woods et al., 2005). Narrative synthesis can also be used to transparently show heterogeneity between studies and issues of quality appraisal (Barnett-Page and Thomas, 2009). However, as with quantitative methods, a narrative synthesis could also introduce significant overlap and result in many primary studies being included more than once, which would lead to biased

results. Therefore, an assessment of study overlap must be undertaken for all umbrella reviews (Pieper et al., 2014).

4.3.9.2 Assessment of study overlap

The overlap in studies included by identified systematic reviews can be calculated using the corrected covered area (Pieper et al., 2014). To calculate the corrected covered area, citation matrices are generated that cross-link individual reviews (column in matrix) with all of the primary publications that were included (row in matrix). The percentage overlap is calculated as follows

$$C_c = \frac{N - r}{rc - r},$$

where C_c is the corrected covered area, N is the number of included publications (including double counting) in evidence synthesis; where r is the number of rows (number of index publications) and c is the number of columns (number of reviews).

While no universally accepted threshold exists, overlap can be classified as minimal (<5%), moderate (5-10%), or high (>10%) (Hennessy and Johnson, 2020).

4.3.9.3 Application in this thesis

A narrative synthesis was undertaken: data were arranged into standard tables, highlighting the context and characteristics of each study, with similarities and differences compared across studies (Barnett-Page and Thomas, 2009). The overlap in studies included by identified systematic reviews was calculated using the corrected covered area (Pieper et al., 2014).

4.4 Interviews with policymakers

Interviews with policymakers were conducted as an important preparatory step to inform the rapid-realist review. They explored Irish policymakers' perspectives on the anticipated aims, potential impacts, and implementation challenges associated with healthcare regionalisation in the Irish context. These interviews provided a

foundational understanding of the policy logic underpinning regionalisation, including the institutional and political constraints shaping reform and the aspirations driving the current policy agenda. Insights from the interviews were then used to define a policy-relevant question to guide the rapid realist review.

Section 4.4 presents the methodological considerations for conducting the interviews with policymakers. For each component of the method, the section first summarises the guidance available in the literature and then explains how this guidance was interpreted and applied in the interviews undertaken for this thesis.

4.4.1 Rationale

Interviews with policymakers were crucial to understanding how evidence on healthcare regionalisation can be applied to real-world policy decisions. As Petticrew et al. (2004), Sheldon (2005), Ogilvie et al. (2009), Chambers and Wilson (2012), and Saul et al. (2013) suggest, the relevance of evidence synthesis outputs often depends on the specific context in which they are to be used. To ensure that evidence is not only credible but also actionable, it is essential to align the research with the knowledge needs of policymakers and the environment in which they operate. Interviewing policymakers allowed this researcher to gain insights into how evidence on healthcare regionalisation was interpreted, the challenges involved in implementing a health system restructure, and the practical considerations that must be taken into account when designing and enacting policy. Furthermore, by incorporating policymakers' perspectives, the study can remain grounded in the realities of policymaking, ensuring that the findings are directly relevant to current policy decisions. This approach facilitates a better understanding of the ways in which evidence can be tailored to inform and shape effective healthcare policy.

4.4.2 Theoretical considerations of interviews with policymakers

Interviews with policymakers are a crucial qualitative research method used to explore decision-making processes, policy development, and the factors influencing policy choices. Theoretically, these interviews are grounded in the

field of interpretivism, which emphasises understanding the meaning and context behind human actions and decisions (Bryman, 2016). Policymakers' views are often shaped by a complex interplay of political, social, economic, and institutional factors, and interviews provide a direct avenue for capturing these subjective experiences and perspectives (Fischer, 2009; Ritchie et al., 2013). A key theoretical consideration in this context is the notion of bounded rationality, which posits that policymakers do not always make perfectly rational decisions due to limitations in information, cognitive biases, and time constraints (Simon, 1997). As a result, interviews with policymakers often reveal insights into the trade-offs and compromises made in the policy process. Additionally, power dynamics play a significant role in shaping the interview context, as policymakers may frame their responses based on political considerations or a desire to project certain narratives (Fischer, 2009). Furthermore, social constructivist theory suggests that policymakers' views are shaped by their interactions with others and the broader political environment, emphasising the importance of understanding how collective experiences and institutional contexts influence individual decision-making (Gergen, 2015). These theoretical frameworks highlight the need for researchers to consider the context of interviews with policymakers, ensuring that interpretations of interview data are informed by an awareness of power relations, cognitive limitations, and the broader social and political environment.

The main methodological considerations related to sampling, data collection, and data analysis are now described. Ethics and confidentiality are also considered.

4.4.3 Sampling

4.4.3.1 What the literature recommends

In contrast to quantitative research, where the goal is to collect a sample that represents the larger population for generalisation, qualitative research sampling does not seek generalisability. Instead, participants are intentionally chosen to represent specific characteristics or groups within a population (Marshall, 1996).

Qualitative research typically uses three main types of sampling methods: purposive, theoretical, and convenience sampling (Coyne, 1997; Marshall, 1996; Ritchie et al., 2003). These are described as:

1. Purposive sampling, also known as criterion-based or purposeful sampling, involves intentionally selecting participants who have specific characteristics that are relevant to the research. The goal is to gain in-depth insights into the issues being studied. Within this approach, there are various subtypes based on the research focus. For example, extreme or deviant case sampling targets outliers; maximum variation sampling seeks a diverse range of perspectives; homogeneous sampling focuses on individuals from the same subculture; and typical case sampling aims to include participants who represent 'normal' or 'average cases'. The key idea behind purposive sampling is to select 'information-rich' cases—participants who can provide valuable insights that are central to the research (Patton, 2015).
2. Theoretical sampling is a subtype of purposive sampling used primarily in grounded theory research. Participants are selected based on their potential to contribute to theory development. This sampling method is iterative, meaning new participants are selected as analysis and emerging theories evolve (Glaser and Strauss, 2017).
3. Convenience sampling involves selecting participants who are easiest to access. While it is often the least time-consuming and costly approach, it is also the least rigorous (Marshall, 1996).

In practice, these sampling methods often overlap, and many studies use a combination of strategies.

4.4.3.2 Application in this thesis

As described in Chapter 6, the sampling strategy for the stakeholder interviews in this study was purposive, specifically targeting Irish healthcare policymakers whose knowledge and involvement in the plans for regionalisation could inform plans for the evidence synthesis.

4.4.4 Data collection

4.4.4.1 What the literature recommends

Semi-structured interviews have three key characteristics: they involve open-ended questions that allow interviewees to express their own thoughts and ideas; they are interactive and flexible, enabling the interviewer to clarify and explore responses; and they have a structured purpose, even in more natural or informal settings (Gillham, 2005). These features are particularly useful when probing sensitive topics or exploring individual perspectives in depth.

Adams (2015) further highlights that semi-structured interviews are especially effective in situations where probing, open-ended questions are required to capture the autonomous views of individuals. This method is particularly beneficial when participants may not feel comfortable discussing sensitive matters in group settings, such as focus groups, or when individual interviews with key stakeholders, such as programme managers or service providers, are needed for formative programme evaluation. These features align with the goals of this study which aims to gather the individual opinions of policymakers about healthcare regionalisation in Ireland. The interview schedule used for this study can be found in Appendix A.

Alternative methods, such as a questionnaire survey, would not have provided the depth or nuance needed to understand the context of the choice to introduce healthcare regionalisation in Ireland. Similarly, while a focus group with different stakeholders from across Ireland might have fostered debate, it would not have allowed for the same level of honesty and openness as participants might have been hesitant to discuss concerns or specific issues in front of peers (Gillham, 2005).

Triangulation, which involves using multiple data sources or methods to confirm findings, is important in qualitative research for enhancing the credibility and validity of the analysis (Bowen, 2009; Merriam et al., 2016; Salkind, 2010). As Patton (2015) explains, triangulation helps test for consistency by comparing different types of data, which may reveal varying insights. Inconsistencies across

data sources are not seen as weaknesses but as opportunities for deeper understanding of the phenomenon being studied.

4.4.4.2 Application in this thesis

Semi-structured interviews were chosen as the preferred method of data collection because they are well-suited to gathering detailed information from stakeholders, particularly policymakers. Triangulation in this study was achieved by interviewing key stakeholders from two distinct perspectives: 1) individuals from the Department of Health, which oversees the health system, and 2) individuals from the Health Service Executive, which manages service delivery. These differing roles were expected to provide diverse perspectives on the issues being studied.

4.4.5 Data analysis

4.4.5.1 What the literature recommends

Qualitative analysis of interview data is influenced by the researcher's underlying epistemological and philosophical assumptions. A key distinction in qualitative analysis methods is between deductive approaches, like framework analysis, where pre-existing theories or hypotheses are tested using the data, and inductive approaches, such as grounded theory analysis, where theory is developed from the data itself (Bryman, 2016).

4.4.5.2 Application in this thesis

For analysis of the stakeholder interviews, an inductive thematic analysis approach was used (Anderson, 2007; Braun and Clarke, 2006; Smith et al., 1992). This was chosen because there was no *a priori* theory or framework being applied to the interview data. The analysis is described in more detail in the Chapter 6, which reports the results of the interviews.

4.4.6 Ethics and confidentiality

Ethics approval for the stakeholder interviews was obtained through the University of Glasgow College of Medical, Veterinary and Life Sciences ethics committee (Project No: 200200004). As the participants were all senior policymakers working

to a high degree of autonomy and independence, and participation was entirely voluntary, the main ethical considerations for the interviews related to informed consent, confidentiality, and data storage. A copy of the approval letter is available in Appendix B.

4.4.7 Reflexivity

Reflexivity is a key component of qualitative research (Barrett et al., 2020; Cunliffe, 2003; Finlay, 2002a, 2002b). It relates to the degree of intentional or unintentional influence the researcher exerts on the finds of a study (Jootun et al., 2009). Parahoo (2014, p. 214) defines reflexivity as “the continuous process of reflection by researchers on how their own values, perceptions, behaviour or presence and those of the respondents can affect the data they collect.”

Reflexivity is necessary to enhance the trustworthiness and integrity of the research (Barrett et al., 2020; Finlay, 2002a). Reflexive analysis in research requires ‘a shift in our understanding of data collection from something objective that is accomplished through detached scrutiny of “what I know and how I know it” to recognising how we actively construct our knowledge’ (Finlay, 2002a, p. 532). In this section I reflect on the influence of my own professional relationship on the qualitative interviews that I have conducted and the concept of regionalisation.

As outlined in Chapter 1, I was an employee of the HRB and was lead author of the report *Regional health organisation: An evidence review* (Quigley et al., 2019). In my three plus years at the HRB, I worked closely with policymakers to develop reports that would inform future policy decisions. I collaborated with several interviewees on the development of the healthcare regionalisation report. As I worked with the team that was introducing the regional health areas to Ireland, I may have had a personal bias towards healthcare regionalisation. However, as a citizen of Ireland, I have also seen how previous health system restructures, for example centralisation with the introduction of the HSE, have failed to make the improvements they were intended to bring about. Therefore, the direction of potential bias in my interpretation of the data is uncertain.

It is impossible for me to remove my previous views completely from the analysis, but I have endeavoured to keep all results grounded in the data and have used quotes to support the findings where appropriate. I have also used data triangulation with interviews which should provide a counterbalance to any inherent bias I have introduced to the analysis.

My prior knowledge of the system has also proved invaluable in the analysis of the contents of the interviews, as well as during the interviews. During the interviews less time was needed to describe the nuances to the Irish healthcare system so more time could be spent on unpacking key questions.

4.5 Scoping review definitions of patient-centred care

Section 4.5 presents the methodological considerations for conducting the scoping review of definitions of patient-centred care. For each component of the method, the section first summarises the guidance available in the literature and then explains how this guidance was interpreted and applied in the scoping review undertaken for this thesis.

4.5.1 Rationale

After conducting interviews with policymakers, it became evident that patient-centred care was a primary focus for Irish policymakers, as presented in Chapter 6. The definition of patient-centred care varies across disciplines. Therefore, as a preliminary step for the rapid-realist review, a scoping review was conducted to identify the different definitions and conceptualisations of patient-centred care across healthcare systems. A scoping review is defined as a type of review that aims to map the key concepts, types of evidence, and research gaps in a specific research area (Peters et al., 2015). They differ from systematic reviews in that they do not focus on synthesising evidence to answer specific research questions but rather aim to provide a broad overview of a field. The methodology for conducting a scoping review is typically more flexible than that of a systematic review. Through this scoping review, the most suitable definition of, and

measurement variables for patient-centred care for the rapid realist review were identified.

4.5.2 Theoretical considerations

Scoping reviews are a valuable method for mapping the existing literature on a broad topic, identifying key concepts, theories, and research gaps. Theoretically, scoping reviews are rooted in a pragmatic approach to evidence synthesis, where the emphasis is on exploring the breadth of a topic rather than synthesising detailed outcomes or evaluating the quality of the evidence (Arksey and O'Malley, 2005). This aligns with the epistemological stance of pragmatism, which values the usefulness of knowledge in addressing real-world problems, rather than strictly focusing on methodological rigour (Creswell, 2012). These theoretical considerations emphasise the exploratory nature of scoping reviews, highlighting their utility in providing a comprehensive overview of a field without delving into detailed analyses of individual studies.

4.5.3 Defining the Research Question

The first step in a scoping review is to clearly define the research question or aim of the review. The research question for a scoping review is usually broad and exploratory, often seeking to map the existing literature on a particular topic (Arksey and O'Malley, 2005). This question can evolve as the review progresses, allowing for flexibility in the types of studies that are included. The research question developed for this study was:

‘What is patient-centred care, and what is the most appropriate definition for use in the context of healthcare regionalisation specifically in Ireland?’

4.5.4 Identifying relevant studies

4.5.4.1 What the literature recommends

A comprehensive search strategy is recommended for identifying relevant studies for inclusion in the scoping review. The search process typically involves a systematic search of multiple databases, along with grey literature sources, to ensure that all potentially relevant studies are identified (Colquhoun et al., 2014).

In contrast to systematic reviews, scoping reviews often include studies with different designs, such as qualitative, quantitative, and mixed-methods studies, to provide a comprehensive overview of the topic (Munn et al., 2018). Despite the goal of inclusivity, pragmatic constraints may mean that not all relevant studies can be included, and decisions must be made about the scope of the review. For instance, a scoping review might focus on particular geographical areas, specific populations, or time periods due to limitations on resources or time (Booth et al., 2016). These pragmatic limitations should be transparently reported, as they can influence the breadth and depth of the findings. A pragmatic approach was taken in this thesis as the scoping review was to inform further research rather than be the basis for decision making.

4.5.4.2 Application in this thesis

A targeted search for definitions and measurements of patient-centred care was carried out in MEDLINE. Systematic reviews were sought with any synthesis method considered. The search was limited from 2014 to the date of the search and by English language to keep the scope manageable in the timeframe of this PhD. This pragmatic year limit was selected to account for the publication of the comprehensive Health Foundation report in 2014 as the work of this thesis builds on that report (De Silva, 2014).

To ensure that the findings remained relevant to Irish policymakers, an additional targeted search for Irish definitions of patient-centred care was undertaken. The Sláintecare reform document, which first introduced the concept of healthcare regionalisation under consideration by Irish policymakers, was reviewed for definitions of patient-centred care. However, no formal definition of patient-centred care was found in these documents. Instead, relevant excerpts mentioning patient-centred care were extracted and used to assess the relevance of definitions from the literature.

4.5.5 Study selection and inclusion criteria

4.5.5.1 What the literature recommends

Once relevant studies are identified, inclusion and exclusion criteria must be established to guide the selection of studies for the review. The criteria typically relates to the research question, the types of studies, the population of interest, and the context of the research. For scoping reviews, there is often more flexibility in terms of the types of studies included, as the goal is to map the breadth of literature rather than assess the quality or specific outcomes of individual studies (Peters et al., 2015).

4.5.5.2 Application in this thesis

For consideration in this review, studies were required to describe a definition or conceptualisation of patient-centred care that was applicable to this research. Papers that collated tools used to measure patient-centred care were also included. Frameworks for the implementation of a patient-centred care system were not considered. Papers that were specific to a particular population e.g. dementia or older people, or specific settings or perspectives, e.g. GP care or nurses were excluded as they were not considered generalisable to a whole health-system intervention such as healthcare regionalisation.

4.5.6 Data charting and reporting results

4.5.6.1 What the literature recommends

Data charting is the process of extracting relevant data from the included studies. Charting involves systematically recording key information such as study characteristics, methodology, and key findings (Levac et al., 2010). This step is essential for organising the data and identifying patterns or trends across studies. Unlike systematic reviews, which often assess the quality of individual studies, scoping reviews typically do not include a quality assessment, as the focus is on mapping the breadth of evidence rather than evaluating its rigour (Arksey and O'Malley, 2005).

Once the data has been charted, the next step is to collate and summarise the findings. The results are typically presented in a descriptive manner, identifying key themes, trends, and gaps in the literature. A key feature of scoping reviews is the ability to identify areas where research is sparse or where future studies are needed (Munn et al., 2018). This step may involve grouping studies based on common themes, outcomes, or methodologies, and it often includes visual representations such as charts or tables to facilitate understanding (Peters et al., 2015).

Scoping reviews should be reported according to the 'Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews' (PRISMA-ScR) (Tricco et al., 2018).

4.5.6.2 Application in this thesis

Data charting was conducted for the identified studies, involving the systematic recording of key information such as study characteristics, methodologies, and definitions. This process was used to organize the data and identify patterns or trends across the studies (Levac et al., 2010). The outcome of this process was the development of a matrix of patient-centred care definitions. Quality assessment was not conducted (Arksey and O'Malley, 2005).

Additionally, the transcripts from interviews described in Chapter 6 were examined for pertinent concepts. The reporting of this scoping review follows PRISMA-ScR (Tricco et al., 2018).

4.6 Rapid-realist review

Section 4.6 presents the methodological considerations for conducting the rapid-realist review. For each component of the method, the section first summarises the guidance available in the literature and then explains how this guidance was interpreted and applied in the rapid-realist review undertaken for this thesis. This structure ensures a clear distinction between established methodological standards and the specific decisions made in this study.

4.6.1 Rationale

As discussed in Chapter 2, rapid-realist review could be a valuable evidence synthesis method for the evidence on healthcare regionalisation due to its ability to provide timely, context-sensitive insights into complex, context-dependent interventions. A realist approach was used for this review because it is particularly suited to the investigation of complex interventions and a mixed body of evidence, incorporating a wide range of primary study designs (Pawson et al., 2005). Unlike traditional systematic reviews, rapid-realist reviews prioritise understanding how and why certain interventions work (or do not work) in specific settings, which is crucial for the nuanced, multi-faceted nature of healthcare regionalisation. This approach allows for the examination of underlying mechanisms, contextual factors, and stakeholder perspectives, offering a more dynamic understanding of how regionalisation strategies impact healthcare delivery and outcomes. Additionally, rapid-realist reviews are designed to be completed within a shorter time frame, making them ideal for informing policy and practice in rapidly evolving contexts, such as healthcare restructuring or regional reforms (Saul et al., 2013). The method's focus on the theory behind interventions also helps to generate actionable recommendations that can be adapted across various regions with differing healthcare needs and resources (Mukumbang et al., 2025; Power et al., 2019). Therefore, rapid-realist review provides a flexible and efficient framework for synthesising evidence on healthcare regionalisation, ensuring that findings are both timely and relevant to local contexts.

This study adapts and works from the rapid-realist review methodology proposed by Saul et al. (2013). Another method for rapid-realist review has been loosely defined by Serrano-Gallarado and Pawson (Serrano-Gallardo et al., 2022). The work by Serrano-Gallarado et al. was uniquely developed during the COVID-19 pandemic and as such the rapid-review methods described are mostly applicable in the context of a rapidly moving field with an overwhelming amount of literature and therefore considered not applicable to this case study.

4.6.2 Theoretical underpinnings of realist review and rapid-realist review

The origins of realist review can be traced back to the early 2000s, when Pawson and colleagues recognised that traditional systematic reviews, which typically focus on evaluating the effectiveness of interventions in a generalisable way, were ill-suited for capturing the complexities of real-world interventions. Systematic reviews tend to emphasise quantitative outcomes and often overlook the underlying mechanisms or contextual factors that influence the effectiveness of interventions (Pawson et al., 2005). Pawson's work emphasised the need to understand *why* and *how* interventions work (or do not work), rather than just whether they work, arguing that such understanding is critical for informing practice, particularly in fields like healthcare and social policy.

Pawson's approach was grounded in the belief that interventions function within specific contexts, which means that understanding the mechanisms that drive change is essential. The key insight was that interventions cannot be fully understood through mere outcome measurement alone. Instead, researchers need to consider how different contexts, mechanisms, and the interplay between them led to particular outcomes (Pawson, 2006). This recognition of the complexity of interventions led to the development of the realist review methodology.

The theory-driven nature of realist review allows researchers to develop and refine theories based on evidence, rather than simply aggregating findings from studies. This approach is often described using the “Context-Mechanism-Outcome” (CMO) configuration, where C refers to the conditions or context in which an intervention is implemented, M refers to the mechanisms that trigger change, and O refers to the outcomes that result from the interplay between context and mechanism (Pawson, 2006).

Rapid-realist review, a more recent adaptation of the realist-review methodology, emerged as a response to the increasing demand for timely evidence in complex decision-making contexts, such as public health and policy (Saul et al., 2013).

While it retains the core principles of realist review, rapid-realist review prioritises efficiency by streamlining the process of data extraction and synthesis. Rapid-realist review focuses on producing actionable insights more quickly, typically within a few months, by utilising fewer resources and reducing the time spent on comprehensive data collection. This is achieved through strategies such as limiting the number of studies to be included, focusing on key theoretical concepts and leveraging expert opinion to build and refine theories rapidly (Saul et al., 2013). Despite its faster pace, rapid-realist review maintains a focus on understanding how interventions work in specific contexts and aims to provide timely yet robust insights for policymakers, practitioners, and stakeholders.

Empirical realism is a key philosophical underpinning of realist review drawing from the notion that knowledge is grounded in real-world experiences but is always shaped by the context in which it is observed. In the context of realist review, empirical realism suggests that interventions are not merely evaluated in terms of outcomes but are understood through the lens of how real-world mechanisms function within specific social, cultural, and institutional settings (Pawson, 2006). This perspective aligns with the view that reality is not a static entity but is constructed through the interaction of various factors, including human agency, institutional structures, and environmental conditions. For realist reviews, this means that interventions can never be fully understood in isolation; their success or failure depends on how they interact with the context in which they are applied. By focusing on understanding the "how" and "why" of interventions, rather than simply measuring whether they work, realist reviews provide a more nuanced, context-sensitive explanation of interventions and their outcomes. Thus, empirical realism in realist review emphasises the importance of understanding interventions as complex, context-dependent processes, with findings that are grounded in the specific realities of the settings under investigation (Pawson, 2006).

4.6.3 Defining the research question

4.6.3.1 What the literature recommends

The first step in a rapid-realist review involves developing the project scope, which requires collaborating with knowledge users to define the content area of

interest for the review (interviews with policymakers section 4.4) ensuring that the process is feasible given the timeline. The next step is to refine the research questions ensuring they are specific and answerable with the available evidence. This step is crucial in shaping the direction of the review. The scoping review of definition of patient-centred care (section 4.5) were part of this step. Following this, the purpose and intended use of the findings must be clarified by formulating a purpose statement, which outlines how the review's results will be applied by the target audience. This element distinguishes rapid-realist reviews from traditional systematic reviews, as it emphasises the practical application of findings, ensuring that the review stays focused on the needs of knowledge users throughout the entire process of searching, data extraction, and synthesis (Saul et al., 2013).

Saul et al. (2013) recommend the convening of two advisory groups as part of their rapid-realist review methodology:

- a local reference group is engaged to ensure that the project will produce results that will be relevant for the context in which they will be used. The reference group typically includes representatives of the funding organisation, as well as knowledge users (the target audience for the findings of the review).
- An expert panel, consisting of researchers and practitioners actively working in the field, focuses the review scope, streamlines the search process, and aids in interpreting results. This panel is often convened quickly thanks to existing connections between knowledge users and content experts.

This aligns with the use of advisory group in realist review. Advisory groups can be a valuable resource in a realist review, offering external and independent perspectives informed by their experience with the topic area (Power et al., 2024). These groups can be engaged at any stage of the review process, with their involvement shaped by the specific needs of the review. The purpose of the advisory group should be defined based on the review's focus and their role should

be guided by the requirements of the review. Proper documentation of their involvement ensures transparency in how the advisory group is utilised.

4.6.3.2 Application in this thesis

In this thesis a pragmatic approach to stakeholder involvement was undertaken. Policymakers were consulted at both the beginning (through semi-structured interviews) and end of the project. The rationale for this approach was three-fold: the project began during the COVID-19 pandemic and so healthcare policymakers were extremely busy; this was a part time PhD and so the project has continued over five years which would require a significant time commitment from any advisory group member; and finally this researcher has significant amount of experience in the study of healthcare regionalisation and so could use this to fulfil the role of the expert advisory group as proposed by Saul et al. (2013).

4.6.4 Literature search strategy

4.6.4.1 What the literature recommends

In comparison to a full realist review in which it is essential to cast a wide net in the search for studies to ensure that the review captures the full spectrum of evidence, methods for study identification must be streamlined in a rapid-realist review (Saul et al., 2013). Saul et al. (2013) recommend that identification of studies for inclusion in the review (both published and grey): begin with a list of documents as identified by knowledge users and content experts.

Similar to full realist reviews, grey literature is particularly important in rapid-realist reviews because it often contains valuable insights that are not available in traditional academic publications, especially for policy interventions. Booth et al. (2016) highlighted the importance of incorporating grey literature in order to address the gap between research and real-world application, ensuring that findings are not overly influenced by the publication bias commonly seen in peer-reviewed journals. This type of literature is crucial in understanding the context and mechanisms behind the success or failure of policy interventions as it often reflects the practical realities of policy implementation and outcomes in diverse settings (Booth et al., 2020). Including grey literature also helps to reduce the risk

of overlooking important studies, especially those that may not be indexed in academic databases but are key to the intervention's real-world impact.

4.6.4.2 Application in this thesis

In this thesis, this step was augmented to make use of my expertise and previous research on healthcare regionalisation – references lists of the HRB evidence review and systematic reviews from the umbrella review (Chapter 5) were the first source of potentially relevant studies. A search in MEDLINE was also undertaken.

As a rapid realist-review was undertaken in this project, a database search was conducted for MEDLINE only. However, significant supplemental searching was undertaken for grey literature as outlined further in Chapter 8.

4.6.5 *Quality appraisal: rigour and relevance*

4.6.5.1 What the literature recommends

The process of quality appraisal is not explicitly defined for a rapid-realist review (Saul et al., 2013). Therefore, the methods for full realist review were applied in this thesis. In realist synthesis, studies are assessed based on two criteria: relevance and rigour. Considering both rigour and relevance is crucial to ensuring that the findings are robust and applicable to real-world contexts. Rigour refers to the systematic and transparent methods used to identify, select, appraise, and synthesise evidence, ensuring that the review process is thorough, repeatable, and free from bias. This involves careful attention to how studies are included and how their quality is assessed, as well as a clear rationale for the synthesis process (Pawson et al., 2005). Relevance, on the other hand, focuses on ensuring that the evidence considered is directly applicable to the context and questions of interest, particularly in relation to the mechanisms, contexts, and outcomes of interventions (Pawson, 2006). In realist reviews, it is essential to balance rigour with relevance by seeking out a diverse range of evidence, including grey literature and context-specific studies, which can provide deeper insights into how and why interventions work in different settings (Booth et al., 2020). As such, the process should not only be methodologically sound but also responsive to the

practical needs of policymakers and practitioners ensuring that the review's findings are both scientifically credible and actionable.

4.6.5.2 Application in this thesis

Two reviewers independently used the full paper descriptions of a study's purpose, methods and analysis and the claims made by its authors to decide if that study was a good fit for this review. A study of good fit is one that appears to be credible and trustworthy, and contains descriptive information that can potentially support developing a theory regarding healthcare regionalisation and patient-centred care (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012). The independent reviewers resolved disagreement through discussion or with the involvement of a third reviewer when necessary. An assessment of rigour, such as through application of a critical appraisal tool, was not formally undertaken as part of this rapid realist review due to the rapid nature of the work.

4.6.6 Data analysis

4.6.6.1 What the literature recommends

Understanding how and why healthcare regionalisation produces different outcomes across settings requires an approach capable of unpacking the underlying causal processes. Realist synthesis provides such an approach by focusing on the interaction between context, mechanism, and outcome – the key building blocks of realist analysis. Within this framework, context-mechanism-outcome (CMO) configurations act as the primary analytical tool for explaining how and why interventions succeed or fail in particular circumstances (Jagosh et al., 2012; Pawson and Tilley, 1997). In realist logic, each CMO configuration represents a causal proposition describing how specific mechanisms are triggered within particular contextual conditions to generate outcomes (Pawson et al., 2005).

4.6.6.2 Application in this thesis

Explanatory propositions were initially articulated using “if-then-because” statements (Pearson et al., 2015a), which express that a given outcome (“then”) occurs because a mechanism (“because”) is activated when a certain contextual condition (“if”) is present. For example, if resources are decentralised (context),

then decision-making may become more responsive (outcome), because local managers perceive greater autonomy and accountability (mechanism). Explanatory accounts were extracted from each included document into a structured data extraction form, with reference back to the original studies when clarification or contextual detail was required (Wong et al., 2013b).

To move beyond individual CMO configurations, recurrent themes within CMO configurations were grouped to identify emerging patterns of CMOs. This involved comparing and grouping similar CMOs to uncover recurrent causal patterns (Jagosh et al., 2014; Rycroft-Malone et al., 2012). Through iterative review, these patterns were refined as the research team became increasingly familiar with the evidence base. Data were revisited across studies to confirm, refute, or refine emerging CMO configurations, ensuring that each was supported by multiple data sources rather than isolated findings. The CMO configurations supported the development and refinement of an initial program theory and strengthened its explanatory power.

The final stage of a rapid-realist review involves the presentation and testing of the initial programme theory with stakeholders (Saul et al., 2013). For this thesis, a meeting was organised with stakeholders who were asked to review and evaluate the presentation of the programme theory which has been developed from the literature. The stakeholders were asked to identify issues in clarity of presentation of the theory and offer guidance on usefulness for policymakers. The research team then refined the theory and its presentation. It is through this iterative process of stakeholder review and refinement that theory is tested and validated in a realist review. (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012). The synthesis of findings in the report should be formatted in a way intended to meet the needs of the knowledge users (Saul et al., 2013).

4.7 Formal comparison of evidence synthesis methods

Comparing evidence synthesis methods involves evaluating the strengths, limitations, and appropriateness of different approaches based on the research

question, the type of evidence available, and the goals of the synthesis. In Chapter 2, the framework by Wickremasinghe et al. (2016) was used to compare methods for evidence synthesis.

While this chapter focuses on describing the evidence synthesis methods used, lessons learned from their application are not collated here. Instead, these reflections are brought together in Chapter 9, where the framework by Wickremasinghe et al. (2016) is used to systematically compare traditional systematic review with umbrella review and rapid realist review undertaken in this thesis. That discussion extends the original framework by incorporating additional considerations relevant to health system reform and policy research, and by including the rapid-realist review within the framework for the first time.

These lessons are then translated into actionable recommendations for researchers working in EIP, providing guidance on selecting evidence synthesis methods to meet the needs of complex health policy contexts.

4.8 Chapter summary

This chapter has provided an overview of the methodological and theoretical considerations that informed the conduct of the umbrella review and rapid-realist review in this thesis. Rather than comparing review types, the focus here was to outline how each method is described in the literature and to detail how those methodological recommendations were operationalised in the context of this research.

This chapter offers a unifying narrative explaining the principles underpinning each method, the rationale for key methodological choices, and the adaptations made to ensure their suitability for evidence-informed policy. It also describes the preparatory steps required for the realist component, including interviews with policymakers and a scoping review of definitions of patient-centred care, which were undertaken to ensure conceptual clarity and policy relevance before progressing into formal theory development.

While the operational detail for each synthesis method is presented in the respective results chapters, this chapter has set out the methodological foundations on which those analyses were built. The findings themselves, along with the cross-method comparison, are reported in Chapters 5 to 9.

Results Part 1

Chapter 5 Regionalisation of healthcare systems: an umbrella review

5.1 Overview

This chapter uses umbrella review methods to synthesise findings from systematic reviews of healthcare regionalisation. As described in Chapter 3, this method is considered to be appropriate for evidence-informed policymaking when time is limited, and there are systematic reviews already published on the topic. As umbrella reviews include existing systematic reviews the chapter also identifies lessons learned on the synthesis of evidence for healthcare regionalisation.

5.2 Introduction

Healthcare regionalisation involves transferring responsibility for healthcare to a regional body, typically through a combination of decentralisation from national agencies and selective centralisation of local services (Quigley et al., 2019). It has been implemented in a range of high-, middle-, and low-income countries, yet the impact of such system-wide reforms remains uncertain with prior reviews producing inconclusive findings (Dwicaksono and Fox, 2018; Quigley et al., 2019).

Fiscal federalism provides a theoretical lens for understanding regionalisation, proposing that decentralisation can improve the alignment of services with local population needs and enable more efficient resource allocation (Oates, 1999, 1972). In practice, regionalisation reflects the interplay of local, regional, and national actors, organisations, and policies, with coordination and integration intended to improve quality, efficiency, equity, and responsiveness of care (Church and Barker, 1998; Lorne et al., 2019; Marchildon, 2015; Schuurmans et al., 2020). However, balancing decentralisation and local centralisation is critical, as excessive focus in either direction may undermine these potential benefits.

Given the heterogeneity of findings, the wide range of system- and patient-level impacts, and the resources required to implement regionalisation, there is a clear need to consolidate existing evidence. Building on the literature review of evidence synthesis methods (Chapter 2) and the methodological limitations identified in the Health Research Board review of regionalisation (Chapter 3), this chapter presents an umbrella review to systematically summarise the impact of regionalisation on health systems and service users (Sutton et al., 2019). In doing so, it addresses gaps identified in earlier chapters and provides a foundation for exploring synthesis approaches capable of capturing contextual and system-level influences in later chapters.

5.3 Methods

An umbrella review is a review of systematic reviews and is considered appropriate when multiple systematic reviews on a topic exist (Belbasis et al., 2022). They are considered particularly useful when the focus is on a broad problem, such as regionalisation, and where there are competing interventions (Grant and Booth, 2009; Sutton et al., 2019). A protocol was developed and uploaded to the OSF registry in February 2021 (<https://doi.org/10.17605/OSF.IO/DH4ES>). Throughout, attention was paid to the preferred reporting items for overviews of reviews (PRIOR) guideline to guide the review process (Gates et al., 2022). This checklist is similar to the PRISMA checklist which is applied to systematic reviews, and is recommended by the Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network (“Reporting Guidelines by the UK EQUATOR Centre,” n.d.).

5.3.1 Search strategy

MEDLINE and Embase index most systematic reviews of health service organisation interventions, therefore, we searched these two databases (Hartling et al., 2016). In addition, searches of the Cochrane database of systematic reviews and the archived Database of Abstracts of Reviews of Effects (DARE) database of systematic reviews were also conducted. Previous work on regionalisation (Quigley et al., 2019) has shown that grey literature is particularly important for this topic and so grey literature searching was also conducted in search engines Google and Google Scholar. The incognito browsing option was used in Google to ensure the search

was not biased by previous searching related to the topic. Search strategies combined controlled vocabulary and free-text terms for systematic review and healthcare regionalisation. Search strategies used in MEDLINE and Embase are provided in Appendix C.

5.3.2 Eligibility criteria

The research question was summarised using the PICOTS format (Population, Intervention, Comparator, Outcome, Time, Study design) as outlined in Table 5-1 (Riva et al., 2012). As this is an umbrella review, eligible study design was specified as systematic and realist reviews.

Table 5-1 PICOTS criteria

Element	Description
Population	A general population with access to public health care
Intervention	Whole health system regionalisation or decentralisation
Comparator	Any comparator
Outcomes	Any outcome
Time period	1990-current
Study design	Systematic reviews with or without meta-analyses; realist reviews

Studies did not have to specify healthcare regionalisation for inclusion but did have to meet our working definition of healthcare regionalisation which is the

movement of responsibility for healthcare towards a regional body. As regionalisation often comprises a large component of decentralisation, studies of decentralisation were also included. Studies of centralisation alone were not included as these studies focus on centralisation as intervention leading to the removal of all regional responsibility for healthcare (Scarffe et al., 2022). The reviews could include any primary study designs. Review protocols were excluded, as were studies not published in English due to a lack of funding for translation.

The review was not geographically limited, given that included reviews may report on studies from a wide range of country settings.

5.3.3 Study selection

Search results were downloaded into EndNote, version X9, and duplicates removed. This software was used to manage references at all stages of the systematic review. Abstracts were reviewed according to the eligibility criteria by two reviewers (JQ all, NH and HT). Following the title and abstract screening, the full texts of potentially eligible reviews were reviewed independently by two reviewers (JQ all, NH and HT). Final decisions on inclusion were made by referring to a third reviewer (NH or HT) and discussion until consensus was reached.

A PRIOR flow chart (Gates et al., 2022) for the review and a list of excluded full papers alongside the reason for exclusion are provided in Figure 5-1 and Appendix D respectively.

5.3.4 Data extraction and synthesis

Data on the study characteristics, main findings, synthesis methods, conclusions, and recommendations for future research were extracted. Data were extracted into a data extraction template, which had been tested for comprehensiveness with two studies. A narrative synthesis of extracted data was undertaken: data were arranged into standard tables, highlighting the context and characteristics of each study, with similarities and differences compared across studies (Barnett-Page and Thomas, 2009). This method is appropriate for the pooling of different types of data, e.g. qualitative and quantitative (Dixon-Woods et al., 2005).

Narrative synthesis can also be used to transparently show heterogeneity between studies, and issues of quality appraisal (Barnett-Page and Thomas, 2009). The overlap in studies included by identified systematic reviews was calculated using the corrected covered area (Pieper et al., 2014).

5.3.5 Assessing methodological quality of included systematic reviews

AMSTAR 2 was used to critically appraise included systematic reviews (Shea et al., 2017). This tool was selected as it has the flexibility to appraise systematic reviews that include randomised or non-randomised studies of interventions, or both. This appraisal was conducted by two independent reviewers (JQ all, KOD and NH). One of four ratings of overall confidence in the review was assigned: high – no or one non-critical weakness, moderate – more than one non-critical weakness, low – one critical flaw with or without non-critical weaknesses, and critically low – more than one critical flaw.

5.4 Results

5.4.1 Search results

Systematic searches conducted in January 2021 and updated in April 2024 identified nine systematic reviews which met the eligibility criteria for this umbrella review. A PRIOR flow chart diagram is given in Figure 5-1, and list of the studies excluded at full paper review is in Appendix D.

5.4.2 Overview of included reviews

An overview of the nine included systematic reviews is reported in Table 5-2. Three reviews included studies from high-, low- and middle-income countries, two included studies from low- and middle-income countries, and one included studies from OECD countries only. One review included only studies from sub-Saharan Africa, one included studies from Indonesia only, and one included studies from Brazil only. The number of primary studies included in the systematic reviews ranged from nine to 57 studies. There is a slight overlap in studies included by the

systematic reviews. The corrected covered area, which is a measure of overlap, was calculated to be 2% (Pieper et al., 2014).

There was no common single definition of regionalisation across studies (Table 5-2). Three of the reviews specifically referred to regionalisation, each using their own unique definition (Mello et al., 2017; Quigley et al., 2019; Ramos et al., 2020). Two reviews focused on decentralisation, defined using a standardised typology consisting of four parts: devolution, delegation, deconcentration and privatisation (Sumah et al., 2016; Zon et al., 2017). One review focused on only one part of decentralisation: devolution (Dwicaksono and Fox, 2018). The remaining three reviews used their own unique definition of decentralisation (Abimbola et al., 2019; Cobos Muñoz et al., 2017; Rakmawati et al., 2019). The systematic review by Ramos et al. included aspects of whole health system regionalisation and regionalisation of specific aspects of a system only, e.g. concentration of procedures in hospitals with high volume of production. The outcomes for whole health-system regionalisation (defined as decentralisation in their study) are reported separately in this paper and so these outcomes are included in this analysis.

There was considerable variation in the outcomes reported in the included reviews, as outlined in Table 5-2. Two reviews reported on the six WHO health system building blocks (leadership and governance, health systems financing, access to essential medicines, health information systems, health workforce, health service delivery) (Cobos Muñoz et al., 2017; Rakmawati et al., 2019), one reported on measures of equity, efficiency, and resilience (Abimbola et al., 2019), one reported only on equity (Sumah et al., 2016), one reported on resource use and service organisation indicators (Zon et al., 2017), one reported on factors that support or hinder regionalisation (Mello et al., 2017). The remaining three reviews (Dwicaksono and Fox, 2018; Quigley et al., 2019; Ramos et al., 2020) included a wide range of health and system indicators such as infant mortality, cost and resource utilisation. Four systematic reviews reported on the wider context in which regionalisation was taking place, for example budgetary constraints. Five

systematic reviews had inclusion criteria requiring included studies to report a counterfactual or control, for example a historical control. Eight of the nine studies were considered to be of critically low quality based on the AMSTAR 2 critical appraisal tool. The breakdown of rating across 16 domain is given in Appendix F.

Figure 5-1 PRIOR Flow diagram

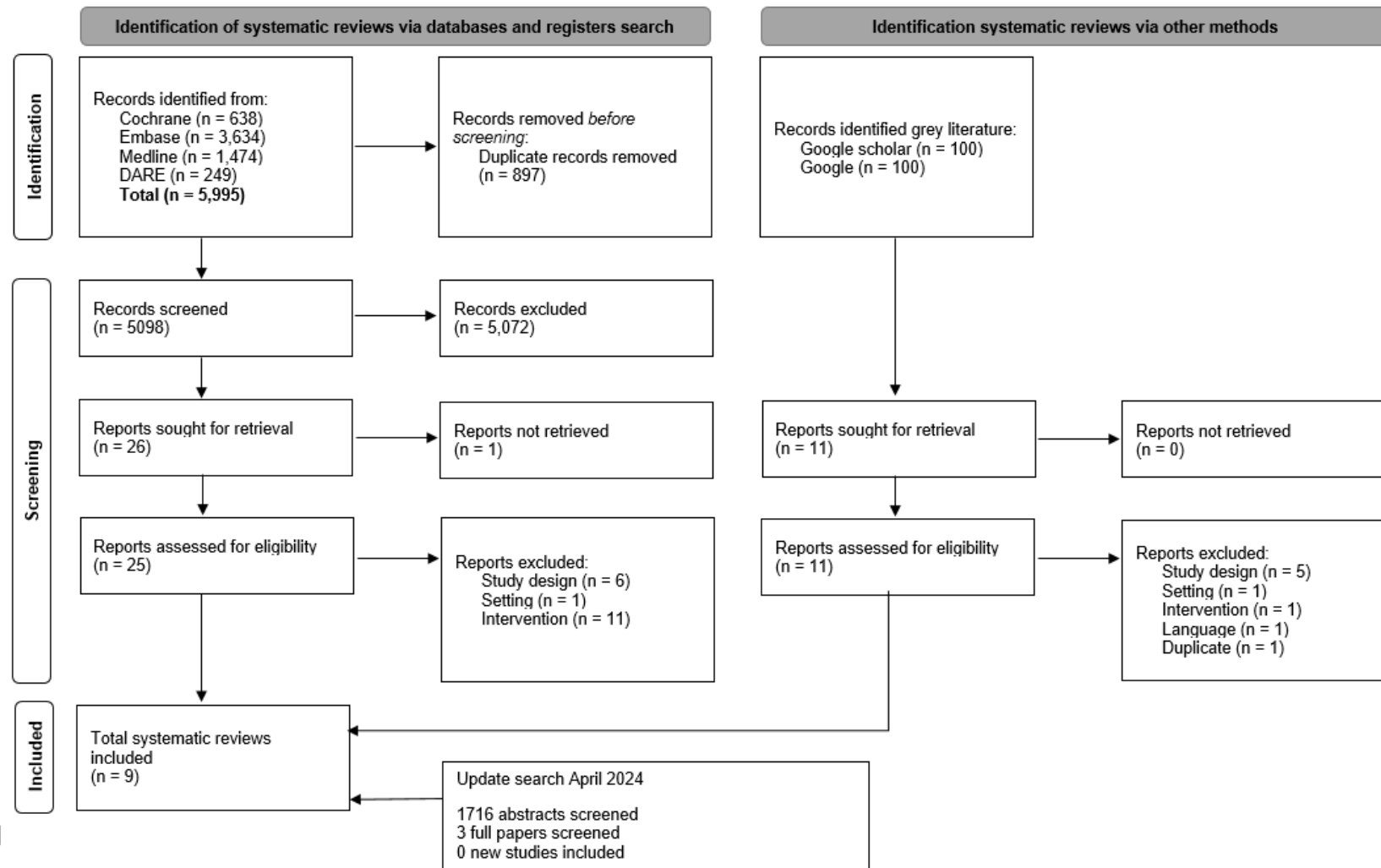


Table 5-2 Overview of included systematic reviews

Study ID	N included studies and breakdown of included study designs	Countries included	Definition of regionalisation	Outcomes studied	Other data extracted for synthesis	Counterfactual required?	Study Aim	AMSTAR 2 rating for systematic review
Sumah 2016	N=9 All quantitative	High-, low- and middle-income countries	Devolution, delegation, de-concentration and privatisation	Health-related equity	-	No	To conduct a systematic literature review of the implications of decentralised governance of health care on equity in health, health care and health financing.	Critically low quality
Cobos-Munoz 2017	N=54 11 qualitative studies, 28 quantitative studies and	Low- and middle-income countries	Decentralisation is a process in which some technical, managerial or fiscal functions of the health	Six WHO building blocks: Leadership and governance, Health systems financing, Access to essential	-	Yes	To provide an updated and comprehensive assessment of the effects of decentralisation in LMICs.	Critically low quality

	15 mixed methods studies		system are transferred from central structures to local structures.	medicines, Health information systems, Health workforce, Health service delivery				
Mello 2017	N=26 2 quantitative studies, 18 qualitative studies and 6 mixed methods studies	Brazil	Upwards regionalisation	Factors that support or hinder regionalisation processes.	-	No	A systematic review of the recent experiences of regional organisation of Brazil's SUS, in search of the main factors conditioning this process in Brazil.	Critically low quality
Zon 2017	N=21 19 primary qualitative studies, 2	Sub-Saharan Africa	Devolution, delegation, de-concentration and privatisation	Financing and resources allocations, Services organization and management,	Context	No	To review the experiences of local governments of Sub-Saharan African countries in the provision of municipal health services	Critically low quality

	literature reviews			Human resources and capacity building, Governance at local level, Use of services			during and after decentralisation reforms.	
Dwicaks ono 2018	N=16 All quantitative	low- and middle-income countries	Devolution, that is a form of decentralisation that entails devolving responsibility, authority, and accountability to lower levels of government units with some degree of political autonomy.	Quantifiable health indicators: Health system inputs (eg, financial, human, and physical resources), Health system performance (eg, changes in service utilisation, changes in service coverage, changes in quality of services), Health	Decentralisation constructs and context	Yes	To identify evidence on whether and how decentralisation processes have impacted health systems.	Critically low quality

				outcomes (eg, infant mortality rates, maternal mortality rates, life expectancy).				
Abimbola 2019	N=51 Individual study designs are not reported.	High-, middle- and low-income countries	Decentralisation as either an intervention or phenomenon. Intervention: an arrangement in which the power, resources or responsibilities are transferred from central to peripheral actors - a top down approach. Phenomenon: power, resources or responsibilities are widely	Equity, efficiency, resilience	Context. Mechanisms that explain the relationship between outcomes and context.	Yes	To understand why, how and under what circumstances decentralisation influences health system equity, efficiency and resilience.	Critically low quality

			distributed in society such that decentralisation describes the default state of affairs in human society, prior to or irrespective of the decision to centralise governance.					
Rakmawati 2019	N=29 21 quantitative , 8 qualitative	Indonesia	Decentralisation as implemented in Indonesia from 2001	Six WHO building blocks and outcomes associated with those: health level, equity, responsiveness, financial protection, efficiency	Potential bias/confounding variables.	No	To assess whether localised health services delivery in Indonesia, which commenced a health system decentralisation process in 2001, achieved its objectives or could be enhanced.	Critically low quality

Quigley 2019	N=57 33 quantitative 33, 9 qualitative, 15 mixed methods	OECD countries	A regional health organisation (RHO) refers to an organisation which is responsible for the provision of acute, primary and social/ community care to a geographically defined population. The health system in that particular country or province/state must be organised on a regional basis and the regional health organisation must have a	Utilisation of resources, Health and care outcomes, Efficiency, Equity, Patient flow, Cost and cost-effectiveness, Staff work experience, Perceived quality of care received and supplied, Public trust	Context including before and after data	Yes	To address what are the documented positive or negative impacts or outcomes of adopting a regionalised healthcare system. What are the documented enablers of, and challenges to, effective regionalised healthcare systems.	Critically low quality

			population-based approach to service provision.					
Ramos 2020*	N=39 All quantitative	High-, middle- and low-income countries	Regionalisation is the integrated organisation of a healthcare system, wherein regional structures are responsible for providing and administrating health services in a specific region.	Primary: any health outcome (mortality rate, infant mortality rate, preventable mortality rate, ambulatory care-sensitive conditions, quality of life, comorbidity) and secondary: any effect on management (governance arrangements; financial arrangements; service delivery arrangements;	-	Yes	To verify effective interventions to improve health and management indicators within the health services regionalisation.	Moderate quality

				implementation interventions)				

*Included both whole health system regionalisation and regionalisation of specific health system aspects. Results for whole health system regionalisation only are used when they were reported separately in the original paper.

5.4.3 Design of studies reported in the reviews

Two systematic reviews restricted their inclusion criteria to only quantitative studies (Dwicaksono and Fox, 2018; Ramos et al., 2020), while the rest included both quantitative and qualitative studies (Table 5-2 and Appendix E). The quantitative studies included by reviews were a heterogeneous mix of before and after studies with or without a control, cross-sectional studies and interrupted time series. No randomised controlled trials were included in any of the systematic reviews, although they were searched for. The qualitative studies included by the reviews were case studies, document analyses, focus groups, key informant interviews, or a combination of these approaches.

Five systematic reviews described limitations in the primary studies included in the review (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019; Ramos et al., 2020; Sumah et al., 2016). Dwicaksono and Fox reported that decentralisation is difficult to test in primary studies because of the complex nature of the intervention and potential for confounding factors:

“The complex nature of relationships between decentralization and health system performance and outcomes poses substantial challenges for testing empirically the theoretical arguments in favor of decentralization” (Dwicaksono and Fox, 2018, p. 326).

The systematic reviews searched for randomised controlled trials (RCTs), which are often regarded as the ‘gold standard’ of impact evaluation. However, they were not considered suitable to evaluate large health system restructure such as regionalisation or decentralisation by three reviews due to the challenges of random assignment of organisational units to intervention and control groups (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019). Ramos et al. suggest that an absence of RCTs was a barrier to understanding the impact of regionalisation as it was not possible to isolate the effects of interventions from other influences (Ramos et al., 2020).

Issues with other study designs were also identified. Cross-sectional data were commonly reported but often a suitable comparison such as continued centralisation was missing (Sumah et al., 2016). The use of longitudinal data to assess a before-and-after effect was generally limited among the included studies due to the lack of suitable data (Sumah et al., 2016). Interrupted time series designs, which were a common design in the systematic review by Quigley et al., cannot control for confounding, due to extraneous interventions or events occurring contemporaneously with regionalisation (Quigley et al., 2019).

One systematic review highlighted the influence of timing of the evaluation on study results (Quigley et al., 2019).

“The timing of the evaluation of a regionalised healthcare system will have an effect on the outcomes. The first two to three years after regionalisation are marked by instability, and conclusions regarding the effectiveness of the reform should not be made based solely on data from this period” (Quigley et al., 2019, p. 152).

Reporting of outcomes and data necessary to understand the impact of healthcare regionalisation was poor (Abimbola et al., 2019; Dwicaksono and Fox, 2018; Mello et al., 2017; Quigley et al., 2019; Rakmawati et al., 2019; Ramos et al., 2020; Sumah et al., 2016). Data on health system measures and context were particularly poorly reported (Dwicaksono and Fox, 2018; Rakmawati et al., 2019; Ramos et al., 2020). Two reviews tried to identify evidence of impact by regionalisation type but there were few studies assessing the same type of regionalisation, limiting inference to other contexts (Mello et al., 2017; Ramos et al., 2020).

Health system interventions at scale, such as required when implementing regionalisation, are also affected by numerous contextual factors. Four out of nine reviews attempted to collect such information, such as political context and budgetary constraints (Abimbola et al., 2019; Dwicaksono and Fox, 2018; Quigley et al., 2019; Zon et al., 2017).

Six studies included qualitative data, with two of these studies (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018) regarding qualitative data as particularly important. Dwicaksono and Fox found qualitative data necessary to understanding how and why decentralisation might work. Cobos Muñoz et al. found that if they had just focused on quantitative data the findings for decentralisation would be positive, whereas the inclusion of qualitative data identified both positive and negative impacts.

The inclusion of grey literature (Dwicaksono and Fox, 2018), non-English language studies (Dwicaksono and Fox, 2018), a large number of outcomes (Quigley et al., 2019), and a counterfactual (Quigley et al., 2019) were considered important.

5.4.4 Synthesis methods

The synthesis methods and rationale for each systematic review are given in Table 5-3. Four of the reviews did not describe their synthesis method. One gave a description of their analysis but made no reference to standard synthesis methods (Cobos Muñoz et al., 2017). One review combined three synthesis methods (meta-analysis, narrative synthesis and thematic synthesis) (Quigley et al., 2019), one review synthesised data based on a causal link model (Dwicaksono and Fox, 2018), and one used realist review methodology (Abimbola et al., 2019). Many of the systematic reviews did not give a clear rationale for their synthesis approach. Four of the reviews investigated the feasibility of meta-analysis. This was considered inappropriate in three of the four reviews due to the heterogeneity and outcomes reported in the included studies (Dwicaksono and Fox, 2018; Sumah et al., 2016; Zon et al., 2017), with the fourth conducting a meta-analysis on a very limited number of studies and outcomes (Quigley et al., 2019). One review by Abimbola et al. conducted a realist synthesis so that context and complexity could be better understood (Abimbola et al., 2019). The authors highlighted an important limitation of this method in that the context-mechanism-outcome configurations that are the usual output of a realist synthesis were not standardisable or reproducible (Abimbola et al., 2019).

Table 5-3 Synthesis method and rationale

Study ID	Synthesis method	Rationale for synthesis method/approach
Sumah 2016	Not described	Synthesis method not described, only reported that meta-analysis was not possible: included studies were largely descriptive and employed substantially different methods. As such, results of the studies were not suitable for meta-analysis and quantitative pooling.
Cobos Munoz et al. 2017	No specific method indicated but analysis described: Indicators from both quantitative studies and quotes from qualitative studies were classified using two categories. First, data were classified as suggesting a positive, neutral or negative effect of decentralisation. Second, each quote or indicator was classified as suggesting an effect on one of the six “building blocks” of the health system as described by WHO (governance; financing; medicines, vaccines and medical equipment; health information; health workforce; and service delivery).	Not reported
Mello 2017	Not described	Not reported

Study ID	Synthesis method	Rationale for synthesis method/approach
Zon 2017	Summarized based on the decision space theory as described in Bossert (1998) and applied for example in Bossert et al. (2003), Bossert and Beauvais (2002), and Bossert and Mitchell (2011). Narrative description and illustration in the form of tables	Given the primarily qualitative nature of the review and the diverse designs of the studies included in the review, no subsequent meta-analysis was conducted.
Dwicaksono 2018	Synthesis based on a causal link model developed by review authors	Data were analysed/organised based on a causal link model. Meta-analysis was not conducted because of the variation in outcome measures, key predictors, and study designs.
Abimbola 2019	Realist review	Previous evaluations have treated decentralisation in different settings as the same, and have not accommodated the possibility that outcomes are triggered by particular mechanism to a different extent in different settings. For these reasons, evaluations have yielded mixed and inconclusive results, and the evidence points to the mediating effects of context. Abimbola et al. have selected a realist approach so that context and complexity can be better accounted for.
Quigley 2019	Meta-analysis, narrative synthesis and thematic synthesis	Rationale for synthesis method not reported, although meta-analysis feasibility assessment presented.

Study ID	Synthesis method	Rationale for synthesis method/approach
Rakmawati 2019	Not described	Not reported
Ramos 2020	Not described	Not reported

The review authors also reflected on the limitation of their overall methods. Systematic review methods are resource intensive and so research teams typically introduced pragmatic limitations to their searches to make a manageable workload. Typical limitations included restrictions to specific types of data for example published literature only or quantitative data only, exclusion of non-English languages studies, and focusing on a small number of outcomes. Several reviews identified issues with these restrictions that are particularly relevant for the study of healthcare regionalisation. For example, when reviews were restricted to English language studies, a lack of data on countries in Latin America where regionalisation has been prominent was identified as a review limitation.

5.4.5 Main findings

Given the heterogeneity of reported outcomes and interventions, drawing comparisons across studies was challenging. The main findings of the systematic reviews regarding the impact on person/patient related outcomes and health system outcomes are summarised in Table 5-4, with a full outline of findings in Appendix E. The review from Mello et al. aimed to analyse the experiences of regional organisations in Brazil to understand the factors that support or hinder their processes (Mello et al., 2017). Therefore, the review did not give a definitive conclusion on the impacts of regionalisation. Review of the person/patient related findings across studies found no consistent impact of regionalisation on these outcomes. Similarly, the findings for the impact of regionalisation on the healthcare system were also mixed.

Two reviews conducted an analysis by type of regionalisation (Cobos Muñoz et al., 2017; Ramos et al., 2020). Ramos et al. broke decentralisation down into six interventions. Each intervention represented a particular component of a decentralised healthcare system, and highlighted those which impacted the health system and patients. Decentralisation of health services were associated with improved system efficiency, expanded population coverage, and reduced health expenditure disparities, while also promoting greater public participation by aligning resource planning with local needs. However, user freedom to choose healthcare professionals remains limited, particularly within regionalised systems. Despite these advantages, the relationship between fiscal decentralisation and health outcomes remained inconclusive. Cobos Munoz et al. examined the impact of regionalisation on several of the WHO building blocks. Again, there was conflicting evidence of the impact. Qualitative data showed that wider decentralisation (four or more building block decentralised) had a less positive impact on stakeholder perceptions, whereas quantitative indicators consistently showed positive effects irrespective of the degree of decentralisation.

Table 5-4 Summary of main findings of systematic reviews

Study ID	Person/patient related findings (including equity)	System related findings
Sumah 2016	Both positive and negative impact on equity.	Not reported
Cobos-Munoz 2017	- Quantitative: positive effects of decentralisation on adult child and maternal mortality. - Qualitative studies showed positive and negative outcomes of decentralisation. Negative aspects identified included corruption at a local level.	There were positive and negative effects of decentralisation of health systems in LMICs: whereas decentralisation of governance, financing and service delivery have been shown to have positive effects on the system; decentralisation of resource management has been challenging in several settings.
Mello 2017	N/A^y	N/A
Zon 2017	- No clear evidence showing the impact of decentralisation on health services. - Minor differences between decentralized and non-decentralised districts in terms of health status, process and outcome indicators. - Increase in health services attendance, particularly hospital attendance is associated with decentralisation.	- Mixed impact on resource allocation. In some countries lack of financing means some precision of medical care has fallen short of local needs. In other countries, care has moved from primary to secondary care (curative services). - Decentralisation has led to improvements in training and capacity building, recruitment, supervision, and attention to primary health services, availability of district funds. - Decentralisation has led to greater community involvement.
Dwicaksono 2018	Decentralisation had a consistently beneficial effect on health outcomes.	Health system inputs: 2 of the 3 studies showed adverse effects of decentralisation on resource allocation, and 1 study did not find significant effects of decentralisation on corruption. Health system performance: Investigated in 7 studies and showed mixed findings.

Abimbola 2019	• Lower-level jurisdiction governments spend in more urban areas and more on curative than pro-equity preventive services to generate revenue. • Generating funds and making spending decision locally leads to more pro-equity spending and greater retention of staff (albeit only low skilled staff) but nepotism can lead to hiring low-quality staff. • Higher level governments may hold lower level sub-national governments to account for equity.	• Cross-border movement of patients from poorer to wealthier jurisdictions means that the latter are able to maximise use of their resources, while the former loses out by paying the former to treat their residents. • Pro-equity spending (e.g. on prevention) lead to efficiency gains. • Wealthier sub-national jurisdictions increase their health budget post-decentralisation and poorer jurisdictions less so, or even experience a decline in their health budget. • Higher level governments may hold lower level sub-national governments accountable for efficiency, and community groups may hold sub-national governments and health providers to account for efficiency. • Difference levels of governance may step in if another level or centre fails.
Rakmawati 2019	Outcomes at the district level in Indonesia post-decentralisation: • No improvement in inequity in child immunization completeness, inequity in accessing maternal health services, higher maternal mortality rate among the poor, higher infant mortality rate among the poor. • Later response from maternal health providers, low responsiveness in malaria referral diagnostics. • Out of pocket payment still exists among insurance holders, higher financial burden for the poor.	• Efficiency: dependency on central government fund
Quigley 2019	• Regionalisation can result in reductions in acute hospital resource use without negatively affecting overall care outcomes such as mortality.	• The long-term cost implications are heavily context dependent. There is an indication that a regionalised healthcare system can be an efficient system, however, careful consideration must be given to what resources are provided in each healthcare setting including acute, primary, community and social care settings.

Ramos 2020*	• Mostly increased provision of healthcare at a regional level following decentralisation • Decentralisation allowed users to have full freedom of choice on whether to be served by public or private service. • Mixed impact for fiscal decentralisation on infant mortality rate and increase in life expectancy at birth. • There was a significant decline in vaccination coverage rates after decentralisation but the study was not controlled for confounding factors.	• Found conflicting effects of decentralisation on efficiency; some positive and negative results.

*The review from Mello et al. aimed to analyse the experiences of regional organisations in Brazil to understand the factors that support or hinder their processes and therefore did not give a definitive conclusion on the impacts of regionalisation.

*Included both whole health system regionalisation and regionalisation of specific health system aspects. Results for whole health system regionalisation only are used when they were reported separately in the original paper.

Key: LMIC – low and middle income countries; N/A – not applicable

5.4.6 Conclusions from systematic reviews

The conclusions from the included systematic reviews regarding the impact of regionalisation/decentralisation on health and system outcomes are summarised in Table 5-5. None of the systematic reviews reached definitive conclusions, although the authors of the realist review felt able to draw more definitive inferences (Abimbola et al., 2019). Reviews that attempted to compare results across geographies found mixed results that were heavily context dependent (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019; Sumah et al., 2016; Zon et al., 2017).

Table 5-5 Conclusions from systematic reviews

Study ID	Summary of conclusions from systematic reviews regarding the impact of regionalisation/decentralisation on health and system outcomes
Sumah 2016	• The implications of decentralised governance of health systems on health-related equity are varied and depend on pre-existing socio-economic and organisational context, the form of decentralisation implemented and the complementary mechanisms implemented alongside decentralisation.
Cobos Munoz et al. 2017	• Effects of health system decentralisation in LMIC were both positive and negative. Whereas quantitative data consistently showed positive effects, qualitative studies reported a more heterogeneous picture of the effects of decentralisation. • Experiences from countries suggested that the decentralisation of governance, financing and service delivery, could have positive effects on the system. • Decentralisation of resource management could be challenging if sufficient capacity at the local level does not exist and transparent accountability mechanisms are not in place. • Factors such as adequate mix of technical skills at the local level to perform decentralized tasks, effective decentralisation of decision-making to the periphery, and political leadership are key factors for a successful decentralisation process.
Zon 2017	• The outcomes of decentralisation on health services delivery in Sub-Saharan Africa are mixed. • The decentralisation in the health care sectors in Sub-Saharan Africa often fails to achieve its objectives since most countries focus on the decentralisation process (e.g. enacting policies, regulations and standards) and not necessarily on the decentralisation outcomes in health services delivery. • The key determinants of good practices in health skills and resources transfer in Sub-Saharan Africa have to do with the type of decentralisation and the will of the central government to make the legislative and administrative changes required for the effectiveness of decentralisation.

	The context-related factors that can facilitate a successful implementation of the decentralisation policy include: the appreciation of the role of all stakeholders by politicians; adequate availability and efficient utilization of resources, reasonably developed infrastructure prior to the policy change, appropriate sensitization and training of those implementing policies, and good will and active involvement of the local community. These factors need to be considered when implementing or amending decentralisation policies in Sub-Saharan Africa.
Mello 2017	<i>This review aimed to analyses the experiences of regional organisations in Brazil to understand the factors that support or hinder their processes. Therefore, the review does not give a definitive conclusion on the impacts of regionalisation.</i>
Dwicaksono 2018	- Mixed empirical findings on the role of decentralisation on health system performance and outcomes highlight the complexity of decentralisation processes and their system wide effects. - There is limited empirical knowledge of the impact of decentralisation on health system performance. - More rigorous empirical research is needed as decentralisation is a complex process (or set of processes) and our understanding of it is still limited.
Abimbola 2019	Identified three mechanisms by which decentralisation may influence equity, efficiency, and resilience from 25 high-, middle- and low-income countries: ‘voting with feet’ (reflecting how de-centralization exacerbates or assuages the existing patterns of inequities in the distribution of people, resources and outcomes in a jurisdiction); ‘close to ground’ (reflecting how bringing governance close to the people allows for use of local initiative, information, feedback, input and control); - and ‘watching the watchers’ (reflecting the many mutual accountability relations between multiple centres of governance within a jurisdiction which are multiplied by decentralisation, involving governments at different levels and also community-level entities).
Rakmawati 2019	- After decentralisation, there are still key challenges across the six WHO building blocks. The findings highlight problematic impacts of decentralisation related to three building blocks: service delivery, health financing, and workforce. - Selected studies have shown a positive impact of decentralisation for the local health system particularly for improving the quality of local health-care services and focusing more efforts in tackling the local health issues. - The leadership/governance element in Indonesian health system planning should be strengthened as the main pillar to support other building blocks, particularly policy evaluation, by prioritizing health service delivery, health workforce numbers, and financing to improve health system performance at the district level. - Health information systems and access to essential medicines should be improved by involving the private sector and empowering community engagement.

	• These approaches, when implemented effectively, can be used to address the existing district-level health system challenges facing Indonesia.
Quigley 2019	• There is some evidence to suggest that a regionalised healthcare system could ultimately lead to a healthier population and a more efficient health system. However, policymakers need to consider the important barriers to and facilitators of effective implementation. • The impact of regionalisation will not be fully estimable for many years post-reform; however, a monitoring and evaluation process will be required at the start of regionalisation to ensure that the short-term and intermediate goals are being met, in order to achieve the ultimate long-term goals of regionalisation. • Regionalisation is a complex process, encompassing a vast array of interconnected elements, which should be reflected in the design of a monitoring and evaluation template. Regionalisation should be implemented and evaluated as a complex intervention for which outcomes are neither straightforward nor predictable, but dependent on a country's socioeconomic and institutional context.
Ramos 2020	• <i>This study included both whole health system regionalisation and regionalisation of specific health system aspects. It was not possible to isolate conclusions directly relevant to whole health system regionalisation only.</i>

5.4.7 Recommendations for future research

Recommendations for future research in each systematic review are listed in Appendix E. The reviews consistently called for the systematic collection of data relating to context in primary studies so that systematic reviews may incorporate context into their syntheses. Three of the reviews (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019) discussed the importance of understanding the complexity of processes that interplay in a decentralised or regionalised health system. Regionalisation was described as complex process, or series of interconnected processes, that should be implemented and evaluated as a complex intervention for which outcomes are neither straightforward nor predictable but dependent on a country's socioeconomic and institutional context (Quigley et al., 2019; Sumah et al., 2016).

Some of the systematic reviews (Dwicaksono and Fox, 2018; Zon et al., 2017) suggested the use of frameworks such as Bossert's 'decision space' approach, and Mills work on the classification of decentralisation in healthcare (Bossert,

1998; Mills, 1994; Mills et al., 1990). These frameworks can help in unpacking the exact format of decentralisation being implemented by making explicit the range of choice under the headings of finance, service organisation, human resources, access rules and governance rules (Bossert, 1998; Marchildon and Bossert, 2018). Dwicaksono and Fox suggest that applying this framework can assist researchers in determining key aspects of decentralisation that may contribute to changes in performance and outcomes under decentralisation (Dwicaksono and Fox, 2018).

5.5 Discussion

5.5.1 Summary of findings

Regionalisation is a complex intervention where multiple processes and external factors interact to determine how regionalisation is implemented. The process of regionalisation may have multiple, context dependent consequences both intended and unintended. These issues are inherent challenges in explicitly establishing causal links between regionalisation and health and system outcomes. There was little overlap in the studies included by the reviews, highlighting the heterogeneity in approaches and perspectives taken by various research groups when conducting their systematic reviews.

Many of the reviews reported heterogeneity in definitions of regionalisation or decentralisation in primary studies, with no conceptual consensus (Dwicaksono and Fox, 2018; Ramos et al., 2020; Sumah et al., 2016). Regionalisation does not represent one single process but rather a vast array of interconnected elements and set of processes. Reviews have suggested that it should therefore be implemented and evaluated as a complex intervention for which outcomes are neither straightforward nor predictable, but dependent on pre-existing socio-economic and institutional contexts (Quigley et al., 2019; Sumah et al., 2016).

In their 2018 work on decentralisation, Marchildon and Bossert state that “it needs to be emphasized that decentralisation is a relative concept that can only be understood given a particular historical and comparative context” (Marchildon and Bossert, 2018). This was reinforced by the reviews identified in this umbrella review. This is not limited to the primary data included in the

reviews: there were also issues in the analysis conducted in the reviews themselves. While some of this difficulty is linked to the lack of appropriate primary data, the complexity of the intervention is a compounding factor. The effects seen in the included studies can be the result of the dynamic interaction of multiple subsystems. Policymakers could be interested not only in the effects of the health system intervention itself, but also in how and why such interventions had this impact. This aligns with the work of Lorne et al. and Schuurmans et al. who described regionalisation as the interplay of local, regional and national actors, organisations and agencies bringing together different policies and priorities, within a web of relations, sometimes in conflict, at other times fitting together more (Lorne et al., 2019; Schuurmans et al., 2020).

There was significant heterogeneity in the outcomes reported by studies included in the systematic reviews. The interpretation of the outcomes was also context dependent, for example in some cases greater access to hospital care was seen as a positive, while reducing acute hospital resource use was also seen as a positive. As a result of this heterogeneity, it is not possible to come to summative conclusion on the impact of healthcare regionalisation.

This umbrella review has identified several key methodological challenges that may be contributing to the lack of clarity in relation to the impact of regionalisation.

With the exception of Abimbola et al.'s realist review (Abimbola et al., 2019) and Rakmawati et al.'s review of regionalisation in Indonesia (Rakmawati et al., 2019), none of the systematic reviews included in this umbrella review reported definitive conclusions. Reviews that attempted to analyse results from different geographies reported mixed results that were heavily context dependent. Several of the reviews found that different results are driven by different country contexts, including political and historical context, and differing decentralisation or regionalisation designs (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019; Ramos et al., 2020). Context was often poorly reported by both primary studies and, therefore, in the systematic reviews themselves, and the impact of context was difficult to

separate from the impact of regionalisation or decentralisation, e.g. when regionalisation was introduced alongside budget cuts (Cobos Muñoz et al., 2017; Dwicaksono and Fox, 2018; Quigley et al., 2019; Ramos et al., 2020). Different country contexts also meant that regionalisation designs were often bespoke to the country which hampered summation of results. Identified primary study designs were limited in their ability to detect and control for confounders.

The primary studies in all the included reviews were heterogeneous, with both quantitative and qualitative study designs included. While RCTs were not considered appropriate to evaluate a large-scale health system restructure, aligning with previous research (Atun, 2012; Mills et al., 2008), the most suitable alternative was not clearly identified by these systematic reviews. Qualitative study designs were also diverse, but no critique or discussion of these methods was provided by the systematic review authors.

The timing of data collection could also be considered critical. The first two to three years after regionalisation can be marked by instability and therefore may not accurately reflect the impact of regionalisation. While long-term follow-up is preferable, the cyclical periodic reform of healthcare systems is a major barrier to this (Quigley et al., 2019). For example, many of the provinces in Canada have each gone through several rounds of regionalisation, followed by de-regionalisation or centralisation.

Many of the included reviews did not clearly explain their synthesis method and there was generally no justification for their approach. Meta-analysis was considered but then ruled out by many of the studies. That meta-analysis was the main synthesis option considered shows that there is still a reliance on methods that were designed to evaluate clearly defined clinical interventions, rather than the complex real-world intervention that is regionalisation (Davies et al., 2000; Skivington et al., 2021).

5.5.2 Implications for future work

Eight of the nine studies were considered to be critically low quality based on the AMSTAR 2 critical appraisal tool. The AMSTAR 2 critical appraisal tool is

designed with systematic reviews of randomised controlled trials of clinical interventions in mind, and so many of the systematic reviews we identified did not report aspects that are critical to AMSTAR ratings such as a full Population, Intervention, Comparison and Outcomes description. AMSTAR 2 has been acknowledged to be of more limited use in evaluating reviews without a formal synthesis and those on non-standard interventions (Perry et al., 2021; Puljak et al., 2023). Despite these constraints, there is a lack of robust alternative tools tailored to newer synthesis designs, which reinforces the continued use of AMSTAR 2. This umbrella review also highlights the need for a clear description of synthesis methods used in reviews of regionalisation. One synthesis method which was clearly described was the realist synthesis, the authors of the realist review felt able to draw more definitive inferences. Identified reviews suggests that methods for primary analysis should progress beyond typical randomised controlled trial designs and perhaps systematic review methods should expand beyond typical Cochrane review methodology, to better account for complexity, context and heterogeneity in primary study designs.

5.5.3 Conclusion

The difficulty with determining suitable methods of evaluation, both primary and secondary, have cumulated in inconclusive findings from the identified systematic reviews. A definitive answer to the question ‘does healthcare regionalisation work?’ may require a better understanding of the interlinking processes that make up regionalisation and the external context facilitating or inhibiting its rollout. The involvement of local policymakers may lead to better insights. For policymakers considering implementing regionalisation, they should establish a clear set of outcomes and criteria for measuring those at appropriate points in the implementation cycle.

However, the methodological and interpretive limitations encountered in using the umbrella review approach also highlighted the need for alternative synthesis methods capable of capturing contextual dynamics, system-level influences, and the mechanisms through which regionalisation produces both intended and unintended effects. These insights informed the direction of the subsequent chapters, which explore and test a synthesis approach designed to provide a

more explanatory understanding of how regionalisation operates within complex health systems.

Results Part 2

Chapter 6 Interviews with policymakers on the plan for regionalisation in the Irish healthcare system

6.1 Overview

As outlined earlier in this thesis, healthcare regionalisation as envisaged for Ireland is the case study intervention. This chapter builds on the description of healthcare regionalisation provided in Chapter 3 by interviewing policymakers in the Irish healthcare system to establish a complete understanding of regionalisation from an Irish perspective. These interviews, alongside the scoping review described in Chapter 7, were prerequisites for the rapid-realist review presented in Chapter 8. The information gathered helped shape the research question and ensure that the rapid realist review was grounded in current policy perspectives.

6.2 Introduction

As outlined in Chapter 3, healthcare regionalisation can be introduced as a strategy to improve system efficiency, responsiveness, and integration of care. However, as the umbrella review reported in Chapter 5 showed, the design and implementation of regionalisation vary significantly between countries due to differences in historical institutional arrangements, financing mechanisms, and political cultures (Quigley et al., 2019; Saltman et al., 2006). In particular, local context plays a critical role in shaping how regionalisation is interpreted and operationalised. In Ireland, where the healthcare system has been characterised by centralised control since 2005, regionalisation represents a major structural reform with wide-reaching implications (Oireachtas Committee on the Future of Healthcare, 2017).

Recent developments in evidence-informed policymaking (Chapter 2) have highlighted the importance of involving policymakers not only in the latter stages of knowledge translation, but also in the early design and framing of research questions. Emerging synthesis methods, such as rapid-realist review,

suggest that engaging policymakers in a more iterative and participatory manner helps to ensure that research is better aligned with policy priorities and practical decision-making needs (Saul et al., 2013). This approach enhances the relevance and uptake of research evidence in policy processes.

In light of this, a series of semi-structured interviews with Irish health policymakers was conducted to explore their perspectives on the anticipated aims, impacts, and implementation challenges associated with healthcare regionalisation in the Irish context. These interviews provide a foundational understanding of the policy logic behind regionalisation, the institutional and political constraints facing reform, and the aspirations that underpin the current reform agenda.

The insights generated from these interviews will inform subsequent chapters of this thesis, including the rapid-realist review (Chapter 8). By gathering the perspectives of those directly involved in the Sláintecare policy development, this chapter is the start of the process of bridging the gap between international empirical evidence and policymaking practice in a way that is both context-sensitive and grounded in real-world considerations.

6.3 Methods

This chapter addresses the following research question:

- What are the specific goals of the introduction of regionalisation in Ireland and what are the specific requirements for an evidence synthesis in this context?

The objectives were to:

- use semi-structured interviews with decision makers to generate data to identify the aim, likely impact and challenges of healthcare regionalisation,
- To use these data to develop research questions for emerging synthesis methods relevant to Irish policymakers and healthcare regionalisation.

The data collection took place between January and June 2021.

6.3.1 Data collection

Semi-structured interviews were chosen as the preferred method of data collection, as they were most likely to garner the required information from policymakers. This approach enabled an in-depth exploration of participants' experiences, beliefs, and expectations while providing sufficient flexibility to probe emerging issues and clarify complex policy contexts (Barriball and While, 1994; Kallio et al., 2016). Semi-structured interviews are particularly well suited to engaging policymakers as they allow for open discussion of sensitive or context-dependent topics while maintaining a consistent framework across interviews (Signal et al., 2018). Prior research has demonstrated that interviews with policymakers can generate valuable insights into decision-making processes and policy dynamics that are often inaccessible through documentary or survey methods (de Leeuw et al., 2014; Martin et al., 2019). Adams (2015) argue semi-structured interviews are considered useful in the following situations:

- if you need to ask probing open-ended questions and want to know the autonomous thoughts of each individual in a group,
- if you need to ask probing open-ended questions on matters that your respondents might not be open about if sitting with peers in a focus group,
- if you need to conduct a formative programme evaluation and want individual interviews with key programme managers and service providers.

All of these features were desirable in the present study, where the aim was to elicit the individual opinion of policymakers. The interview schedule is in Appendix A.

Interviews took place between January and June 2021, were conducted via Zoom video conferencing and recorded for analysis ("Video Conferencing, Web Conferencing, Webinars, Screen Sharing," n.d.). Interviews were scheduled for one hour.

6.3.2 Impact of COVID-19

Recruitment for this study was severely hampered by the COVID-19 pandemic. Recruitment was initially planned to begin in Spring 2020, this was pushed to Autumn 2020, however no participants were actually recruited until January 2021.

The sampling strategy began by making initial contact with the policymakers in the Department of Health who commissioned the HRB's research project 'Regional health organisations: An evidence review' (Quigley et al., 2019). The members of this team were part of the Health Systems and Structures Unit of the Department of Health, and this unit was disbanded in 2020 so that human resource could be deployed to work on the COVID-19 pandemic response. The team were moved on to assignments that were considered more urgent, with the majority of team members assigned to assist the National Public Health Emergency Team, while the rest retired. The disbanding of this unit, who were actively working on regionalisation was the first blow to the recruitment strategy. Those who had moved on to work on the National Public Health Emergency Team declined to participate as they did not have the time, and I was unable to contact the staff members who had retired due to data protection issues.

During the COVID-19 pandemic, one staff member in the Department of Health was assigned to work part-time on the restructure. Pragmatic decisions on sample size were required and are discussed in section 6.3.3.

6.3.3 Participants and sampling

The key stakeholders for healthcare regionalisation in Ireland were the Department of Health, elected officials, and the Health Service Executive (HSE). The HSE runs the Irish health and social care system with public funds. Another stakeholder group of relevance would be service users, however, the views of service users fall outside of the scope of this PhD study. The participants of interest for this research study were the authors of the Sláintecare report, who were elected officials, policy advisors, and healthcare policymakers working in

the Irish civil service. They were responsible for the roll-out of healthcare regionalisation in Ireland.

Purposeful sampling (sometimes also referred to as purposive sampling) was used to identify interview participants. The understanding and power of purposeful sampling derives from the emphasis on the in-depth understanding of specific cases known as information rich cases (Patton, 2015).

In order to identify information-rich cases I used criterion-based selection whereby the key attributes of a sample central to the study aim were decided in advance and then people that met those criteria were identified (Merriam et al., 2016). In line with the aim of this work, the criteria were as follows:

- participants must have been working in the Department of Health or HSE or contracted as such for at least one year to ensure they had a good understanding of the regionalisation plan,
- they must also have worked in a division that was directly involved in planning the restructure such as the Sláintecare office, operations or strategy and planning, to ensure they had direct knowledge of the regionalisation plan,
- only participants from the HSE's central division were invited to participate as restructuring decisions were expected to be made centrally.

Initial contact was made with the policymakers in the Department of Health who commissioned the HRB's research project 'Regional health organisations: An evidence review' (Quigley et al., 2019). Each of these policymakers was invited to be interviewed, where if the participant declined to participate, they were given the option to recommend another candidate. I then used a snowball sampling approach, whereby interview participants can nominate other individuals to be invited for participation. Snowball sampling is a non-probability sampling method commonly used in qualitative research to access hard-to-reach or specialised populations by leveraging existing participant networks (Noy, 2008). This technique is particularly useful in policy research where key

informants may be dispersed across institutions or roles and are best identified through professional networks (Noy, 2008).

Ten policymakers were invited to interview and seven accepted the invite. Of note, and discussed further in section 6.3.2, only one Department of Health staff member was directly working on the regionalisation plan during the time the interviews took place due to the COVID-19 pandemic.

6.3.4 Data management

Data confidentiality and anonymity of the participant was paramount in this study. A copy of the participant information sheet is in Appendix G, the consent form is in Appendix H and the privacy note is in Appendix I.

Interviews were recorded with permission from participants and transcribed automatically using Zoom software (“Using audio transcription for cloud recordings,” n.d.). The recordings and transcripts were not saved on the Zoom server, the option to save the recordings to local storage was selected. Once the interview transcript document was checked the original recording was destroyed. Each interviewee was given a unique identifier (e.g. P1 = the first interviewee) to allow anonymisation and the transcripts were checked for any other identifying features which were then altered or redacted.

Files were saved by unique identifier and only one researcher had access to the codes. There is one interview transcript document per participant.

6.3.5 Data analysis

Data were analysed using the six-phase approach to thematic analysis outlined by Braun and Clarke (2006). This involved:

1. **Familiarisation** with the data through repeated reading of transcripts;
2. **Generating initial codes** systematically across the entire dataset;
3. **Searching for themes** by grouping codes into potential themes;

4. **Reviewing themes** in relation to both coded extracts and the full dataset;
5. **Defining and naming themes** to ensure clarity and distinctiveness;
6. **Producing the report**, linking the analysis back to the research questions and literature.

Coding was conducted inductively, meaning that themes were derived from the data rather than imposed based on prior theoretical frameworks. Coding was carried out manually without the use of specialist software. Transcripts were read several times to ensure familiarity with the data, and initial codes were identified and recorded in a structured table. Codes were then grouped into broader themes through an iterative process of comparison and refinement, with attention paid to both semantic content and underlying meanings. To enhance the trustworthiness of the analysis, theme development was discussed and agreed with my supervisory team. Reflexivity was maintained throughout the process, with the researcher considering how their own position and assumptions might influence data interpretation (Nowell et al., 2017).

Thematic analysis was chosen because it allows for a nuanced interpretation of policymaker perspectives while remaining grounded in the data. It is particularly appropriate in the context of this study, where the aim was to capture both the shared and divergent opinion of policymakers early in implementation of healthcare regionalisation in Ireland.

6.3.6 Credibility and validity

To enhance the internal validity and credibility of this qualitative analysis, methodological triangulation was employed (Merriam et al., 2016).

Triangulation, in this context, refers to the use of multiple data sources or perspectives to examine the same phenomenon, with the goal of achieving a more comprehensive understanding (Denzin, 2017; Salkind, 2010). By incorporating a variety of viewpoints, triangulation increases the credibility of conclusions by contributing to the verification and validation of qualitative analysis (Patton, 2015).

The primary purpose of triangulation is not necessarily to produce convergence in data, but rather to explore differences and identify patterns that contribute to a richer understanding of the research topic. As Patton (2015, p. 957) notes, “different kinds of data may yield somewhat different results because different types of inquiry are sensitive to different real-world nuances. Thus, understanding inconsistencies in findings across different kinds of data can be illuminative and important. Finding such inconsistencies ought not to be viewed as weakening the credibility of results but, rather, as offering opportunities for deeper insight into the relationship between inquiry approach and the phenomenon under study.”

In this study, triangulation was achieved through semi-structured interviews with participants from two distinct organisational perspectives within the Irish healthcare system: (1) key stakeholders from the Department of Health, which has a policy-making and oversight role; and (2) stakeholders from the Health Service Executive (HSE), which is responsible for the operational delivery of healthcare services. These contrasting institutional functions were deliberately selected to elicit differing, and potentially divergent, perspectives on the topic under investigation.

The inclusion of these varied perspectives enabled a degree of cross-validation of emerging themes and allowed for an assessment of internal consistency across narratives. While the number of interviews was relatively small ($n = 7$), the deliberate selection of participants from contrasting institutional roles provided valuable diversity of insight. This approach contributes to internal validity by reducing the risk of single-source bias and enhancing the credibility of the findings (Creswell, 2012; Shenton, 2004). Although the modest sample size limits the generalisability of the results, the depth and contextual richness of the data offer meaningful, analytically robust insights into the research question (Morse, 2015).

6.3.7 Ethics

Ethics approval for the stakeholder interviews was obtained through the University of Glasgow MVLS ethics committee (Project No: 200200004). As the

participants were all senior policymakers working to a high degree of autonomy and independence, and participation was entirely voluntary, the main ethical considerations for the interviews related to informed consent, confidentiality, and data storage.

6.4 Results

Seven stakeholders were interviewed: three were from the Department of Health, one was from the HSE; two were policy advisors; and one was a member of parliament. All interviewees had been working in their respective roles for at least three years.

Analysis identified three overarching themes: (1) expected impact of regionalisation; (2) challenges and enablers shaping the implementation of regionalisation; and (3) navigating uncertainty in implementing regionalisation. Identified subthemes are organised under these overarching themes.

6.4.1 Expected impact of regionalisation

Interviewees largely viewed regionalisation as a necessary reform to overcome fragmentation and strengthen integration, governance, accountability, and responsiveness. Five interrelated subthemes captured how participants anticipated the new regional structures would affect the health system: (1) integration of hospital and community care, (2) enhanced governance, financial control, and accountability, (3) improving patient-centred care; expectations and challenges, (4) frontline staff perspectives and the promise of local autonomy, and (5) balancing national consistency with local responsiveness.

6.4.1.1 Integration of hospital and community care

A dominant theme was the expectation that regionalisation would improve coordination between hospital and community services. Participants repeatedly described the current system as fragmented with poor alignment of budgets, management structures, and care pathways:

‘At the moment, the way that services are planned and delivered in Ireland is quite fragmented, even within the HSE between hospital

and community. The sort of design, the planning, the design, the delivery, and the financial flows around all of that are siloed' (P1).

This was confounded by issues with hospitals. Participant two reported that hospitals were part of the issue with the current system and not built around community needs:

'[Hospitals] have their own footprints and they're very much built around academic excellence and training in the hospitals. They're not built around what the community needs. They're not built around commuting patterns' (P2).

Regionalisation was seen as a way to unite these elements under shared governance and a single regional budget, thereby supporting integrated care delivery. The shared budget across hospitals and community care would enable movement of funding from hospitals to the community:

'The theory is that you, you take funding from the hospitals and put it into community... the whole theory of the restructuring proposed in Sláintecare is that you would have a regional structure within each region. And that would include all community and social care services, plus hospital services, so there would be a single budget. And within each region there would be a management structure that is accountable for the provision of services and the spending of resources. So that I think is the key to ensuring that money will be spent where it's most cost effective and effective from the point of view of providing health care' (P6).

Integration was also viewed as a cultural shift, intended to promote collaboration and reduce hospital dominance in decision-making. One participant described the 'animosity and territorialism' that emerged during regionalisation discussions, noting that

‘People wanted the power they had, particularly the hospitals, whereas... the community could see the benefit of it’ (P3).

6.4.1.2 Enhanced governance, financial control and accountability

Participants associated regionalisation with the potential for clearer lines of accountability, more transparent financial management, and improved value for money. Several viewed current arrangements as opaque, with limited understanding of where resources were directed. A regional model was expected to provide stronger and more local accountability through single budgets and more consistent data collection:

‘So if you had regional structures, particularly as they are envisaged, setup with their own boards you might have stronger and more local accountability for delivering services’ (P1).

It was suggested the establishment of regional structures would enable the move of resources to where they would be most effective in the community (P6). But, there was considerable debate amongst participants about whether the reform would be cost saving. Some anticipated efficiency gains, while others cautioned that the main benefit would be in better oversight and control, rather than cost savings *per se*. Overall, accountability and information systems were seen as essential to ensuring that regionalisation leads to tangible improvements in governance. Participants expected a large amount of upfront costs to be needed but according to participant four this could be a barrier to effective implementation:

‘You know the difficulty here is it’s like a lot of transactional costs that there’s actually a lot of front loading of costs, before you actually have a chance to see the benefit and what our story tells us as I’ve mentioned before, is that when we when we don’t seem to be able to find the route to getting some of those early wins, then it all becomes about the process and we run out of steam, and I think that’s a toxic story’ (P4).

Two of the participants felt that the new model of service provision should be cost saving (P3, P6). When asked if the regionalisation restructure will save money Participant six responded:

‘Well. Yes, I do it absolutely because it is a lower cost model of care and that's a key element of Sláintecare that's moving away from hospital centric, expensive model of care, to a lower cost model of care, which is also more effective’ (P6).

Cost-containment and budgetary control were seen as important outcomes to the Department of Health. Participant four indicated that there was a systematic thinking that any restructure must lead to cost savings:

‘I think there would be you know, a sense that somehow or other, it has to create a more efficient health system. And I would see that probably that's the primary lens through which most organisational changes are perceived and imagined and judged’ (P4).

Participants one and two were also hopeful that regional control of a shared budget would lead to better value for money and financial control rather than cost-containment:

‘Then the idea would be that you might have better financial control better value for money... I suppose one of the outcomes or parts of the drivers in terms of reform appropriately is around cost containment. I'd probably go a bit further from a public health perspective and say, not just containing costs, but making sure that you're getting the best value. This idea of kind of value based healthcare’ (P1).

6.4.1.3 Improving patient-centred care; expectations and challenges

Improving the patient experience was consistently described as the ultimate goal of regionalisation. Participants hoped that integrated governance and funding structures would create a more seamless, person-centred system, where patients no longer experienced care as disjointed or hospital dominated.

Regionalisation was expected to support continuity of care and reduce unnecessary travel by aligning services around population needs. As one participant explained:

‘Ultimately, this has to be about, you know, a better experience of the health system for an individual around all their needs, across their life, in a way that they experience better health outcomes as a result’ (P1).

However, participants also recognised that structural reform alone would not guarantee improvements for patients, the benefits depended on whether integrated care models translate into accessible, coordinated services on the ground. Participant four highlighted that patients are unlikely to notice changes in organisational structures, but will experience meaningful differences when care becomes more timely, effective, and personalised:

‘You know people on the ground they’re never ever going to be exercised by organisational change. They’re never going to get excited. People just want to feel the difference in the results and the outcomes and the difference in their care or that they get access to a quick diagnosis or they get you know they get medical attention when they need it or they get a home help you know allocated to them, you know, in a timely fashion’ (P4).

Several participants described patient-centred care as more than convenience or access, it was about ensuring that each patient experiences integrated care across providers and settings. Participant seven reflected on how population-based budgeting could enable more tailored services and reduce unnecessary patient travel:

‘We’re hoping for subtle shifts... a subtle feeling of care that’s more integrated. Care that can be provided closer to their homes that’s more tailored to their needs, by enabling that population-based budget we’ll be taking the unique health and social care needs of

each individual area into account when allocating money... people won't feel the need to travel so far for some of their services' (P7).

Participant two similarly emphasised that regionalisation should facilitate patient-led, integrated care:

'I think on balance and overall people are thinking we do need a system where care is more integrated. There is a greater push for more patient-centred, patient-led care and an understanding that we don't have a system that is integrated vertically, horizontally, whatever way you look at it, so I think the purpose is clear' (P2).

Overall, participants framed patient-centred care as the lens through which the success of regionalisation should be judged: structural and governance reforms are valuable only insofar as they translate into tangible improvements in patient experience, access, and outcomes.

6.4.1.4 Frontline staff perspectives and the promise of local autonomy

Most participants felt that frontline staff would not experience immediate change, describing the reform as primarily structural. However, several anticipated that, over time, greater local autonomy might empower staff and enhance morale by giving them more influence over decision-making. One participant noted that while: 'staff on the frontline are not that bothered' (P4) initially, the reform could eventually foster a more enabled and empowered workforce (P4, P1, P7). The perceived impact on staff therefore related less to daily operations and more to the potential for cultural change and reduced bureaucratic distance from decision-makers.

6.4.1.5 Balancing national consistency with local responsiveness

A shift to regional planning and population-based resource allocation was seen as critical to improving responsiveness and reducing delays in decision-making. Participants viewed regionalisation as an opportunity to align priorities more closely with local needs and to reintroduce the sense of connection that existed under the old health board model.

Three of the participants (P5, P4 and P7) felt that local decision making could lead to faster decisions that are based on local population needs as people on the ground know what their patients need:

‘So really it's about kind of reducing that time to decision making and reducing that distance from people who have real knowledge on the ground of what it is that they know their patients need and actually being able to implement that’ (P7).

The reform was therefore framed as balancing national consistency with regional flexibility, enabling decisions that are both evidence-informed and contextually relevant.

6.4.2 Challenges and enablers shaping the implementation of regionalisation

Three interrelated subthemes emerged in relation to the barriers, enablers, and external influences affecting regionalisation; restructuring fatigue was identified as a significant concern, political will was recognised as a critical enabler, and institutional alignment was noted as a key challenge.

6.4.2.1 Restructuring fatigue

A strong sense of ‘reform fatigue’ was evident across interviews. Participants noted that Ireland’s health system has undergone repeated reorganisations, such as the transition from health boards to the HSE, often with limited visible improvement. Many described staff and the public as sceptical about whether yet another restructure would succeed where previous efforts had not. According to participant six the introduction of regional health areas will be a difficulty for people who've been through previous attempts at restructuring:

‘I think there are a lot of people in the health service that take quite a jaundiced view of restructuring. And that's perfectly understandable because over the last 20 years the health service has been through a number of different restructuring proposals from the health boards to the HSE... Organisational consultants come in. The whole things

thrown up in the air. You're told no we're going to operate in a different way and, like it's more of the same, or ends up as more of the same or further dysfunction. So there is that kind of restructuring fatigue and I think that has to be recognised' (P6).

Participant two believed there had been too many false starts with regards healthcare restructure in Ireland:

'We've had too many false starts like I said it's up down up and down and reform in our healthcare system. Staff are really pissed off like you know they're really cynical' (P2).

Participants attributed this fatigue to reforms being introduced too rapidly and without sufficient time for embedding change. Despite this, there remained some optimism that regionalisation could succeed if managed carefully and communicated transparently. As one interviewee suggested:

'People's fatigue in terms of a constantly changing environment... we're a bit worried about that so we want to do that in a way that's as minimally disruptive as possible' (P7).

6.4.2.2 Political will

Political commitment was consistently identified as a critical enabler. Participants viewed sustained political support as essential to avoid the stop-start pattern that characterised earlier health reforms. Several emphasised that political interference in service delivery had historically hindered structural change, while others argued that cross-party backing for Sláintecare offered a unique window of opportunity. One participant warned about what would happen without political buy-in:

'If there isn't that kind of political satisfaction around what happens with all of this, then we could just find ourselves in that never ending spiral around reform again' (P1).

Others viewed the inclusion of Regional Health Areas (RHAs) in multiple government strategies as an encouraging sign (P7). However, some cautioned that political priorities can shift and that politicians' commitment often follows public sentiment:

'If politicians get a whiff that the population will buy into it well then they'll be on board' (P4).

Participants also noted the challenge of vested interests—both political and professional—potentially slowing reform. As one reflected:

'The Irish health service has always been dogged by vested interest. I meant its undoubtedly the case and, like there's money to be made out of people being sick. And, and I often think like there isn't money to be made out of people being well, but they're massive advantages for country and for the public' (P6).

These views suggested that reform success depends on maintaining public and political focus on long-term population health rather than short-term interests.

6.4.2.3 Institutional alignment

Institutional alignment between the Department of Health, the HSE, and the proposed Regional Health Areas was seen as both crucial and problematic. Participants highlighted a lack of coherence between and within organisations, with 'mixed thinking' (P4) and 'if not necessarily conflicting accountabilities, they are certainly complicated accountabilities, divided accountabilities' (P4) leading to uncertainty about leadership and roles.

Some described parts of the Department as supportive of Sláintecare, while others appeared detached: 'support for Sláintecare... depends where you sit in the Department' (P2). The need for strong, coordinated leadership at senior civil service level was repeatedly emphasised. Participants also identified cultural resistance within the HSE, where certain senior leaders were viewed as 'control and command' managers reluctant to devolve power (P4).

Beyond leadership, participants described the system as a ‘collective more than a system’ (P4), where institutional silos and strong organisational identities hinder integration. The relationship between the new RHAs, the Department, and the HSE was seen as underdeveloped: ‘we have a clear view that we want six delivery structures regionally... but what is the new HSE in that?’ (P1).

Despite these challenges, some saw increased governance and clearer accountability as key enablers of success (P3). Others stressed the importance of engaging the public and managing expectations to build understanding of what high-quality, community-based care looks like (P1).

6.4.3 Navigating uncertainty in implementing regionalisation

When asked about their main areas of uncertainty, participants identified a range of issues that could challenge the effective implementation of regionalisation. These uncertainties centred on (1) governance roles and collaboration, (2) the influence of hospitals and professional groups, (3) data and accountability systems, (4) evaluation and sustainability of reform, and (5) resource allocation and outcomes.

6.4.3.1 Governance roles and collaboration

A key uncertainty concerned the distribution of responsibilities between the Department of Health, the HSE, and the new RHAs. Participants questioned whether sufficient groundwork had been done to clarify relationships between these bodies and the wider “health family.” As one participant noted,

‘The role of the HSE and the Department in the context of six regional health areas is a big area of uncertainty’ (P1).

Concerns were also raised about interagency collaboration, with several interviewees suggesting that insufficient attention had been given to how different organisations would work together across boundaries.

6.4.3.2 Influence of hospitals and professional groups

Many participants viewed the power of hospitals, particularly voluntary hospitals, as a major uncertainty for reform. The hospital sector was described as ‘extremely powerful’ with the capacity to ‘show their muscle’ in funding and governance debates (P6). Clinicians and medical representative bodies were also seen as potential sources of resistance, based on previous experiences where reforms were ‘scuppered by clinical pushback’ (P4).

6.4.3.3 Data, accountability and information systems

Several participants questioned whether the necessary data infrastructure was in place to support accountability and performance monitoring at regional level. One participant commented that:

‘It’s very hard to hold somebody to account if you don’t have information. would we be able to assemble a suite of information that would allow them to assess accountability for the delivery of services to meet the needs of the population effectively and efficiently within the region? I don’t know’ (P1).

Without accessible, reliable data, participants feared that RHAs might struggle to demonstrate progress or justify resource decisions. This was viewed as a technical as well as organisational risk, potentially undermining the transparency and learning culture the reform seeks to create.

6.4.3.4 Evaluation and sustainability of reform

Participants expressed unease about how the reform’s impact would be assessed over time. Some worried that the absence of a clear evaluation framework could make it difficult to track progress or learn from implementation. As one interviewee put it:

‘My biggest question mark is figuring out how I’m going to measure the impact... I’m quite nervous about being able to isolate this from every other change that’s going on in the health sector at the moment’ (P7).

There was also a perception that Ireland has a history of ‘endless reform’ (P1) driven by structural change rather than sustained improvement. Several suggested that reform fatigue and a lack of demonstrable results could threaten the long-term success of regionalisation.

6.4.3.5 Resource allocation and outcomes

Finally, participants were uncertain about how population-based resource allocation would work in practice, and whether it might create unintended inequities. Participant seven reported uncertainty about how policymakers would adjust to the new allocation models:

‘It’s difficult to discuss regional health areas without discussing that population based resource allocation component and I do think that that is going to be quite a shift for how we policymakers think about money, and how we policymakers allocate money, and there’s definitely going to be a hard learning curve on that over the course of a couple of years, so I do have some fears about making sure that nothing is left behind, that that we haven’t, we don’t suddenly defund something that’s really important’ (P7).

This was seen as a hard learning curve requiring major cultural adjustment among policymakers. Questions were also raised about whether regionalisation would ultimately lead to better outcomes for patients, or simply another layer of structural change. As one participant observed:

‘Ultimately, this has to be about... a better experience of the health system... the role that regionalisation has to play in all of that I think would be very uncertain’ (P1).

Overall, uncertainty was not framed as resistance to change, but as concern about the practicalities of implementation. Participants viewed unresolved governance roles, entrenched institutional power, limited data infrastructure, and unclear evaluation mechanisms as potential obstacles to achieving the intended benefits of regionalisation. These findings highlight the importance of

sustained leadership, transparent communication, and robust information systems to manage uncertainty during reform.

6.5 Discussion

This chapter presents findings from a series of semi-structured interviews conducted with Irish policymakers to explore their perspectives on the expected impact of healthcare regionalisation, perceived barriers and enablers, relevant external factors, and key areas of uncertainty. In particular, discussions of uncertainty focused on elements of the implementation plan where participants felt there was a lack of evidence.

Policymakers identified several anticipated impacts of regionalisation. These were grouped into five key themes: (1) integration of hospital and community care, (2) enhanced governance, financial control and accountability, (3) improving patient-centred care; expectations and challenges, (4) frontline staff perspectives and the promise of local autonomy, and (5) balancing national consistency with local responsiveness. Participants generally viewed regionalisation as a means to improve accountability and coordination rather than a cost-saving measure.

Three major themes emerged in relation to the challenges and enablers shaping the implementation of regionalisation. First, restructuring fatigue was identified as a significant concern. Policymakers expressed apprehension that the healthcare system, particularly staff, may become overwhelmed by the scale and pace of organisational change, particularly given Ireland's history of frequent reforms. Second, political will was recognised as a critical enabler, with participants emphasising that sustained political leadership and commitment are essential for driving the reform forward. Participants noted that while political will appeared stronger under Sláintecare than in previous reform efforts, sustaining this momentum would be crucial. Third, institutional alignment was noted as a key challenge. Interviewees highlighted that the goals and interests of central agencies and existing institutions do not always align with the objectives of regionalisation, potentially leading to resistance or fragmentation during implementation. These themes reflect the complexity of

delivering structural reform within a system that has undergone much reorganisation and is characterised by competing priorities.

In addition to these themes, participants raised important areas of uncertainty that may influence the success of the reform. Concerns were expressed regarding whether sufficient buy-in would be achieved from hospitals and healthcare staff, and whether meaningful collaboration across care settings could be established to support integrated service delivery. Uncertainty also surrounded the operational design of the RHAs, including the division of functions between the HSE, Department of Health, and new regional entities. Of particular importance, there was uncertainty about whether regionalisation would ultimately translate into a more patient-centred healthcare system or deliver tangible improvements in patient experience and outcomes. Several participants questioned whether the structural changes proposed under regionalisation would make a visible or meaningful difference to the patient, especially in the short to medium term.

6.5.1 Limitations

It was difficult to disentangle the specific goals and expected outcomes of regionalisation from the broader Sláintecare reform programme. Many interviewees were unable to articulate the rationale behind the design of RHAs without referring to the wider reform agenda. Although probing questions were used to focus specifically on the RHA component, it became evident that regionalisation is inseparable from the wider Sláintecare reform agenda, both conceptually and in practice. As outlined in Chapter 5 (umbrella review), the literature consistently highlights the importance of context in interpreting the design and impact of system-level interventions. Accordingly, this chapter includes discussion of broader Sláintecare reforms to provide essential background and context for understanding the implementation of RHAs in Ireland.

The interviews that informed this chapter were undertaken during the COVID-19 pandemic. As a result of the pandemic and the health systems response, only a limited number of interviewees were available. It is possible if more interviews

had been conducted some of the uncertainty would have been addressed or more conflicting views would have been identified. This is a limitation of the analysis.

Since collecting this interview data in the first half of 2021, there have been subsequent developments to the plan for the rollout of RHAs which are not captured in this chapter. The aim of this chapter was to capture the early thoughts of policymakers on the structure and aims of healthcare regionalisation, at a point at which evidence could be gathered to help inform subsequent design decisions. Therefore, the data described in this chapter is not completely reflective of the RHAs that are functional in 2025 but rather shows the earlier visions as described by the initial policy proposers.

6.5.2 Implications for a rapid-realist review

The semi-structured interviews with policymakers were used to identify areas of uncertainty and priority issues in implementing regionalisation in Ireland. From these interviews, I generated a list of 24 potential research questions that captured the main gaps in understanding, contested assumptions, and implementation challenges raised by participants. One of these research questions was to be selected for the rapid-realist review. The list of questions was discussed with my supervision team, and the list was narrowed by iterative group discussion using the following criteria:

- Novelty — Excluded questions already being addressed by other research groups or formal evaluations.
- Feasibility within a rapid review timeframe — Questions had to be addressed through existing literature rather than new empirical data collection.
- Relevance and usefulness to policymakers — Priority was given to questions whose answers could directly inform regionalisation implementation.

- Compatibility with realist methods – The question needed to lend itself to theory-driven analysis and the development of testable programme theories.
- Clear implications for practice – The question should produce findings that could guide decision-making or highlight implementation risks.

Three research questions were identified that best met these criteria and further scoping work was undertaken. The initial research questions were:

1. **Timing of evaluation:** *What is the right time to evaluate regional health areas?*
 - How long does it take for the impact of a major health system restructure to be felt, particularly on patient outcomes?
2. **Regionalisation as a mechanism for integration:** *Are RHAs a mechanism to bring about the integration of health and social care?*
 - Will a shared budget between health and social care lead to better patient outcomes?
 - Will shared budgets promote integration across community, hospital, and social settings?
 - Will joint decision-making enhance efficiency, responsiveness, and alignment with local needs?
3. **Patient-centred care as an outcome of regionalisation:** *How, why, and under what circumstances does regionalisation support more patient-centred care?*

Each of these questions was briefly scoped to assess the nature, depth, and accessibility of existing evidence. The question on timing of evaluation appeared in several primary studies and commentaries, particularly in public health and preventive care literature, where difficulties in determining appropriate timeframes for assessing system-level impacts are well documented. As such, this topic, while relevant, was found to be conceptually complex and heavily dependent on context-specific data, making it less suitable for a rapid- realist review.

The integration question also emerged as important, with strong policy interest and overlap with broader system integration debates. However, the scoping revealed substantial conceptual and empirical overlap between integration and patient-centred care, including integration could be described as the mechanism through which patient-centred outcomes might be achieved. Given this overlap, and the potential to subsume aspects of integration within an analysis of how regionalisation shapes patient experiences, it was decided to focus the review on patient-centred care as the primary outcome of interest.

The final rapid-realist question was therefore agreed as:

- Under what circumstances, and through what mechanisms, can healthcare regionalisation contribute to an increase or improvement in patient-centred care?

The interviews had consistently emphasised improving the patient experience and delivering more patient-centred care as central objectives of the regionalisation reform. Yet, the scoping work showed a notable gap in existing evidence synthesis on how regionalisation might achieve these outcomes. This combination of policy importance and evidence scarcity made patient-centred care the most appropriate focus for the rapid-realist review.

One limitation of the interviews was the lack of a clear definition of patient-centred care as an outcome. To overcome this, a scoping review of definitions of

patient-centred care was also considered necessary and this is reported in Chapter 7. As discussed in Chapter 3, the early and ongoing involvement of policymakers in evidence synthesis processes is strongly recommended to ensure relevance and applicability to policy needs. Policymakers continued to contribute to this research in subsequent stages, including the rapid-realist review described in Chapter 8, where they participated in validating programme theories as part of a stakeholder group.

6.5.3 Conclusions

In summary, this chapter has provided insight into Irish policymakers' perspectives on the aims, anticipated impacts, and challenges associated with healthcare regionalisation. Importantly, questions remain about whether regionalisation will lead to meaningful improvements in patient-centred care and cross-sector collaboration. These insights inform the evidence synthesis and theory-building that now follow, particularly Chapters 7 and 8, and provide a crucial context for understanding how best to support the design and implementation of effective, sustainable regional healthcare structures in Ireland.

Chapter 7 Definitions of patient-centred care

7.1 Overview

In Chapter 6, I presented the results of interviews with Irish policymakers. The interviews identified patient-centred care as a primary aim of healthcare regionalisation in Ireland. However, patient-centred care was not clearly defined by interviewees or Irish policy documents. Before conducting a rapid realist synthesis to better understand the impact of regionalisation on patient-centred care, a clear definition of patient-centred care is required. This chapter presents a scoping review of the literature on definitions of patient-centred care. A definition was then identified which is used to inform the rapid-realist review described in Chapter 8.

7.2 Introduction

In Chapter 6, semi-structured interviews with policymakers highlighted that a central objective of healthcare regionalisation in Ireland is to promote patient-centred care (PCC), and to improve the degree to which care is patient centred. However, PCC is not defined in the overarching Sláintecare report, which is the policy document outlining the move to a regionalised healthcare system. What is considered as PCC can vary across different care contexts, in relation to different patient groups, and as a reflection of different ethical perspectives (Fridberg et al., 2022; Mitchell et al., 2022).

The conceptual complexity of PCC has long been recognised. Foundational models such as Stewart et al.'s *Patient-Centered Clinical Method* emphasise understanding the illness experience, seeing the patient as a whole person, and building a therapeutic partnership (Stewart et al., 1995). Mead and Bower's (2000) influential model further emphasises dimensions such as biopsychosocial perspectives, the patient-as-person, shared decision-making, therapeutic alliance, and recognition of the clinician-as-person. More recent work by Epstein and Street (2011) further highlights the role of respectful communication, patient preferences, and emotional support in defining patient-centred interactions. Yet, despite over two decades of conceptual development,

considerable variation persists in how PCC is defined and operationalised across the literature.

These definitional inconsistencies have important implications for policy and evaluation. The Health Foundation's review of commonly used PCC measurement tools demonstrates how differences in underlying definitions influence what is measured and how patient-centredness is interpreted at system, organisational, and clinical levels (De Silva, 2014). Given these issues a targeted review and assessment of definitions was warranted. This chapter describes the process used to identify a working definition of PCC which will be used in the rapid realist review described in Chapter 8.

7.3 Methods

7.3.1 Search

A targeted search for definitions and measurements of patient centred care was carried out in MEDLINE on 11 May 2023. A copy of the search string is in Appendix J. Systematic reviews were sought with any synthesis method considered. The search was limited from 2014 to the date of the search and by English language. This pragmatic year limit was selected to account for the publication of the comprehensive Health Foundation report in 2014 as the work of this thesis builds on that report (De Silva, 2014).

7.3.2 Eligibility for scoping review

For consideration, studies were required to describe a definition or conceptualisation of PCC that was applicable to this research. Papers that collated tools used to measure PCC were also included. Frameworks for the implementation of a PCC system were not considered. Papers that were specific to a particular population, e.g. dementia or older people, or specific settings or perspectives e.g. GP care or nurses were excluded.

7.3.3 Synthesis and selection of a definition

Data charting was conducted for the identified studies, involving the systematic recording of key information such as study characteristics, methodologies, and

definitions. This process was used to organise the data and identify patterns or trends across the studies (Levac et al., 2010). The outcome of this process was the development of a matrix of PCC definitions. Unlike systematic reviews, which typically assess the quality of individual studies, scoping reviews focus on mapping the breadth of evidence rather than evaluating its rigor. As such, quality assessment was not conducted (Arksey and O'Malley, 2005).

As outlined in Chapter 3, this work was initiated in response to a request from Irish policymakers. To ensure that the findings remained relevant to these policymakers, an additional targeted search for Irish definitions of PCC was undertaken. The Sláintecare reform document, which first introduced the concept of healthcare regionalisation under consideration by Irish policymakers, was reviewed for definitions of PCC. However, no formal definition of PCC was found in these documents. Instead, relevant excerpts mentioning PCC were extracted and used to assess the relevance of definitions from the literature. Additionally, the transcripts from interviews described in Chapter 6 were examined for pertinent concepts. The reporting of this scoping review follows the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (Tricco et al., 2018).

7.4 Results

7.4.1 Definitions of PCC

7.4.1.1 Results of the search

Database searching identified 593 records for title and abstract screening, of which 20 were selected for full paper review. Six studies were subsequently identified that provided definitions of PCC. An overview of identified studies is provided in Table 7-1.

Table 7-1 Overview of definition studies

Study ID (Reference)	Study design	Date range	Study aim	Number of dimensions
Grover 2022 (Grover et al., 2022)	Umbrella review	Database inception to	To identify core elements of PCC and synthesise implementation facilitators and barriers.	12

Study ID (Reference)	Study design	Date range	Study aim	Number of dimensions
		December 2020		
Mørup-Langberg 2019 (Mørup-Langberg et al., 2019)	Systematic review	January 2000 to June 2017	This study aims to provide an overview of how patient-centredness has been defined in the literature since Mead and Bower's review in 2000, and to provide an updated definition of the concept.	6
Scholl 2014 (Scholl et al., 2014)	Systematic review with concept analysis	Database inception to January 2012	To identify and analyse the different dimensions of patient-centeredness described in the literature and to propose an integrative model of patient centeredness based on these results.	15
Sharma 2015 (Sharma et al., 2015)	Overview of reviews	January 2005 to April 2014	(1) identify and define components of person-centred care; (2) explore nursing and health-care provider behaviours that are person-centred; and (3) identify systems level supports required to enable person-centred care.	6
Sidani 2014 (Sidani and Fox, 2014)	Integrative review	1995-2012	To delineate the specific and non-specific elements of PCC that transcend healthcare professions. The specific elements were described in components and activities that characterize PCC and the non-specific elements were reflected in the medium for delivering PCC.	4

Study ID (Reference)	Study design	Date range	Study aim	Number of dimensions
Sturgiss 2022 (Sturgiss et al., 2022)	Scoping review	January 1990 to August 2019	Aimed to identify the core elements of centredness in healthcare literature	9

Key: PCC – patient centred care.

7.4.1.2 Definitions identified from literature

The studies described between four and 15 dimensions of PCC (Table 7-1). A full description of the dimensions reported in each study is provided in Appendix J. Across the studies, 45 dimension labels were initially identified. These included concepts such as biopsychosocial perspective, collaborative care, holistic care, and shared decision-making, though the number, terminology, and granularity of dimensions varied considerably. Despite this variation, substantial conceptual overlap was evident across studies.

Because the same underlying concepts were often described using different labels, the initial list of 45 labels did not represent 45 unique dimensions. To enable meaningful comparison, overlapping concepts were grouped and duplicate labels were removed. This consolidation reduced the list to a smaller set of conceptually distinct dimensions, which formed the basis for the subsequent comparative analysis. To support this comparison, the two most recent studies, both published in 2022, were examined in greater depth (Grover et al., 2022; Sturgiss et al., 2022). These were selected because contemporary reviews tend to synthesise earlier conceptual work and therefore provide up-to-date, potentially comprehensive definitions that could serve as reference points for comparing older studies. Grover et al. did not provide standardised definitions for the dimensions; instead, they included examples from the studies they reviewed, using direct quotes to illustrate the dimensions reported in the original sources. As a result Sturgiss et al. (2022) was used as the primary reference for comparing definitions.

A comparison matrix is provided in Table 7-2. Sturgiss et al. offer the most comprehensive definition of PCC, encompassing all the dimensions identified in the other studies, except for two specific dimensions: communication and responsive care. Communication was explicitly identified as a distinct dimension by two studies (Grover et al., 2022; Sharma et al., 2015). Responsive care, defined by Sidani and Fox (2014) as the individualisation of care to align services with patients' needs, values, and preferences was not included by Sturgiss et al. Furthermore, Sturgiss et al. were the only authors to identify access and continuity of care as explicit dimensions of PCC.

Table 7-2 Matrix of patient centred care dimensions covered by studies

Study ID Dimensions from Sturgiss	Mørup-Lanberg 2019	Scholl 2014	Sidani 2014	Grover 2022	Sharma 2015
1. Sharing power^Y	✓	✓		✓	✓
2. Sharing responsibility		✓		✓	✓
3. Therapeutic relationship/bond/alliance[∞]	✓		✓	✓	✓
4. Patient as a person^Y	✓	✓	✓	✓	✓
5. Biopsychosocial[±]	✓	✓	✓	✓	
6. Provider as a person^z	✓	✓		✓	
7. Co-ordinated care	✓			✓	
8. Access					
9. Continuity of care					

^Y including seen as equals and empowerment

[∞] including compassion and emotional engagement

^Y (including Person as part of a collective, Spirituality, cultural needs, Comprehensive care, and Strengths based)

[±] (including Social determinants of health)

^z (including Professional clinical responsibilities, and Advocate for the patient)

7.4.2 Tools for the measurement of patient-centred care

An evidence review by the Health Foundation, published in 2014 identified the tools most commonly used to measure person-centred care (De Silva, 2014). In the scoping search conducted for this chapter, one review of reviews was identified which provided an update on how to measure patient-centred care (Louw et al., 2020). The most commonly used tools from the Health Foundation evidence review and the preferred measurement tools from Louw et al. 2020 are detailed in Table 7-3. The tools for measurement were used as part of search strategies in the rapid-realist review outlined in Chapter 8.

Table 7-3 Measures of patient-centred care

Full name	Common abbreviation of measure	Source
Communication Skills Attitude Scale	-	The Health Foundation
Consultation and Relational Empathy	CARE	Both
Consultation Care Measure	CCM	Louw 2020
Consumer Assessment of Healthcare Providers and Systems Survey	CAHPS	The Health Foundation
Decisional Conflict Scale	-	The Health Foundation
Doctor-Patient Communication	DPC-13	Louw 2020
Doctors' Interpersonal Skills Questionnaire	DISQ	Both
Facilitation of Patient Involvement in Care	FPI	Louw 2020
General Practice Patient Survey	-	The Health Foundation
Health Care Communication Questionnaire	HCCQ	The Health Foundation

Individualised care scale	ICS	The Health Foundation
Jefferson Scale of Physician Empathy	JSPE	The Health Foundation
Measure of Processes of Care	MPOC	The Health Foundation
Observing Patient Involvement in Decision Making scale	OPTION	The Health Foundation
Organisational Values Questionnaire	-	The Health Foundation
Partners in Health Survey	-	The Health Foundation
Patient Activation Measure	PAM	The Health Foundation
Patient Assessment of Chronic Illness Care	PACIC	The Health Foundation
Patient Feedback Questionnaire on Communication Skills	PFC	Louw 2020
Patient Perception of Patient-Centredness	PPPC-14	Louw 2020
Patient-Centred Behaviour Coding Instrument	PCBI	Louw 2020
Patient-Centred Observation Form	PCOF	Louw 2020
Patient-Practitioner Orientation Scale	-	The Health Foundation
Person-centred Care Assessment Tool	P-CAT	The Health Foundation
Person-centred Climate Questionnaire	PCCQ	The Health Foundation

Practices in Self-management Support	-	The Health Foundation
Questionnaire on Quality of Physician-Patient Interaction	QQPPI	Louw 2020
Resources and Support for Chronic Illness Self-management Scale	-	The Health Foundation
Set the stage, Elicit information, Give information, Understand the patient's perspective, and End the encounter	SEGUE	Louw 2020
Shared decision-making	SDM-Q-9	Louw 2020

Key: '-' – no common abbreviation identified

7.4.3 Irish documents and research

7.4.3.1 Sláintecare

Neither the initial *Sláintecare report*, nor the *Implementation Plan* that was derived the following year, define PCC. The *Sláintecare* report described eight fundamental principles of the report which framed the committee's discussions and underpin its recommendations. Four of these principles, fall under the heading of 'nature of integrated care', while broader than just PCC, they aligned with the concepts of patient-centred care described in section 7.4.1:

1. All care planned and provided so that the patient is paramount (ensuring appropriate care pathways and seamless transition backed-up by full patient record and information)
2. Timely access to all health and social care according to medical need
3. Care provided free at point of delivery, based entirely on clinical need
4. Patients accessing care at most appropriate, cost effective service level with a strong emphasis on prevention and public health (Houses of the Oireachtas and Committee on the Future of Healthcare, 2017).

The implementation plan also included some references to PCC stating that:

“Care will be patient-centred, with a lead clinician always known and responsible for each patient journey through the hospital”

(Department of Health, 2018b) (p43), and

“Clinical leaders working in a coordinated multi-disciplinary and patient-centred way such that patients are treated and discharged without delay by the most appropriate senior clinician” (Department of Health, 2018b) (p44).

7.4.3.2 Irish research into a definition of PCC

In 2021, a group of Irish researchers working in partnership with an umbrella patient led organisation (Irish Platform for Patient Organisations, Science and Industry (IPPOSI)) and the HSE published a co-developed definition of person-centred coordinated care. This was the definition agreed and it is written from a service-user perspective:

‘Person-centred coordinated care provides me with access to and continuity in the services I need when and where I need them. It is underpinned by a complete assessment of my life and my world combined with the information and support I need. It respects my choices, building care around me and those involved in my care.’ (Phelan et al., 2021) (p8)

As described by IPPOSI study authors this definition reflected the essential aspects of integrated care which included access, and a comprehensive care plan which enables care when and where it is needed (Phelan et al., 2021). Additionally, care is focused on the individual and their perspectives rather than an inflexible system approach. Again, this definition aligned with the definition described in Table 7-2.

7.4.3.3 Interviews with policymakers

As outlined in chapter 6, I conducted semi-structured interviews with policymakers and through analysis of these interviews, as well as policy

documents, I determined that patient-centred care was a key outcome in the Irish plan for healthcare regionalisation. I re-examined the interview transcripts to extract information on the conceptualisation of patient-centred care by Irish policymakers.

Only two of the policymakers described what patient-centred care might look like, although all seven participants reflected on the importance of integrated care (considered in this instance to be the seamless transition of patients between primary and secondary care) in improving patient experience.

Participant two focused on the patient experience and how patients should be placed at the centre of how the system is organised. In their view, it was important to ensure that care was “a joined-up experience” and easy to navigate.

Participant seven described patient-centred care as the key outcome:

“what we're really looking for in patient experience surveys for people to... when they're talking about their experience with their transition of care that they say that they know who they go to next, that they say that they understand their discharge plan, they understand where they're going to or that their family was involved and decisions about their transition of care and that is kind of understood at those junctures.”

7.5 Discussion and selection of definition to use

Consideration was given to both using a published definition in its entirety and adapting one or more definitions as appropriate for the objectives of this project. The definition by Sturgiss et al. (2022) was selected in its entirety, without adaptation, as it was the most comprehensive and aligned with the study objectives. A limitation of this approach is that no consultation or sense-checking with patients was undertaken, which may have further informed the relevance or interpretation of the chosen definition.

Sturgiss et al. provided the most comprehensive definition of patient-centred care (PCC) among the studies reviewed, notably, it was the only definition to

explicitly include access and continuity of care as distinct dimensions. This is especially significant in the context of healthcare regionalisation, where equity in access to services across different geographic regions is a key consideration (Chapter 3). In Ireland, for instance, regional reforms aim to align community and acute services within health regions to improve access closer to home (Department of Health, 2022). While Sturgiss et al. omitted two dimensions, communication and responsive care, their exclusion does not necessarily undermine their definition's applicability. Communication is specifically identified as a distinct dimension by Grover et al. and Sharma et al. However, communication can also be considered an integral component of all dimensions of PCC, particularly during interactions between patients and providers, as well as between healthcare providers. Responsive care, as defined by Sidani and Fox (2014), refers to the customisation of care to meet the individual needs of patients, aligning with several of the dimensions of PCC outlined by Sturgiss et al. The detailed descriptions and breakdowns of PCC dimensions were cross-checked against each other and relevant Irish policy literature to ensure that a comprehensive and applicable definition was selected. The definition provided by Sturgiss et al., along with the identified measurement tools, were used to inform the selection of studies related to PCC in the rapid realist review described in Chapter 8.

This review was a targeted scoping review aimed at identifying definitions of PCC. A scoping review is designed to provide an overview of a specific area rather than an exhaustive assessment of all relevant literature. While this approach may have resulted in the exclusion of some studies, the use of broad search terms minimised the likelihood of missing key studies. Furthermore, the focus on systematic reviews could be considered a limitation. However, the primary goal of this work was to identify a general, widely applicable definition of PCC, which justifies the synthesis of evidence from systematic reviews rather than individual studies. Additionally, this approach was aligned with the resource constraints of the PhD project.

In summary, the definition of PCC proposed by Sturgiss et al. offers a comprehensive framework that includes the majority of dimensions identified in the recent literature. Although some dimensions, such as communication and

responsive care, were noted separately by other studies, these aspects remain integral to the overall understanding of PCC as reported by Sturgiss et al. This review synthesised evidence to arrive at a broadly applicable definition, which can guide future research and inform policy in diverse healthcare settings.

Building on this scoping review, Chapter 8 uses the Sturgiss et al. definition to examine the impact of healthcare regionalisation on patient-centred care. The chapter generates substantive insights into how regionalisation initiatives may support or hinder the delivery of PCC, including the mechanisms and contextual factors that influence equity, access, and continuity of care.

Chapter 8 Rapid realist review

8.1 Overview

In Chapter 3, through a review of relevant literature, emerging synthesis methods such as rapid realist review were identified as being potential approaches for use in the evaluation of complex interventions. In Chapter 6 interviews with policymakers identified achieving patient-centred care as an aim and expected outcome of healthcare regionalisation. Regionalisation is a complex intervention, and therefore this chapter has a two-fold purpose aligned with the overall objectives of the thesis. Its primary purpose is to generate substantive insights into how regionalisation may impact patient-centred care, contributing to the thesis objective of understanding how evidence can inform complex health system reforms. Its secondary but complementary purpose, is to critically evaluate the rapid realist review as a method for investigating complex policy questions, assessing its suitability, efficiency and methodological fit in comparison to alternative evidence synthesis approaches discussed earlier in the thesis. Together, these dual aims address both the substantive policy focus of the thesis and its methodological inquiry.

8.2 Introduction

8.2.1 Rationale for the review

Healthcare regionalisation is the movement of responsibility for healthcare towards regional bodies. Regionalisation has been formally defined as an “organizational arrangement involving the creation of an intermediary administrative and governance structure to carry out functions or exercise authority previously assigned to either central or local structures” (Church and Barker, 1998, p. 468). This can be downward movement from centralised bodies or government (a process known as decentralisation) or upwards from more local bodies such as local authorities (a process known as centralisation). In practice, restructuring of a healthcare system to a regionalised healthcare system, involves a large degree of decentralisation, with a small amount of local centralisation of services, as responsibility for health is moved down from a national government agency to a regional body (Quigley et al., 2019).

Healthcare regionalisation has been implemented in many forms across high-, middle- and low-income countries. The exact impact of introducing this system-wide reform, however, is unknown (Quigley et al., 2019). Several comprehensive reviews and evaluations have been undertaken, but the findings have been inconclusive (Dwicaksono and Fox, 2018; Quigley et al., 2019). A review of reviews (reported in Chapter 5) found nine systematic reviews of healthcare regionalisation; two reviews reported on the six WHO health system building blocks (leadership and governance, health systems financing, access to essential medicines, health information systems, health workforce, health service delivery) (Cobos Muñoz et al., 2017; Rakmawati et al., 2019), one reported on measures of equity, efficiency, and resilience (Abimbola et al., 2019), one reported only on equity (Sumah et al., 2016), one reported on resource use and service organisation indicators (Zon et al., 2017), and one reported on factors that support or hinder regionalisation (Mello et al., 2017). The remaining three reviews (Dwicaksono and Fox, 2018; Quigley et al., 2019; Ramos et al., 2020) included a wide range of health and system indicators such as infant mortality, cost and resource utilisation. These previous systematic reviews have produced inconclusive evidence on whether healthcare regionalisation improves outcomes, largely due to the complexity of regionalisation processes and variation in context.

Improving patient-centred care is a major priority outcome for health system reform (Chapter 6) and is a policy priority for the WHO (WHO Western Pacific, 2013). However, none of these nine reviews included patient-centred care as an outcome of interest. In addition, the systematic reviews identified in the umbrella review (Chapter 5) did not unpack how and why regionalisation may be responsible for the outcomes reported in each review. Further explanatory depth, explaining how regionalisation can lead to certain outcomes, would be useful to policymakers considering the same restructure, as enabling factors and unintended consequences would be identified and explained. The one exception from the umbrella review, which considered the outcomes seen in more explanatory depth, was a realist review by Abimbola et al. (2019). They set out to understand why, how and under what circumstances decentralisation influences health system equity, efficiency and resilience. They identified

mechanisms through which decentralisation impacts these three outcomes including how decentralisation either exacerbates or improves existing patterns of inequity. Abimbola et al. also identified institutional, socio-economic and geographic contextual factors that influence each of these mechanisms. Applying a realist review approach may therefore help to develop our understanding of the mechanisms that drive changes in patient-centred care in the context of a whole health system change such as regionalisation.

There is no universally accepted definition of patient-centred care, with definitions differing by population group and setting (Fridberg et al., 2022; Harding et al., 2015). For example models of patient-centred care in dementia care focus on personhood, models in cancer care pioneered shared decision making, and patient-centred care models in paediatrics help strengthen family involvement (Harding et al., 2015). Given the variability in definition and lack of consensus, a scoping review of definitions was undertaken (Chapter 7) and six recently published definitions or concepts of patient-centred care were identified (Grover et al., 2022; Mørup-Langberg et al., 2019; Scholl et al., 2014; Sharma et al., 2015; Sidani and Fox, 2014; Sturgiss et al., 2022). The most recent comprehensive definition was from 2022 and had nine dimensions comprising; 1. Sharing power, 2. Sharing responsibility, 3. Therapeutic relationship/bond/alliance, 4. Patient as a person, 5. Biopsychosocial, 6. Provider as a person, 7. Co-ordinated care, 8. Access, and 9. Continuity of care (Sturgiss et al., 2022). However, to date, as there is little evidence about the impact of healthcare regionalisation on patients, research should move beyond the impact on the system to identify the mechanisms that shape patient experience, access, and outcomes. This gap in the evidence is particularly relevant in the Irish context, where regionalisation is being implemented as part of the Sláintecare reforms without a clear understanding of its potential implications for patients. Linking system restructuring to patient-centred outcomes is therefore essential to ensure that regionalisation, as planned in Ireland, enhances rather than unintentionally undermines patient experience and equity of care.

8.2.2 Purpose of the review

The purpose of this study is to understand how, and under what circumstance, healthcare regionalisation might lead to an increase in patient-centred care or improvements in patient-centred care.

8.3 Methods

A realist approach was used for this review because it is particularly suited to the investigation of complex interventions where there is a mixed body of evidence, incorporating a wide range of primary study designs (Pawson et al., 2005). Realist review, or synthesis, is a theory-driven method of synthesis which seeks to identify and build programme theories about how and why a particular intervention or policy is successful or not (Wong et al., 2014). A programme theory is the set of assumptions that describes how those designing the intervention or policy expect an intervention to achieve its aim and under which conditions (Marchal et al., 2018). A realist review attempts to provide decision makers with a transferable theory or theories that suggests how an intervention is more or less likely to work in certain situations, for particular groups, according to certain contexts (Saul et al., 2013). Realist research typically employs context-mechanism-outcome-configurations (CMOCs) as a heuristic technique to understand the generative causal processes leading to identified outcomes (Marchal et al., 2018). CMOCs outline the mechanism(s) that lead to an outcome and the contexts in which mechanisms are activated (Wong et al., 2017).

The realist synthesis approach as outlined by Pawson et al. (2005) can be time and human resource intensive due to its complex and iterative nature, and for those reasons a potentially expensive endeavour (Rycroft-Malone et al., 2012; Saul et al., 2013). It can take up to 24 months to complete a full realist review (Saul et al., 2013). This is longer than the typical six to twelve months available to rapid response teams and dedicated evidence synthesis units established by government departments (Chapter 2). For example, the work which was the motivation for this thesis, the Health Research Board evidence review of healthcare regionalisation took 16 months comprising two reports, one of which was internationally peer-reviewed within that time. Additionally, due to their

iterative and exploratory nature, realist reviews can often suffer from ‘scope creep’ (Saul et al., 2013). The time and resource investments required may not always suit the time-sensitive demands of many policymakers; for evidence to inform real time decision making within the constraints of electoral election cycles, it must be delivered rapidly. Rapid realist reviews have emerged as a method that combines elements of rapid reviews with a realist approach to knowledge synthesis, aiming to meet the time-sensitive evidence needs of policymakers while preserving the core elements of realist methodology and providing nuanced evidence for responding to emerging issues (Saul et al., 2013; Schick-Makaroff et al., 2016). This work tests the utility of a rapid realist review to generate knowledge on the impact of regionalisation on patient-centred care, within typical resource constraints.

The study was registered with PROSPERO (CRD42024461588) and OSF. The protocol was published on the OSF website (Quigley, 2024).

8.3.1 Search strategy

A search strategy was developed in conjunction with a subject librarian at the University of Glasgow. This was adapted from a search strategy used by the Irish Health Research Board in a systematic review of the impact of healthcare regionalisation (Quigley et al., 2019), but with some important differences. First, search terms for different study designs were not included, as the realist approach does not exclude studies on the basis of design (for example qualitative studies can provide useful information on potential mechanisms). Secondly, as this was a rapid review the formal database search was limited to OVID MEDLINE only. Whilst potentially relevant references could be missed through this limitation, this was a pragmatic decision to save on required resources. Resources saved include time spent translating the search for additional databases, deduplication of records, and the screening of additional records that would have been identified. Additional targeted searches (section 8.3.1.1), including screening of systematic review reference lists and grey literature databases, helped mitigate the risk of missed studies. Combining a MEDLINE search with appropriate supplemental searching can be considered appropriate for rapid reviews (Klerings et al., 2023). Thirdly, given the interest

in impact on patient-centred care, terms for patient-centred care were included in the search. These were developed using the findings of a scoping review of definitions of patient-centred care (Chapter 7). The search strategy can be found in Appendix K.

8.3.1.1 Additional searching

The reference lists of reviews included in an umbrella review of healthcare regionalisation (Chapter 5) were screened for studies relevant to this rapid-realist review. Searches were conducted in Google and Google Scholar to supplement the MEDLINE search and the first ten pages of records in each searched. The Kings Fund Library database was also be searched to find relevant grey literature reports. The following key words were used in all supplemental searches: regionalisation, decentralisation, and regional health organisation/area.

8.3.2 Study selection

There were three-levels to screening, title only screen, abstract screening and full paper screening. This approach was chosen as screening via a titles-first approach may be more efficient than screening titles and abstracts together and there were a large number of clearly irrelevant articles in the search results (Mateen et al., 2013). The question used for title screening was: “Could this article be about healthcare regionalisation and patient outcomes?”

The question for abstract and full paper screening was “Could this article provide useful information about the relationship between healthcare regionalisation and patient-centred care?”

At full paper review, articles were confirmed as meeting the full eligibility criteria for this review. (Table 8-1)

Table 8-1 Eligibility criteria

	Inclusion	Exclusion
Intervention	Healthcare regionalisation across the health system	Health regionalisation on a condition specific basis only e.g. cancer services
Outcome	Describes the concept of patient- or person-centred care	No focus on aspects of patient-centred care
Geography	High income countries in the OECD	Low or middle income countries
Language	The document is written in English	The document is not written in English

As detailed in Chapter 7, the elements of patient-centred care were drawn from the definitions provided by Sturgiss et al. (2022). Sturgiss et al. defined nine dimensions of patient-centred care: sharing power (equality and empowerment), sharing responsibility, fostering a therapeutic relationship (compassion and emotional engagement), viewing the patient as a person (considering their collective, spiritual, cultural needs, comprehensive care, and strengths), addressing biopsychosocial factors (including social determinants of health), recognizing the provider as a person (with professional responsibilities and advocacy for the patient), ensuring coordinated care, providing access, and ensuring continuity of care. Each dimension was included as a component in the search strategy and used to screen studies for eligibility.

All screening was conducted independently by two reviewers (JQ, COD, ER and NH). Where there were disagreements, consensus was reached through discussion or consultation with a third reviewer.

8.3.3 Quality appraisal: rigour and relevance

Pawson's criteria of rigour and relevance are used to appraise evidence in realist research under a 'fitness to purpose' lens (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012). Rigour relates to the methodological quality of a study, while relevance refers to the extent that a research study can potentially contribute information toward the development of programme theory (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012). Two reviewers independently used the full paper descriptions of a study's purpose, methods and analysis and the claims made by its authors to decide if that study was a good fit for this review. A study of good fit is one that appears to be credible and trustworthy, and contains descriptive information that can potentially support developing a theory regarding healthcare regionalisation and patient-centred care (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012). The independent reviewers resolved disagreement through discussion or with the involvement of a third reviewer when necessary. An assessment of rigour, such as through application of a critical appraisal tool, was not formally undertaken as part of this rapid realist review due to the rapid nature of the work. However, all studies were considered of sufficient methodological quality to inform this synthesis.

8.3.4 Descriptive analysis

As in most realist reviews, the data extraction phase occurred in an iterative manner (Rycroft-Malone et al., 2012). Initially top-level data were extracted. A standardised, pre-piloted form was used to extract data from the included studies including study setting, characteristics of the service, study population, participant demographics and baseline characteristics, details of the intervention and control conditions (if appropriate), sample size, study methodology, results relevant to patient-centred care and access, any suggestion by the authors of mechanisms of action of the chosen intervention, and theory/theories underpinning interventions. This was adapted from a previous realist review (Blane et al., 2020). The data extraction form is in Appendix L.

8.3.5 *Realist synthesis*

Interactions between contexts, mechanisms and outcome are the core component of realist synthesis; “context-mechanism-outcome” (CMO) configurations are the heuristic device at the heart of realist analysis (Jagosh et al., 2012). These explanatory accounts were extracted from the data extraction form and, if necessary, by return to the original paper. Explanatory accounts were expressed in the form of “if-then-because” statements that assume an “x-y because of z” relationship. That is, a given outcome “y” occurs because mechanism “z” is triggered when the contextual condition “x” is present (Wong et al., 2013b). “If-Then-Because” statements broadly represent the elements of Context, Outcome, and Mechanism, respectively (Pearson et al., 2015b).

Contexts were defined according to the ‘*four Is*’: the *individuals* who participate in the programme, the *interrelationships* between stakeholders, the *institutional* arrangement into which the programme is embedded, and the *infrastructure* which is the wider societal, economic and cultural setting of the programme (Pawson, 2018). I also defined and considered context as existing at the time of introduction of regionalisation (Lacouture et al., 2015). Factors that arose after implementation of regionalisation were not considered contextual.

Mechanisms were understood not as programme activities or components, but as the underlying processes that explain how participants respond to the resources introduced by an intervention, in this case regionalisation (Pawson and Tilley, 1997). Following Dalkin et al. (2015), mechanisms were conceptualised as operating through an interaction between resources (what the programme provides, enables or changes) and reasoning (how actors interpret and respond to those resources). Mechanisms are often hidden, sensitive to context and expressed through changes in thinking, decision-making, behaviours or social norms. They do not reside in programmes themselves but are triggered under particular contextual conditions. During this review, statements were only classified as mechanisms if they reflected this explanatory function, revealing *why* change occurred, rather than simply describing programme activities (implementation), contextual conditions, or observed outcomes. This approach

ensured that mechanisms were treated as generative causal forces, consistent with realist ontology.

In practice, mechanisms were identified through an iterative interpretive process during data extraction and synthesis. Particular attention was paid to language that revealed reasoning (e.g. beliefs, motivations, expectations, decision-making, trust, perceptions of risk or fairness) or access to new resources (e.g. information, authority, incentives, professional support, infrastructure) that shaped behaviour (Pawson and Tilley, 1997; Westthorp, 2018; Wong et al., 2013b). Statements indicating changes in stakeholder responses to the intervention, such as improved collaboration, defensive behaviours, or shifts in clinical autonomy, were examined as potential mechanisms, provided they reflected explanatory processes rather than observable outcomes alone. Candidate mechanisms were tested and refined through constant comparison across studies and linked back to the contexts that appeared to trigger or suppress them. This approach ensured that mechanisms were grounded in empirical data while remaining theoretically robust. Evaluation of mechanism was guided by parsimony, preferring models of mechanisms that either have the most empirical data or are the most testable (Williams, 2018).

As part of the analysis, attention was paid to both outcome footprints and outcome signatures related to patient-centred care during data synthesis. Outcome footprints refer to early or partial signs of change that suggest a programme is beginning to have an effect, even if final outcomes have not yet materialised. These helped to trace how impacts unfolded over time and to identify proximal outcomes within longer outcome chains. Outcome signatures, on the other hand, are recurring patterns of outcomes observed across different studies or cases. These align with Pawson and Tilley's (1997) concept of demi-regularities, whereby similar patterns of outcomes indicate that similar mechanisms may be triggered under comparable contextual conditions. Identifying these early traces of change and recurring outcome patterns helped to refine and strengthen the programme theories developed in this realist analysis. Recurrent themes within mechanisms were grouped to ascertain emerging patterns of CMOs. Iterative review of the emerging themes was

conducted as I became more familiar with the included documents. I then looked for data from across all included documents to confirm, dismiss, or refocus these CMO configurations. The CMO configurations supported the development and refinement of an initial program theory.

The final stage of a rapid realist review involves the presentation and testing of the initial programme theory with stakeholders (Saul et al., 2013). A meeting was organised, during which stakeholders were asked to review and evaluate the presentation of the programme theory which has been developed from the literature. The stakeholders were asked to identify issues in clarity of presentation of the theory and offer guidance on usefulness for policymakers. I then refined the theory and its presentation. It is through this iterative process of stakeholder review and refinement that theory is tested and validated in a realist review (Pawson, 2006, 2003; Pawson et al., 2005; Rycroft-Malone et al., 2012).

8.3.6 Note on terminology

As described in the introduction, regionalisation and decentralisation are similar terms. Standardised terminology has been used to facilitate ease of reading. In this review regionalisation is used to describe all forms of strengthening of the region including elements of decentralisation and centralisation. Regional Health organisation (RHO) is used to describe a regional Health authority, or body, or regional government with responsibility for healthcare, regardless of the name given in that particular jurisdiction.

8.3.7 Theoretical framework for the evidence synthesis

Rapid realist reviews can begin with the development of initial programme theories (IPTs), which provide provisional explanations of how, why, and under what circumstances an intervention is expected to work (Pawson and Tilley, 1997; Saul et al., 2013). Unlike fixed theories, IPTs in a rapid realist review are tentative starting points, often developed collaboratively with stakeholders or expert panels, and are iteratively refined as evidence is identified and analysed (Wong et al., 2013b). In this study, the initial theories were informed by a scoping of the literature on healthcare regionalisation. Two recurrent

theoretical perspectives were identified: fiscal federalism theory, which proposes that decentralising decision-making can improve efficiency and responsiveness by aligning resources with local needs (Oates, 1999), and transaction cost theory, which suggests that organisational restructuring is shaped by efforts to minimise coordination and governance costs (Williamson, 1979). In this study, the initial theories, fiscal federalism theory and transaction cost theory, helped identify potential mechanisms and contextual factors relevant to healthcare regionalisation. While these theories were not developed specifically with patient-centred care in mind, they provided a useful lens for anticipating how structural and economic factors could shape opportunities for patient-centred care, such as access, continuity, and coordination of care.

Fiscal federalism is a theory that examines the division of financial responsibilities and resources between different levels of government, typically central and regional or local governments, in a federal system. It focuses on how governments should allocate taxation powers, spending responsibilities, and financial transfers to achieve efficient and equitable outcomes. The theory suggests that the decentralisation of fiscal powers can enhance efficiency by tailoring public services to local needs, while also promoting accountability and responsiveness (Oates, 1999, 1972).

The transaction cost theory was first proposed by Coase in 1937 and expanded on by Williamson in the 1970s and 1980s (Coase, 1937; Williamson, 1981, 1979). The theory offers an economic explanation of why people choose to form ‘firms’ or organisations for purchases and outlines why there is a limit to how big a ‘firm’ can grow to before it is no longer the optimal unit for transactions (Coase, 1937). Transaction cost theory explores the costs incurred when making an economic exchange, beyond the price of the goods or services themselves. These costs include searching for information, negotiating contracts, monitoring and enforcing agreements, and dealing with potential uncertainties. The theory suggests that firms exist because they can reduce these transaction costs compared to the open market. In other words, firms may find it more cost-effective to organise certain activities internally rather than rely on external market transactions. However, firms cannot endlessly expand because, as firms

grow, their internal transaction costs, such as coordination, communication, and management, tend to increase. While initially, firms may reduce transaction costs by internalising activities that would be costly to conduct through the market, beyond a certain point, the costs of managing and overseeing a larger organization become significant. This is why firms often reach an optimal size or scope, where the cost of further expansion exceeds the benefits.

The theories are, by their nature, broad in their potential application. In their application to the effects of regionalisation on patient-centred care they eventually became mechanisms outlined in Table 8-5. Initially, these theories were used to inform the development of CMO configurations by helping to identify potential mechanisms and contextual factors that influence the outcomes of interest. We systematically reviewed identified literature to identify instances where these theories were applied, considering how context (e.g., socioeconomic status, budgetary constraints) influenced the mechanisms and ultimately the outcomes i.e. patient-centred care). This theoretical integration provided a structured approach to understanding the complex interactions between context, mechanisms, and outcomes in the healthcare interventions under review (Pawson et al., 2005). The data also revealed additional mechanisms and CMO patterns that were not directly predicted by these theories, reflecting other influences on patient-centred care. In this way, the IPTs provided a conceptual scaffold, but the iterative synthesis allowed the review to incorporate emergent, data-driven CMOs, ensuring that programme theories were both grounded in the literature and responsive to the complexity of the interventions under study.

8.4 Results

8.4.1 Results of the search

A search was run on 20 September 2023. A PRISMA flow chart is in Appendix M. Nineteen studies were included in this review.

8.4.2 Descriptive analysis

The characteristics of the included studies are given in Table 8-2. Study designs are summarised in this table, while full details of the study design as provided by

the authors are given in Table A 4 in Appendix N. The studies were set in Canada, Spain, Italy, Sweden and one was conducted across twenty European countries. Data were collected for the studies between 1990 and 2017. The setting of the studies was mixed. Most studies used a historical control.

Participant characteristics are presented in Table A 5 in Appendix N. The number of participants ranged from 35 to 130,880. Baseline characteristics such as average age of participants, proportion female, ethnicity and socio-economic status were poorly reported. Where these data were missing, it was often because the study authors had obtained summary level data from a survey for analysis, with full details of the survey published elsewhere.

Table 8-3 summarises the findings by outcome from the 19 included studies. The six outcome categories are 1) access, 2) equity/equality, 3) citizens' perceptions and health system satisfaction, 4) coordination and continuity of care, 5) empowerment, and 6) healthcare quality indicators. Access and equity/equality outcomes were most commonly reported. Individual outcomes were measured in many different ways in the studies and outcome categories were assigned to studies by the researcher. These outcome categories map onto several of the nine dimensions of patient-centred care defined by Sturgiss et al. (2022) particularly access, continuity and coordination of care, empowerment, and aspects of sharing power and viewing the patient as a person. Equity/equality outcomes also reflect the Sturgiss dimension of addressing biopsychosocial factors, insofar as they capture how social determinants and structural conditions shape patients' ability to engage with and benefit from care. The predominance of outcomes aligned with these dimensions reflects how the Sturgiss framework informed both the search strategy and the eligibility criteria used in this chapter.

Table 8-2 Study characteristics

Study identifier (reference)	Study design	Country study set in	Year(s) study conducted	Setting of care	Details of control conditions (if appropriate)
Anton 2014	Cross-sectional survey	Spain	1996-2009	Primary and hospital care	Historical control, pre-regionalisation
Bergevin 2016	Qualitative interview supported by literature review	Canada	2015	NR	No control
Cloutier-Fisher 2006	Quantitative based on administrative data	British Columbia, Canada	1990-2000	Secondary and primary care	Historical control, pre-regionalisation
Costa-Font 2005	Quantitative analysis of survey data	Spain	1997	NR	Comparison to Insalud regions (centralised)
Costa-Font 2009	Quantitative analysis of before and after data	Spain	2001	NR	Regionalised vs centralised
Costa-Font 2018	Quantitative analysis of before and after data	Spain, Italy	1998 to 2009	NR	Before and after regionalisation, and other country

Study identifier (reference)	Study design	Country study set in	Year(s) study conducted	Setting of care	Details of control conditions (if appropriate)
Curtis 2005	Retrospective chart audit and survey	Newfoundland and Labrador, Canada	1995-96, 1998-99, 2000-01	Secondary and tertiary care sites	Pre and post regionalisation
Fooks 2015	Listed as a commentary but takes form of literature review	Ontario, Canada	2005-2006 and 2014 for extracted data	NR	Pre-regionalisation
Fredriksson 2008	Quantitative case study	Sweden	2006	Secondary care	No control
Gregory 2005	Quantitative survey	Newfoundland and Labrador, Canada	2000, 2002	Acute care	During and after restructuring
Hanlon 2003	Quantitative analysis of administrative data	Nova Scotia, Canada	1992-93 to 1999-00	Secondary care	Before and after regionalisation
Jimenez-Rubio 2008	Quantitative analysis of survey data	Canada	2001	Primary, secondary and tertiary care	Different types of regionalisation
Jovell 2007	Quantitative survey	Spain	2005, 2006	NR	Historical control

Study identifier (reference)	Study design	Country study set in	Year(s) study conducted	Setting of care	Details of control conditions (if appropriate)
Landi 2020	Quantitative analysis of survey data	Italy	2013	Secondary care	No control
Martinussen 2021	Quantitative secondary analysis	20 European countries	2014, 2016	Public health, secondary/tertiary care, primary care	Comparisons to other countries with different levels of regionalisation
Neville 2005	Qualitative	Newfoundland and Labrador, Canada	2002	NR	No control
Rotulo 2022	Quantitative analysis	Italy	2001-2017	Primary and secondary care	First year of fiscal regionalisation
Toth 2014	Quantitative analysis survey data	Italy	1999-2009	NR	Historical control
Zhong 2010	Before and after study	Canada	1994-1995, 1998-1999, and 2000-2001	General practitioner (GP), medical specialist, and hospital services	Pre Canadian Health and Social Transfer and post

Key: NR – not reported

Table 8-3 Descriptive summary of results by patient-centred care outcome categories

Study	Country study set in	Summary of findings	Impact on patient-centred care
Access			
Anton 2014	Spain	For primary and specialised healthcare, regionalisation had a significant negative effect (which increased over time) on the care and assistance received from medical staff, the ease of getting appointments, and the waiting times for patients before being seen by their physicians at health centres.	Negative
Anton 2014	Spain	Regionalisation had no effect on waiting times for non-urgent hospital admissions or on the information provided to patients about their health issues.	No effect/association
Bergevin 2016	Manitoba and PEI, Canada	Integration through regionalisation improved access to mental health, long term and home care	Positive
Bergevin 2016	All provinces, Canada	Regionalisation improved access to specialised care in rural areas of provinces	Positive
Bergevin 2016	All provinces, Canada	There was little focus on client-centered care and the importance of the local level and proximity services in the context of regionalisation.	No effect/association
Cloutier-Fisher 2006	British Columbia, Canada	The difference between rural and urban areas in terms of avoidable hospitalisations persisted following regionalisation	No effect/association
Curtis 2005	Newfoundland and Labrador, Canada	Median wait time increased for all diagnostic tests after regionalisation.	Negative
Curtis 2005	Newfoundland and Labrador, Canada	Overall waiting time to see a specialist and then receive treatment increased after regionalisation.	Negative
Fooks 2015	Ontario, Canada	In 2005, the year before regionalisation, 91.1% of Ontarians reported having a regular medical doctor. In 2014 93.6% of Ontarians had a primary care provider (post-regionalisation).	Positive
Fooks 2015	Ontario, Canada	In 2005, the year before regionalisation was introduced, people in the longest waiting group waited over 350 days for hip replacements and 440 days for knee replacements. By 2014, most	Positive

Study	Country study set in	Summary of findings	Impact on patient-centred care
		hip and knee replacements were completed much faster, with 86% of hip surgeries and 83% of knee surgeries done within the recommended wait time of 182 days.	
Hanlon 2003	Nova Scotia, Canada	RHOs with more secondary-level healthcare services, usually in urban areas, had lower rates of unnecessary travel for residents. This trend continued after regionalisation.	No effect/association
Jovell 2007	Spain	In 2005, after Spain fully regionalised its healthcare system, fewer people believed the system needed to be completely rebuilt compared to 1991, when much of healthcare was still centrally controlled. However, many Spaniards still felt that important changes were needed..	Positive
Jovell 2007	Spain	There was a statistically significant increase in satisfaction with medical and health services after full regionalisation, with 79% of people satisfied in 2005 compared to 71% in 1991. People over 65 were more likely to be very satisfied (50%), while those aged 18 to 34 were less likely (22%). Satisfaction levels were similar across income groups and regions, indicating a high level of equity in the healthcare system.	Positive
Jovell 2007	Spain	There was small but statistically significant decrease in public dissatisfaction with health services, from 28% in 1991 to 19% in 2005 when full regionalisation was in place.	Positive
Landi 2020	Italy	Inequalities in waiting times for healthcare exist both between and within regions in Italy. People living in central or southern Italy are more likely to experience long waits compared to those in the north. The regional healthcare system plays a role in these differences, but an individual's socioeconomic status also affects their waiting time, even within the same region.	Negative
Neville 2005	Newfoundland and Labrador, Canada	Fewer than 20% of participants felt that RHOs had enough resources to attract and keep specialist staff, build expertise, offer new programs, and improve access to care.	Positive
Rotulo 2022	Italy	The results show that as regionalisation increases, the number of hospital patients within a region decreases by 0.29%, with more patients seeking treatment in other regions. This finding is statistically significant at the 1% level.	Negative
Rotulo 2022	Italy	Regionalisation decreased availability of staff and hospital beds suggesting increased disparities in access to healthcare post-regionalisation	Negative

Study	Country study set in	Summary of findings	Impact on patient-centred care
Rotulo 2022	Italy	Regionalisation decreased utilisation of care, measured by hospitalisation rates suggesting increased disparities in access to healthcare post-regionalisation	Negative
Citizens' perceptions and health system satisfaction			
Anton 2014	Spain	Regionalisation had no effect on citizens' opinions about the medical equipment and technology in primary and specialised healthcare.	No effect/association
Anton 2014	Spain	Citizens' perception of confidence transmitted by doctors decreased the first years after regionalisation	Negative
Anton 2014	Spain	Hospital care and assistance received from doctors, and administrative procedures to be admitted to a hospital, were negatively affected by regionalisation but this result was not statistically significant	Mixed or undetermined
Anton 2014	Spain	Regionalisation had a negative impact on the number of people sharing a hospital room, with this effect becoming more pronounced over time	Negative
Gregory 2005	Newfoundland and Labrador, Canada	After the restructuring, satisfaction levels were significantly lower in regions outside the capital, St. John's ($P < 0.001$). In 2002, after the move to RHOs was completed in 2001, satisfaction ratings for all scale items generally decreased, with 50-70% of ratings shifting from "very satisfied" to "satisfied."	Negative
Martinussen 2021	20 European countries	Regionalised healthcare provision was associated with increased health system satisfaction, with a 0.4-point increase overall. Regionalisation of secondary or tertiary healthcare led to a 0.3-point increase in satisfaction. Higher levels of overall healthcare regionalisation were linked to a 1.3-point increase for intermediate-level of regionalisation and a 1.1-point increase for high-level of regionalisation. Additionally, in sensitivity analyses, regionalised healthcare implementation, public healthcare, and primary healthcare were significantly associated with healthcare satisfaction.	Positive
Martinussen 2021	20 European countries	There was no significant association between regionalisation and self-rated health.	No effect/association

Study	Country study set in	Summary of findings	Impact on patient-centred care
Coordination and continuity of care			
Bergevin 2016	Alberta, Canada	Regionalised structures led to improved integration and continuity of care and reduced inter-facility competition	Positive
Bergevin 2016	Saskatchewan, Quebec, Newfoundland & Labrador, Canada	Integration through regionalisation improved coordination of care	Positive
Bergevin 2016	Quebec, Canada	Integration through regionalisation led to the integration of social services with health, which improved co-ordination of care	Positive
Bergevin 2016	Quebec, Canada	Integration through regionalisation led to a wider set of services and approaches to deal with problems, thus leading to more effective solutions	Positive
Bergevin 2016	Saskatchewan, Canada	Regionalisation fostered partnerships with local ambulance providers and homeless shelters to improve access of homeless populations to mental health and addiction services	Positive
Bergevin 2016	Alberta, Manitoba, Canada	Regionalisation led to improvements in access to and the coordination of healthcare services	Positive
Bergevin 2016	All provinces, Canada	Regionalisation led to the consolidation of services, a reduction in the fragmentation of care, vertical and horizontal integration of services, all of which improved continuity of care for patients	Positive
Neville 2005	Newfoundland and Labrador, Canada	The integration of services through regionalisation did not achieve the expected continuity of care for individuals or families because most primary care and medications were not included in the RHO's responsibilities.	No effect/association
Empowerment			
Fredriksson 2008	Sweden	Support for patient choice of caregiver varies widely depending on the RHO in Sweden, meaning the ability to choose a secondary care provider differs across regions. As a result, the Patient Choice Recommendation is not implemented equally nationwide. Support for patient	Mixed or undetermined

Study	Country study set in	Summary of findings	Impact on patient-centred care
		choice was shown to decrease as you move north, with support ranging from 0.2 to 0.96 on a scale of 0 to 1.	
Fredriksson 2008	Sweden	RHOs with stronger economies were more likely to support patient choice of care provider.	Mixed or undetermined
Fredriksson 2008	Sweden	RHOs governed by right-wing parties tended to support patient choice of care provider more, as right-wing parties traditionally favour freedom of choice in welfare policies. This suggests that the governing party's ideology influences attitudes and decisions about patient choice.	Mixed or undetermined
Equity/equality			
Costa-Font 2005	Spain	Although there are small inter-regional inequalities in self-perceived health status, do not appear to be due to the regionalisation of healthcare. The study used the concentration index to measure socioeconomic inequality in health perception and found no consistent difference in health equality between regionalised and centrally controlled regions.	No effect/association
Costa-Font 2009	Spain	There were no consistent inequalities in healthcare use in regionalised areas, based on the likelihood of visiting a physician.	No effect/association
Costa-Font 2009	Spain	Regions with healthcare responsibilities (regionalised) did not exhibit higher inequalities in self-reported health status than those with centralised healthcare responsibilities.	No effect/association
Costa-Font 2009	Spain	Regionalised areas generally showed better equity, but no significance test performed	Positive
Costa-Font 2018	Spain, Italy	In Spain, regionalisation decreased inequality in health system satisfaction, despite increasing - at least in the short-term - differences in spending.	Positive
Costa-Font 2018	Spain, Italy	In Italy, inequality in health spending decreased significantly after regionalisation (t-test significant at the 1% level), but inequality in health system satisfaction did not change significantly	No effect/association
Costa-Font 2018	Spain, Italy	After regionalisation, Italian regions became more diverse in terms of needs post-regionalisation, but this was not strongly reflected in the differences in spending per capita.	Negative
Costa-Font 2018	Spain, Italy	Inequality in need decreased in Spain after regionalisation	Positive

Study	Country study set in	Summary of findings	Impact on patient-centred care
Jimenez-Rubio 2008	All provinces, Canada	There is no evidence that regionalisation has an impact equity in health. The study found that inequities in access to GP visits, hospital stays, and specialist care are mainly due to differences between provinces. This suggests that the federal government's redistributive efforts in Canada may not be enough to achieve key equity goals.	Negative
Jimenez-Rubio 2008	All provinces, Canada	The decomposition analysis of income-related health (self-reported health) inequality in Canada showed that the pro-rich distribution of self-reported health is mainly due to health differences between high and low-income individuals within provinces, rather than health gaps between provinces with unequal average incomes.	Positive
Toth 2014	Italy	From 1999 to 2009, more residents from southern Italy sought medical treatment in the north compared to the opposite flow. However, there was significant variation between regions, with some northern regions struggling to treat their own residents, while some southern regions showed improvement.	Negative
Toth 2014	Italy	Post-reform, levels of dissatisfaction with the health service decreased in the north of Italy (higher per capita income), whereas they increased in the south of Italy (lower per capita income). The gap between the regions has widened suggesting increased inequity	Negative
Zhong 2010	All provinces, Canada	The introduction of the Canada Health and Social Transfer in 1996/1997 may have an impact on within province distribution of health care utilization. Increased regionalisation was linked to lower income-related inequalities in the use of GP and hospital services both within provinces and between provinces.	Positive
Zhong 2010	All provinces, Canada	Inequality (income-related) in health status was small and mainly driven by variations within provinces. The overall, within-province, and between-province inequalities (income-related) all increased over time.	Negative

Key: HCP – health care provider, RHO – regional health organisation

8.4.3 Realist synthesis

In this realist synthesis results are presented by outcome category. The rationale, or context, for introducing regionalisation varied across settings and may influence how regionalisation unfolds and with what effects. Table 8-4 summarises the 12 contextual factors identified in the realist review. These are grouped into (1) factors common across most forms of administrative healthcare regionalisation and (2) additional factors relevant when regions have greater fiscal autonomy, including the ability to raise their own revenue or capital. Contextual factors often appeared in several papers as indicated in the description column of Table 8-4. The description of the context was developed by the researcher based on data extracted from included studies. Healthcare regionalisation can take different institutional forms—for example, through the creation of regional health organisations within a national system or as part of broader political decentralisation where regions have authority over multiple sectors, including taxation. The latter form can introduce additional contextual dynamics (e.g. inter-regional financial imbalance), which are reflected in the second grouping of contextual factors in Table 8-4.

Table 8-4 Contexts influencing the regionalisation process and outcomes

Context	Description
Contexts common to all forms of regionalisation	
Service delivery is centralised in urban hubs within some regionalised arrangements	Regionalisation can involve consolidating services like hospitals in urban areas, leading to the closure of smaller community hospitals. This process often moves authority from local to regional levels and results in infrastructure and organizational changes primarily concentrated in urban areas (Bergevin et al., 2016; Cloutier-Fisher et al., 2006; Gregory et al., 2005; Hanlon, 2003).
Regionalisation is introduced in the context of ongoing fiscal restraints	Several countries and provinces introduced regionalisation in the context of budget cutbacks in the hope that regionalisation would lead to reductions in spending or more balanced budgets (Fredriksson and Winblad, 2008; Jiménez-Rubio et al., 2008; Neville et al., 2005; Zhong, 2010).

Context	Description
Following regionalisation, RHOs face reduced allocations from central government	Regions depend on central funding for services, and with funding cutbacks, they still have the flexibility to shape health policy within these constraints (Jiménez-Rubio et al., 2008; Zhong, 2010).
Regionalisation where some services outside remit of RHOs	In some countries or provinces funding for some healthcare providers and services such long-term care and general practitioners is outside of the control of the RHO (Curtis et al., 2005; Neville et al., 2005).
Regionalisation provides a context that supports policy innovation and diffusion	RHOs may be set up in a way that encourages them to innovate and try to work in new ways (Antón et al., 2014; Costa-Font and Turati, 2018).
Regionalisation brings decision-making, and relevant information closer to the point of care, and closer to patients, citizens and communities	Regionalisation brings decision-making closer to patients and communities, improving local decision-makers' understanding of local conditions and enabling quicker, more effective responses to local needs (Bergevin et al., 2016; Martinussen and Rydland, 2021).
Through regionalisation, central government allocates healthcare funding with minimum healthcare requirements	In some countries regions are only required to provide the most basic healthcare to receive central funding, allowing RHOs a lot of freedom to determine how they spend money received (Antón et al., 2014; Bergevin et al., 2016; Costa-i-Font, 2005; Zhong, 2010).
In some cases there is a high use of private health insurance before regionalisation	In some cases there is a high use of private health insurance before regionalisation (Costa-i-Font, 2005).
Regionalised health system promotes integration of a comprehensive array services	Regionalised health system promotes integration of a comprehensive array services (Bergevin et al., 2016).
RHO serves a population size that is above or below its operational capacity	Studies have suggested that an RHO population size of between 350,000 and 500,000 could be optimal (Antón et al., 2014; Bergevin et al., 2016).
There are socioeconomic disparities in access before regionalisation	People in lower-income communities may have limited access to quality healthcare services (Landi et al., 2021)
Ability of patients to access care across regions	Patients can travel to another region including those with more healthcare resources (Hanlon, 2003; Rotulo et al., 2021).
Contexts specific to regions with revenue-raising powers (fiscal component)	
Government uses equalisation grants which compensate RHOs for differences in per capita spend on health guaranteeing	In countries with devolved fiscal responsibility, in which regional government have the ability to set and raise taxes, national governments use centrally set equalization grants which compensate some regions for differences in initial disposable resources fiscal capacity

Context	Description
roughly the same resources per capita to all regions	(Costa-Font and Gil, 2009; Costa-Font and Turati, 2018; Toth, 2014).
Regionalisation means that regions can rely on a blend of their own resources and central government funding	Regionalisation means that regions can rely on a blend of their own resources and central government funding (Toth, 2014).

Key: HCP – health care provider, RHO – regional health organisation

Numerous mechanisms were identified as causal processes generating outcomes when active within the various contexts described in Table 8-4. These mechanisms are described in Table 8-5. Similar individual mechanisms were grouped into seven overarching mechanisms. This attempt to distil the data into a more manageable number of mechanisms, which may be transferable across different settings, resonates with previous realist research (Pawson, 2006; Pawson et al., 2011). For ease of reference, and following the examples of previous realist reviews, each mechanism has been given a title that encapsulates how the mechanism works (Blane et al., 2020; Westthorp et al., 2014). These overarching mechanisms are used in the context-mechanism-outcome configurations described below, and in the overall programme theory.

Table 8-5 Description of mechanisms

Overarching mechanism title	Individual mechanisms grouped under overarching mechanism	Description
M1: Perceived threat to local service access triggers resistance among rural stakeholders	- Rural hospitals increase/prolong hospitalisation to improve viability - Rural areas do not buy-in to the perceived benefits of regionalisation - A loss of voice in decision-making	When rural stakeholders perceive that regionalisation threatens local service access, they interpret the change as unfair and respond by mobilising resistance to protect community services.
M2: Alignment of population size with capacity enables efficient planning and coordination	- Unsustainable population size triggers decisions to centralise or outsource services, causing fragmented care pathways - Programmes can be run effectively and efficiently in	This overarching mechanism aligns with the transaction cost theory. It suggests that there is an optimal size for a region to function if it is too big or too small there will be a knock-on effect on people.

Overarching mechanism title	Individual mechanisms grouped under overarching mechanism	Description
	an RHO with an optimal population size	
M3: Competitive rivalry between regions to gain patients	- Hospitals target out of region patients to maximise reimbursement rates from the region of origin. - Greater pressure on RHO resources leads to longer delays in admitting patients for secondary care. - Regions devise new programmes that are subsequently adopted in other regions. - Citizens will compare their own region to others which have the service they would like - Patient use of care outside their home RHO can increase costs due to duplication and cross-boundary billing	Regions compete with each other to attract patients from external regions which can lead to innovation, but also unintended consequences such as additional costs for home RHOs.
M4: Wealthier regions have money to invest in health systems over and above basic care	- Poorer regions may rely on hospital services for medical conditions that are treated in primary care in wealthier regions - Individual socioeconomic status and the regional health system of belonging are strong predictors of inequality - Poorer regions do not have the same ability to spend money on healthcare - Poorer regions do not have additional funds for large scale improvements	Before regionalisation, regions have differences in quality of services and ability to fund large scale improvements. Differences in wealth of regions are not counteracted by healthcare regionalisation. Wealthier regions can spend on services, the poor regions cannot afford.
M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway	- There is a lack of co-ordination and cooperation - Regions did not have the power to force integration - Vertical and horizontal integration of services leads to consolidation of services - The mobilisation of the whole system during a crisis through integration	Full integration of HCPs, such as primary care/general practitioners, under the control of a RHO leads to opportunities for cohesion and cooperation across the whole health system.

Overarching mechanism title	Individual mechanisms grouped under overarching mechanism	Description
M6: Responsiveness to local needs and preferences	- Needs of locals can be gauged and responded to - There will be a way to consistently gather the evidence that should inform local decision making - Redistribution according to local circumstances and preferences - Regulation limits the expansion of diversity of outputs - Regional policy is more responsive to regional specificities, which include differences in values and preferences - Easier to adapt health services to the preferences of the citizens at a regional level - There is a channel for feedback about local preferences	This overarching mechanism links to the theory of fiscal federalism. The theory suggests that the decentralisation of fiscal powers can enhance efficiency by tailoring public services to local needs, while also promoting accountability and responsiveness.
M7: RHOs must balance budgets	- RHOs maybe have to cut services to stay within lower budgets - Short-term budget constraints lead to more outsourcing and more participation of private health care producers - When efficiency measure are applied those with private health insurance are not affected - There are limited resources to introduce new programmes	RHOs rely on grants from central government to cover all their outcomes. Services must be provided within the budget provided. Those who are more fiscally independent might not be as badly affected, but depends on their wealth.

Key: HCP – health care provider, RHO – regional health organisation

Context-mechanism-outcome configurations (CMOCs) are detailed in Table 8-6 to Table 8-11. In these tables a particular context or mechanism can appear multiple times as particular contexts can affect multiple different outcomes and trigger different mechanisms. In creating CMOCs, a common approach in realist research is to start with the outcomes of interest and ‘work backwards’ to discern potential mechanisms and contextual factors that affect those mechanisms (Byng et al.,

2005; Jackson and Kolla, 2012; Pearson et al., 2015b). This approach was taken here, and CMOCs are split into outcome by table. The mechanisms have been presented here as ‘resources’ plus ‘reasoning’, in keeping with traditional realist methods, (Dalkin et al., 2015; Pawson, 2006) with a separate column for contexts (generally enabling but occasionally constraining). The analysis was also organised by outcome as policymakers will be familiar with this layout, as it is similar to a standard systematic review and therefore may better facilitate ease of understanding. It is important to note that CMOCs may describe both positive and negative outcomes, depending on how mechanisms are triggered within particular contexts. For example, a mechanism that promotes coordination of care in one context may lead to improved patient satisfaction, whereas the same mechanism may fail or produce unintended consequences in a different context, such as when key providers are excluded from the care pathway. By capturing these variations, CMOCs provide a nuanced understanding of how and why interventions succeed or fail, which is central to realist evaluation.

8.4.3.1 Access

CMOCs related to access are outlined in Table 8-6. Seven contexts were seen to trigger mechanisms which affected the outcome of access. Regionalisation results in service consolidation in urban areas, causing an urban rural divide and competition between both areas. As a result, rural areas might try to ensure viability of rural hospitals through increased avoidable hospitalisations (Cloutier-Fisher et al., 2006). Rural patients might have to travel further for care as it will be more efficient for the RHOs to treat patients at a larger centre (Hanlon, 2003).

RHOs function better when they serve their optimal population size. If RHOs serve a population size that is too small, services can be fragmented, with some services not available. This has led to situations in which patients ‘fall through the cracks’, and have poor access to care (Bergevin et al., 2016).

In some locations, patients can travel to another region including those with more healthcare resources. This can trigger competitive rivalry between regions to gain patients. People will travel to obtain care, which can be beneficial for the RHOs

where the patient travels to, but is likely more costly for the RHO the patient has travelled from (Hanlon, 2003). However, it will mean inter-regional inequities persist or are exaggerated in regions with poor resources (Rotulo et al., 2021).

In the context of a cut to budget being allocated from central government after regionalisation is introduced, wealthier regions will likely fare better. Wealthier regions have money to invest in health systems over and above basic care, whereas poorer regions may rely on hospital services for medical conditions that are treated in primary care in wealthier regions (Jiménez-Rubio et al., 2008). Poorer RHOs maybe have to cut services to stay within lower annual budgets which could lead to a drop in GP and specialist visits, and hospital stays (Zhong, 2010).

In some cases, certain healthcare providers (HCPs) and services fall outside the remit of RHOs, and the lack of a cooperation mechanism among all HCPs and services results in delayed discharges, preventing improvements in access to secondary care services (Curtis et al., 2005).

Socioeconomic disparities in access to healthcare existed prior to regionalisation, with wealthier regions able to invest beyond basic care, while poorer RHOs lacked such resources (Landi et al., 2021). As a result, regional inequalities in access to healthcare persist after regionalisation.

Table 8-6 CMOCs related to access

Context	Mechanism	Outcome
Service delivery is centralised in urban hubs within some regionalised arrangements	M1: Perceived threat to local service access triggers resistance among rural stakeholders M2: Alignment of population size with capacity enables efficient planning and coordination	Avoidable hospitalisation in rural areas remains high compared to urban areas (Cloutier-Fisher et al., 2006) Rural patients have to travel further for care (Hanlon, 2003)
RHO serves a population size that is above or below its operational capacity	M2: Alignment of population size with capacity enables	Some people will have poor access to care in small RHOs (Bergevin et al., 2016)

Context	Mechanism	Outcome
	efficient planning and coordination	
Ability of patients to access care across regions	M3: Competitive rivalry between regions to gain patients	Inter-regional inequities persist or are exaggerated in regions with poor resources (Rotulo et al., 2021) Greater numbers will seek alternative locations to obtain care, which can be beneficial for the RHOs were the patient travels to, but is likely more costly for the RHO the patient has travelled from (Hanlon, 2003)
Following regionalisation, RHOs face reduced allocations from central government	M7: RHOs must balance budgets	Inequity in access to preventative/primary care (Jiménez-Rubio et al., 2008) Drop in GP and specialist visits, and hospital stays. (Zhong, 2010)
Regionalisation where some services are outside the remit of RHOs	M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway	Delayed discharges and consequently no improvement in access to secondary care services (Curtis et al., 2005)
There are socioeconomic disparities in access before regionalisation	M4: Wealthier regions have money to invest in health systems over and above basic care	Inequalities in access by region persist after regionalisation (Landi et al., 2021)

8.4.3.2 Citizens' perceptions and health system satisfaction

CMOCs related to citizens' perceptions and health system satisfaction are reported in Table 8-7. Regionalisation can allow regions to have more freedom to organize health care, as only minimum healthcare requirements are stipulated. This can trigger three separate mechanisms. Competitive rivalry between regions means citizens will compare their own region to others which have the service they would like, and this can lead to patient dissatisfaction (Antón et al., 2014). Wealthier

regions have money to invest in health systems over and above basic care but in cash strapped RHOs budget constraints lead to more outsourcing and more participation of private health care providers, which can be negatively perceived by citizens (Antón et al., 2014). Specifying minimum requirements for services means it is easier to adapt health services to the preferences of the citizens at a regional level, this could mean patients may be more satisfied in all regions (Antón et al., 2014).

Regions function better when they serve an optimal population size, small RHOs cannot offer every kind of treatment and health service, and so patients may leave to be treated in another RHO (Antón et al., 2014). Regionalisation also results in the consolidation of services in urban areas, leading rural populations to perceive a lack of improvements and experience lower satisfaction with care (Gregory et al., 2005).

Historically regionalisation has been introduced in the context of ongoing fiscal restraints, for example in many provinces in Canada. RHOs are required to stay within their annual budget allocation. This often does not allow for the increase in capital necessary to increase preventative care (Neville et al., 2005).

Regionalisation brings decision-making, and relevant information closer to the point of care, and closer to patients, citizens and communities, which allows RHOs to be responsive to local needs and preferences, meaning preferences of local people are met (Martinussen and Rydland, 2021).

Table 8-7 CMOCs related to citizens' perceptions and health system satisfaction

Context	Mechanism	Outcome
Through regionalisation, central government allocates healthcare funding with minimum healthcare requirements	M3: Competitive rivalry between regions to gain patients M4: Wealthier regions have money to invest in health systems over and above basic care M6: Responsiveness to local needs and preferences	Patients will be dissatisfied (Antón et al., 2014) Perceived negatively by citizens (Antón et al., 2014) Patients will be satisfied in all regions (Antón et al., 2014)
RHO serves a population size that is above or below its operational capacity	M2: Alignment of population size with capacity enables efficient planning and coordination	Patients may leave to be treated in other regions (Antón et al., 2014)
Service delivery is centralised in urban hubs within some regionalised arrangements	M1: Perceived threat to local service access triggers resistance among rural stakeholders	Rural patients will be less satisfied with care (Gregory et al., 2005)
Regionalisation is introduced in the context of ongoing fiscal restraints	M7: RHOs must balance budgets	No increase in preventative care (Neville et al., 2005)
Regionalisation brings decision-making, and relevant information closer to the point of care, and closer to patients, citizens and communities	M6: Responsiveness to local needs and preferences	Preferences of local people are met (Martinussen and Rydland, 2021)

8.4.3.3 Coordination and continuity of care

CMOCs related to coordination and continuity of care are reported in Table 8-8. Ongoing fiscal constraint can have an impact on coordination and continuity of care. RHOs must balance budgets, which means they may not have funds to create a seamless system of care (Neville et al., 2005). Regionalised health systems can promote integration of a comprehensive array of services, which facilitates cooperation of all HCPs and services who are part of the same RHO, leading to a reduction in the fragmentation of care (Bergevin et al., 2016). However, in some countries some HCPs and services remain outside the control of RHOs, for example

primary care. This hampers cooperation in the healthcare system and the desired level of continuity of care for the individual/family will not be reached (Neville et al., 2005).

Table 8-8 CMOCs related to coordination and continuity of care

Context	Mechanism	Outcome
Regionalisation is introduced in the context of ongoing fiscal restraints	M7: RHOs must balance budgets	Cannot create a seamless system of integration of services/continuity of care for the individual/family (Neville et al., 2005)
Regionalisation where some services are outside the remit of RHOs	M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway	The desired level of continuity of care for the individual/family will not be reached (Neville et al., 2005)
Regionalised health system promotes integration of a comprehensive array services	M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway	Reduction in the fragmentation of care (Bergevin et al., 2016)

8.4.3.4 Empowerment

CMOCs related to empowerment are reported in Table 8-9. Regionalisation involves the consolidation of some local services, which mostly affects rural and small communities. As a result, these communities may feel a decline in the empowerment of citizens, as they are no longer involved in local community governance. For example in some Canadian provinces, a loss of citizen engagement in governance and of a local sense of ownership of the healthcare system were attributed to the centralisation of authority from the local to the regional level and the dissolution of local institutional boards (Bergevin et al., 2016). In contrast regionalisation can also bring decision-making, and relevant information closer to the point of care, and closer to patients, citizens and communities. This means that RHOs can be responsiveness to local needs and preferences, and services better meet local needs. This is evident when responsibility is decentralised from

central government to RHOs (Bergevin et al., 2016). If regionalisation is introduced in the context of ongoing fiscal restraints, citizens in poorer regions might be more limited in choice of care provider as the RHOs do not have money to invest over and above basic care (Fredriksson and Winblad, 2008).

Table 8-9 CMOCs related to empowerment

Context	Mechanism	Outcome
Service delivery is centralised in urban hubs within some regionalised arrangements	M1: Perceived threat to local service access triggers resistance among rural stakeholders	Decline in the empowerment of citizens and a local sense of ownership of the system (Bergevin et al., 2016)
Regionalisation brings decision-making, and relevant information closer to the point of care, and closer to patients, citizens and communities	M6: Responsiveness to local needs and preferences	Services better meet local needs (Bergevin et al., 2016)
Regionalisation is introduced in the context of ongoing fiscal restraints	M4: Wealthier regions have money to invest in health systems over and above basic care	Patients in poorer regions will have less patient choice in care provider (Fredriksson and Winblad, 2008)

8.4.3.5 Healthcare quality indicators

CMOCs related to healthcare quality indicators are reported in Table 8-10.

Regionalised health systems promote integration of a comprehensive array of services, which aids in the cooperation of all HCPs and services who are part of the same RHO. This leads to better responses and outcomes in a healthcare crisis (Bergevin et al., 2016). When an RHO is set up to serve an optimal population size, regions function better and are more responsive to local needs and preferences leading to better health outcomes (Bergevin et al., 2016). In systems with wider regionalisation including a fiscal component, regions can rely on a blend of their own resources and central government funding. In these circumstances wealthier regions have money to invest in health systems over and above basic care, whereas poorer regions do not. This can mean poorer regions may have worse healthcare outcomes (Toth, 2014).

Table 8-10 CMOCs related to healthcare quality indicators

Context	Mechanism	Outcome
Regionalised health system promotes integration of a comprehensive array of services	M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway	Better responses and outcomes in a healthcare crisis (Bergevin et al., 2016)
RHO serves a population size that is above or below its operational capacity	M2: Alignment of population size with capacity enables efficient planning and coordination M6: Responsiveness to local needs and preferences	There will be better health outcomes (Bergevin et al., 2016)
Regionalisation means that regions can rely on a blend of their own resources and central government funding	M4: Wealthier regions have money to invest in health systems over and above basic care	Poorer regions may have worse healthcare outcomes (Toth, 2014)

8.4.3.6 Equity/equality

CMOCs related to equity and equality are reported in Table 8-11. Through regionalisation, central government allocates healthcare funding with minimum healthcare requirements, this enables RHOs to be responsive to local needs and preferences reducing income-related inequity in their RHO (Zhong, 2010).

In many regionalised healthcare systems governments use equalisation grants which compensate RHOs for differences in per capita spend on health guaranteeing roughly the same resources per capita to all regions. This can mean that regions are responsive to local needs and therefore there can be a reduction of avoidable health inequalities (Costa-Font and Gil, 2009; Costa-Font and Turati, 2018). However, even with equalisation grants, wealthier regions have money to invest in health systems over and above basic care, this means that the gap between poor and rich regions will persist after regionalisation (Toth, 2014).

Regionalisation exerts incentives for policy innovation and diffusion, leading to competitive rivalry between regions to gain patients which can help to limit

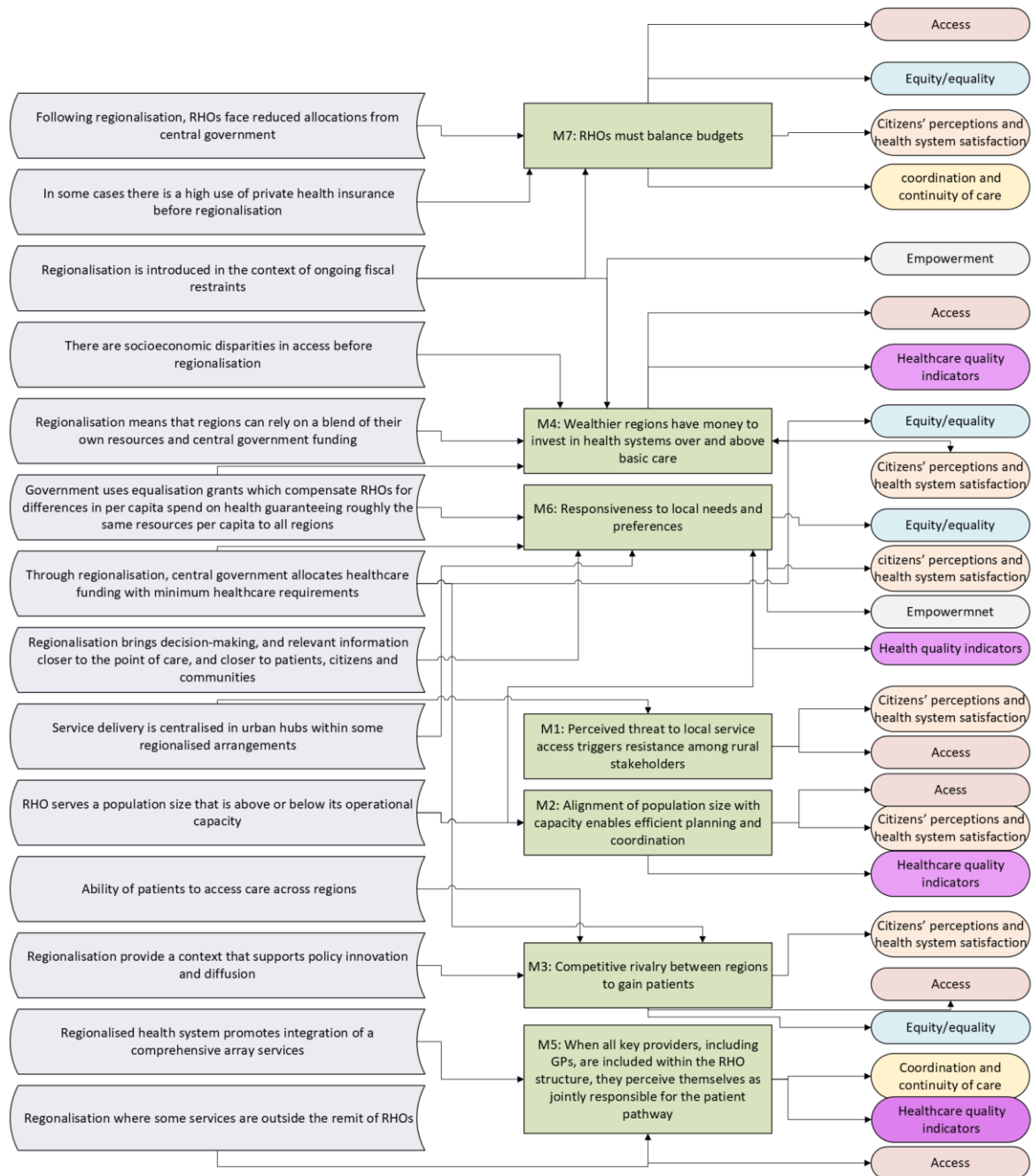
regional inequalities (Costa-Font and Turati, 2018). In some cases there is a high use of private health insurance before regionalisation, in all cases RHOs must balance budgets, and so socioeconomic inequality in health status may persist as those without health insurance are still worse off (Costa-i-Font, 2005).

Table 8-11 CMOCs related to equity/equality

Context	Mechanism	Outcome
Through regionalisation, central government allocates healthcare funding with minimum healthcare requirements	M6: Responsiveness to local needs and preferences	Less income-related inequity (Zhong, 2010)
Government uses equalisation grants which compensate RHOs for differences in per capita spend on health guaranteeing roughly the same resources per capita to all regions	M6: Responsiveness to local needs and preferences M4: Wealthier regions have money to invest in health systems over and above basic care	Limited regional inequalities (Costa-Font and Turati, 2018) Reduction of ‘avoidable’ health inequalities (Costa-Font and Gil, 2009) The gap between poor and rich regions will persist (Toth, 2014)
Regionalisation provides a context that supports policy innovation and diffusion	M3: Competitive rivalry between regions to gain patients	Limited regional inequalities (Costa-Font and Turati, 2018)
In some cases there is a high use of private health insurance before regionalisation	M7: RHOs must balance budgets	Socioeconomic inequality in health status may persist (Costa-i-Font, 2005)

The final programme theory and connections between CMOCs are depicted in Figure 8-1.

Figure 8-1 Final programme theory illustrating how contextual factors trigger mechanisms to influence patient-centred care outcomes following regionalisation



8.5 Discussion

8.5.1 Summary of findings and comparison with previous literature

As outlined in the introduction to this chapter, the regionalisation of a healthcare system is a major structural change that likely affects patient-centred care, but these effects have not been thoroughly examined. This is the first rapid realist review exploring health regionalisation, with a focus on impacts (both intended and unintended) on patient-centred care. We identified 19 studies, from a total of 5,774 records screened.

The synthesis identified seven mechanisms through which regionalisation may impact on patient-centred care. These mechanisms are M1: Perceived threat to local service access triggers resistance among rural stakeholders, M2: Alignment of population size with capacity enables efficient planning and coordination, M3: Competitive rivalry between regions to gain patients, M4: Wealthier regions have money to invest in health systems over and above basic care, M5: When all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient pathway, M6: Responsiveness to local needs and preferences, and M7: RHOs must balance budgets. This rapid realist review also identified contextual factors, that influence the extent to which these mechanisms are activated to produce desired outcomes. These include population size of region, impact of equalisation grants, and fiscal implications.

Regionalisation is a complex and multifaceted process, which has been introduced in many diverse geographical contexts. The realist approach has enabled the identification of contexts and mechanisms which are applicable to other geographies, and which can facilitate or hinder intervention success in relation to patient-centred care.

The mechanisms identified in this review resonate with some of those described in a realist review by Abimbola et al, of the impacts of decentralisation on health system equity, efficiency, and resilience. From the outcomes they analysed only equity would fall within the remit of patient-centred care. Two mechanisms they describe are of particular importance. First they describe 'Voting with feet':

reflecting how decentralisation either exacerbates or assuages the existing patterns of inequities in the distribution of people, resources and outcomes in a jurisdiction, this comprises parts of both M1 and M4 of this rapid realist review. Secondly, they describe 'Close to ground': reflecting how bringing governance closer to the people allows for use of local initiative, information, feedback, input and control, which aligns with M6 of this review. Through our review we were able to further expand on learnings from Abimbola et al. to provide a deeper understanding of the consequences of a whole system restructure for all service users.

8.5.2 Strengths, limitations, and future research directions

The strengths of this review are, firstly, that it is the first rapid realist review exploring the ways in which healthcare regionalisation impacts on patient-centred care. Second, the work has unpacked key interactions between theoretical mechanisms of regionalisation success and the enabling or constraining contexts in which these interventions take place, thus making an important contribution to policy and practice development in this area.

One of the main limitations of this rapid realist review – in keeping with most realist reviews (Greenhalgh et al., 2016) – is that the primary studies often lacked sufficient detail about context, and were largely empirical studies with no theoretical basis, making it difficult to produce robust CMO configurations (Wells et al., 2012). The seven mechanisms proposed in this review and the range of contextual factors identified should be considered as preliminary and in need of further empirical testing. The second limitation of this review is due to its rapid nature. Pragmatic decisions were made to limit the scope of the search, to ensure that the results could be achieved rapidly. It is possible that through these methods some relevant studies were missed, however, the use of additional searching including checking reference lists of reviews included in an umbrella review of healthcare regionalisation mitigated this risk.

Additional investigation of the mechanisms identified in this review in relation to other health system interventions is warranted. Similarities between this work and

that of Abimbola et al. suggests that there is likely to be transferability of mechanisms involved in interventions that restructure a healthcare system, but further empirical testing of this assumption is required.

8.5.3 Conclusions

The findings of this rapid realist review show that the context in which regionalisation is introduced will influence how patients are affected by the intervention. The fiscal and geographical contexts are key. The mechanisms underlying a successful experience for patients included optimal region population size for operation, cooperation of all healthcare providers who are part of the same RHO, and responsiveness to local needs and preferences. Policymakers contemplating health system restructures should consider all presented context and mechanisms when developing an implementation plan for the reform.

Chapter 9 Discussion

9.1 Overview

As stated in Chapter 1, the primary aim of this thesis is to assess the applicability and effectiveness of emerging evidence synthesis methods in supporting health policy research and evidence-informed policymaking, particularly in contexts where time and resources are constrained. This work has a particular focus on healthcare reform, using the Irish experience of healthcare regionalisation as a case study to test and apply these methods in a real-world policy setting.

A central methodological element of the thesis is the use of the evidence synthesis selection framework developed by Wickremasinghe et al. (2016) to support the structured comparison of different synthesis approaches. While this framework was developed to guide the selection of evidence synthesis methods for policy audiences, it has not previously been empirically tested through the practical comparison of multiple synthesis approaches within a single research programme. This thesis therefore applies the framework to compare umbrella reviews, rapid realist reviews, and traditional systematic review approaches within the context of a complex policy case study. The overarching research question guiding the discussion is:

How do umbrella reviews, rapid realist reviews, and traditional systematic reviews compare in terms of their ability to generate timely, relevant, and context-sensitive evidence, when assessed under a suitable evidence synthesis selection framework, and how can that framework be expanded with new considerations arising from this thesis?

This chapter responds to this question by reflecting on the insights gained from applying and comparing these evidence synthesis methods to the case of healthcare regionalisation. The discussion considers how the methods performed across the domains identified in the Wickremasinghe framework, including utility, technical characteristics, and resource requirements. It also draws on the practical

experience of conducting these reviews to identify methodological strengths and limitations, highlighting the challenges and opportunities associated with applying different synthesis approaches to complex policy questions.

In doing so, the chapter considers how the Wickremasinghe framework functioned as a tool for comparing synthesis methods in practice and explores how insights from this case study may contribute to its further refinement. The findings therefore provide both a reflection on the practical use of different evidence synthesis approaches in evidence-informed policy and a basis for considering how existing methodological frameworks might be further developed to better support applied policy research.

9.2 Aims of this chapter

This chapter has five aims. First it compares the evidence synthesis methods considered in this thesis, including both rapid and more traditional approaches (such as the HRB evidence review), using the domains outlined in the Wickremasinghe evidence synthesis selection framework including utility, technical characteristics and resources.

Second, it reflects on how these methods performed when applied to a real-world policy question, considering their respective strengths and limitations in generating timely, relevant, and context-sensitive evidence for policymakers.

Third, the chapter considers the implications of these findings for researchers and policymakers who seek to use evidence synthesis to support complex health system decision-making.

Fourth, it discusses the strengths and limitations of the research presented in this thesis.

Finally, the chapter considers how insights generated through the empirical application of these methods may inform the further development of frameworks used to guide the selection of evidence synthesis approaches for policy-relevant research, drawing on healthcare regionalisation as an illustrative case.

9.3 Comparison of the findings of the umbrella review and rapid realist review with the HRB review

When comparing the three reviews, a number of commonalities and divergences emerge in relation to the impacts of healthcare regionalisation. All three reviews, the umbrella review, the rapid realist review, and the HRB evidence review, converge on the conclusion that the effects of regionalisation are highly mixed and context dependent. None presented regionalisation as a universally effective reform; instead, outcomes varied considerably according to fiscal, geographic, and organisational conditions. Each review also underscored the persistence of equity concerns, with inequities most frequently arising between urban and rural populations and between wealthier and poorer regions. Furthermore, all three reviews emphasised the centrality of care integration: regional reforms tended to be more successful when they achieved meaningful integration across hospital, community, and primary services, whereas fragmentation or partial integration was consistently associated with poorer outcomes. Fiscal arrangements were also identified as pivotal across all three reviews. Funding allocation, resource disparities, and budgetary constraints were repeatedly found to shape the distribution of benefits under regionalisation and to determine whether reforms achieved efficiency gains or, conversely, exacerbated inequities.

Alongside these shared findings, there were also notable overlaps across pairs of reviews. Both the rapid realist review and the HRB review highlighted the significance of population size, pointing to an optimal range for regional populations of approximately 350,000-500,000; regions below this threshold risked fragmentation and inefficiency, whereas excessively large regions struggled with coordination. Similarly, both reviews identified patient satisfaction as being closely tied to responsiveness to local needs, with citizens more likely to view regionalisation positively when services were visibly attuned to their communities.

The umbrella review and HRB review, meanwhile, both warned of governance risks, noting that poorly designed or weakly accountable regional structures left systems vulnerable to abuse or corruption. A likely explanation for this convergence is the degree of overlap in the underlying evidence base across the different synthesis approaches. Although each method applied distinct inclusion criteria and analytic lenses, several of the same studies were captured by more than one method. This inevitably increases the likelihood of similar themes being identified across reviews.

However, the methods did not produce identical sets of included studies. The rapid realist review, for example, included evidence that contributed to theory development and explanation, while the umbrella review was limited to existing systematic reviews and the HRB report drew on a broader policy-oriented evidence base. This variation in scope and selection helps explain why some findings (e.g. optimal population size, local responsiveness) were consistently identified, while others (such as governance risks) were more prominent in particular synthesis types. This suggests that convergence reflects not only overlap in sources, but also the robustness and recurrence of these issues across diverse contexts and analytical perspectives.

The umbrella review and HRB evidence review also converged in raising concerns about the limitations of the evidence base: the umbrella review found that eight of the nine systematic reviews it included were rated “critically low” on AMSTAR-2 quality assessment, while the HRB Review similarly cautioned that most available studies were observational and heterogeneous, which limited confidence in generalisable findings. In contrast, the rapid realist review did not include a formal quality appraisal of individual studies, in keeping with its emphasis on explanatory power, relevance to programme theory, and timeliness. As a result, concerns about the underlying quality of the evidence were less explicitly foregrounded in its findings. This difference may, in part, reflect the methodological orientation of rapid realist review, which prioritises understanding mechanisms and context over formal assessment of study quality. While this is a recognised strength in addressing complex interventions, it may also represent a limitation of the

approach where the overall robustness of the evidence base is a primary consideration. Finally, both the umbrella and HRB reviews noted that the impacts of regionalisation may differ in the short versus the long term, with early instability sometimes masking eventual outcomes.

Each review also contributed unique insights. The umbrella review, drawing on the broadest range of international literature, provided a wide descriptive map of potential benefits and risks but was constrained by the generally poor quality of included reviews. The HRB Review, while also international in scope, was explicitly commissioned to answer questions arising from the Irish Sláintecare reform agenda. It therefore applied international lessons to the Irish context, particularly emphasising governance, accountability, and the political feasibility of establishing new regional health areas. The rapid realist review, in contrast, offered the most explanatory power. Unlike the other two reviews, it systematically incorporated context into its synthesis and explicitly examined how contextual factors interacted with mechanisms to produce outcomes. Through the realist approach, it identified causal pathways such as perceived threats to local service access triggers resistance among rural stakeholders, competitive rivalry between regions, and the role of responsiveness to local needs and preferences in shaping patient satisfaction. In this way, the rapid realist review was able to qualify the impact of context: it demonstrated that regionalisation could empower communities when structures were designed to be locally responsive, but could equally exacerbate inequalities or disempower citizens where centralised or urban-centred models predominated.

Taken together, these reviews suggest that while the evidence base on regionalisation remains uneven, certain themes emerge consistently including: equity, fiscal arrangements, integration, and governance and are decisive in shaping outcomes. Yet it is the rapid realist review that most clearly shows **why** outcomes diverge, by demonstrating the interaction of context, mechanism, and outcome. By contrast, the umbrella and HRB reviews could map the terrain of results and risks but lacked the methodological tools to explain observed variation.

9.4 Addressing limitations of the original review: time and context

The comparison of findings across the three reviews not only highlights similarities and differences in their conclusions but also demonstrates the different methodological contributions each makes to evidence-informed policy. The HRB evidence review provided a rigorous and transparent synthesis of international evidence but was time-intensive and less able to unpack the influence of context. The umbrella review, though constrained by the quality of its underlying studies, proved much faster to complete and offered policymakers a timely overview of international experience. The rapid realist review, by contrast, was uniquely able to show how contextual factors interacted with mechanisms to produce outcomes, offering the most explanatory power for a complex reform such as regionalisation. These contrasts provide an entry point into assessing the extent to which the umbrella review and rapid realist review addressed the two key limitations identified in the HRB review: the time and resources taken to produce findings, and the limited consideration of context.

9.4.1 *Timing and Team Size*

The time required to complete each synthesis varied considerably. The HRB systematic review, conducted as a mixed-methods evidence synthesis, took 16 months to complete. There were three researchers assigned to work fulltime on the project, and they were supported by a librarian for relevant parts of the project. This reflected the volume of evidence to be screened, the need for detailed quality appraisal, and the scale of synthesis work involved.

In contrast, the umbrella review conducted as part of this thesis was completed over approximately 18 months by one researcher working part-time, sporadically supported by others when double review or appraisal was required. Therefore, it could be completed far more rapidly with a larger team working full-time. By relying on and synthesising existing systematic reviews, the scope of primary searching, screening, and data extraction was substantially reduced. In my experience, this significantly shortened the overall project timeline compared to

traditional systematic review and lowered the staffing requirements, while still producing findings that were meaningful and accessible to policymakers.

The rapid realist review was less predictable in terms of time requirements. While it was ultimately completed in approximately 22 months by one researcher working part-time (supported by others when needed as for the umbrella review), the iterative, theory-building nature of the method made it more difficult to estimate the duration in advance than either the systematic or umbrella review. My supervisory team had experience of realist review methodology; however, as the primary researcher did not have prior experience of conducting a realist review, this learning curve may have contributed to a slower process. At the same time, my existing familiarity with healthcare regionalisation helped to partially offset this, supporting theory development and interpretation. In practice, the duration of a realist review is variable and dependent on the scope of the questions and the depth of engagement with stakeholders. While it can be completed in a timeframe similar to that of a systematic review, it also has the potential to extend much longer. The interpretive and theory-driven nature of the work meant that additional reviewers without realist experience may not have increased efficiency. This suggests that a key constraint on rapid realist review is not only time, but access to suitably skilled and knowledgeable reviewers, which should be explicitly acknowledged in comparisons of evidence synthesis methods. Additionally, in this thesis there were two necessary preliminary steps for the rapid-realism review, interviews with policymakers and a scoping review of definitions of patient-centred care, which are not factored in the 22-month estimate. A research team planning a rapid-realism review would also need to allocate time for necessary preliminary steps.

The approximate resource hours required to complete each evidence synthesis are outlined in Table 9-1. These estimates provide an indicative comparison of the relative resource requirements of each method; however, they should be interpreted with caution. The hours reported for the umbrella review and rapid realist review are approximations, as these reviews were conducted by a single researcher working part-time over an extended period, making precise time

tracking difficult. In addition, familiarity with the topic of healthcare regionalisation gained during earlier stages of the thesis may have reduced the time required for the later reviews, particularly in relation to identifying relevant literature and interpreting findings. Overall, the systematic review required the greatest level of resource investment (approximately 6,035 hours), followed by the rapid realist review (approximately 1,230 hours), while the umbrella review required the least time (approximately 950 hours), making it the most rapid of the three approaches examined in this thesis. The estimates also do not include the prerequisite stages undertaken prior to the rapid realist review—namely the interviews with policymakers and the scoping review of definitions of patient-centred care—which were necessary to inform the scope and theoretical framing of that synthesis. Consequently, while the table provides a useful indication of relative effort across methods, actual resource requirements may vary depending on team structure, prior topic knowledge, and the preparatory work required to support the review.

Table 9-1 Approximate hours to develop each evidence synthesis

	Systematic review	Umbrella review	Rapid-realist review
Main analyst	3,000	820	1,000
Supporting analyst	3,000	125	220
Librarian	35	5	10
Total	6,035	950	1,230

9.4.2 Context

The consideration of context was the second area in which the umbrella and rapid realist reviews offered a contrast with the HRB review, albeit in different ways. The umbrella review did acknowledge that the impacts of regionalisation varied across settings and populations, thereby reinforcing the idea that outcomes were context-dependent. However, its ability to explore this further was limited by the nature of its descriptive and aggregative methodology, which could not disentangle how or why specific contextual features influenced outcomes.

Only the rapid realist review formally incorporated context into its analysis, using the context-mechanism-outcome framework to show not simply that results were context dependent, but how particular contextual factors shaped the outcomes of regionalisation. Rather than just noting that context mattered, the rapid realist review helped to explain how context shaped outcomes and through which mechanisms these effects were produced. This explanatory leverage is particularly valuable to policymakers, who need to assess whether international findings are relevant to their own institutional and political settings. In this respect, the rapid realist review most directly addressed the HRB review's limitation in relation to context, by moving beyond description to explanation.

9.5 Transferability of findings to future reviews of system-level health interventions

In sum, the three reviews illustrate an important trade-off between speed and explanatory depth. The umbrella review demonstrates clear advantages in terms of timeliness and efficiency, making it particularly valuable when policymakers require rapid access to international evidence to inform urgent reform debates. However, its capacity to address context is limited, restricting its ability to explain why outcomes vary across settings.

The rapid realist review, while less predictable in terms of time and resource requirements, offered substantially greater explanatory power through its formal integration of context into the synthesis process. By identifying how outcomes were shaped by specific organisational, professional and system-level conditions, it was able to illuminate the circumstances under which regionalisation was more or less likely to achieve its intended effects. The HRB mixed methods evidence review, although comprehensive and methodologically rigorous, was time-intensive and limited in its treatment of context, making it less agile and informative for fast-moving policy environments.

Taken together, these findings suggest that no single review method is sufficient for the review of complex health system reforms. Rather, choice of method involves an explicit balancing of rigour, relevance, resources, timelines, and the

degree of explanatory insight required. This insight is transferable beyond the specific case of healthcare regionalisation. Researchers and policymakers engaged in the review of other system-level interventions, such as integrated care models, service reconfiguration, workforce reform or population-health initiatives, can draw on these learnings to make more informed decisions about the most appropriate approach to evidence synthesis.

The following section (9.6) uses the Wickremasinghe et al. evidence synthesis framework (first described in Chapter 2) as an analytical tool to critically compare and evaluate the three review types, systematic review, umbrella review and rapid realist review in greater detail. This framework is used to structure a systematic, domain-by-domain comparison of their features, utility, technical characteristics and resource requirements. Subsequently, new methodological insights generated through the conduct of this thesis are used to expand the framework itself, incorporating additional considerations relevant to complex health system reform and explicitly recognising rapid realist review as a distinct and valuable evidence synthesis approach for policy. The revised framework can therefore be used as a practical tool to guide future method selection in similar policy and system-level research contexts.

9.6 Comparison of evidence synthesis methods

The previous section outlined the strengths and weaknesses of each method in terms of resources and consideration of context. However, a more detailed comparison is presented here, using the framework developed by Wickremasinghe and colleagues. As described in Chapter 2, this framework classifies ten evidence synthesis methods under four domains: key features, utility, technical characteristics, and resources. By grounding the comparison in this framework, the analysis considers not only methodological characteristics but also the alignment of each method with the needs of evidence users, including policymakers.

The Wickremasinghe framework categorises evidence synthesis methods across four domains: key features, utility, technical characteristics, and resources required. As discussed in Chapter 2, these domains can be considered alongside

the 4 Rs – Rigour, Relevance, Readability, and Resources – to ensure that review design meets both technical standards and the practical needs of evidence users.

In the following sections, each review type is evaluated in terms of these four framework domains, highlighting how they differ in their capacity to support evidence-informed policy and to respond to complex system-level questions. The Wickremasinghe framework serves as the main tool to facilitate this comparison, providing a structured and transparent basis for assessing how systematic, umbrella, and rapid realist reviews perform across methodological and practical dimensions. Secondly, the framework has been expanded in light of new evidence collected in this thesis, incorporating additional considerations for health system reform and policy for systematic and umbrella reviews, and explicitly including rapid realist review for the first time. In the subsequent sections, umbrella review, systematic review and rapid-realist review will be discussed under the four framework domains: key features, utility, technical characteristics, and resources.

9.6.1 Comparison of key features of selected evidence synthesis methods

The key features of systematic review, umbrella review, and rapid realist review are summarised in Table 9-2. Throughout this chapter, items added to the evidence synthesis framework (Wickremasinghe et al., 2016) are indicated in blue in Table 9-2 to Table 9-6. Rapid-realist review was not included in the original framework and so all additions for this method are based on experience from this thesis. In contrast, the key features of systematic review and umbrella review are well established, and no new information on the key features of these methods was generated from this thesis.

Table 9-2 Key features of evidence synthesis methods

	Systematic review	Umbrella review	Rapid-realist review
Also known as	-	Review of reviews Overview of reviews	Rapid realist synthesis
Description	Includes a map of evidence, critical appraisal and qualitative or quantitative evidence synthesis Includes the criteria (e.g. quality, date range, method) applied to select evidence for synthesis Incorporates peer-reviewed and significant grey literature Draws a clear scientific conclusion	Includes existing reviews, and draws a conclusion statement	Theory-driven method Designed to be completed in a relatively short time Iterative searching for literature Incorporates quantitative and qualitative studies from grey literature and peer-reviewed sources Produces a theory about how an intervention works

Key: Text in blue is additional to the Wickremasinghe et al. framework

9.6.2 Utility of different forms of evidence synthesis

The utility section of the Wickremasinghe evidence-synthesis framework focuses on who the primary user groups is for each evidence synthesis method and when would that audience use the method (Table 9-3). Drawing on the original framework and the applied experience gained through this thesis, the primary audience for systematic review is professionals and other evidence users, while umbrella review and rapid realist review are most clearly aligned with the needs of researchers/academics and policymakers. Wickremasinghe et al. (2016) suggested the primary audience for systematic reviews are professionals and practitioners for example healthcare practitioners who are responsible for policy implementation. However, the systematic review has almost universal appeal across all knowledge

users, and its outputs are widely understood. This may be attributed to heavy investment in training and collaboration initiatives such as Cochrane. The evidence-synthesis framework suggested that the primary users of umbrella reviews would be researchers and academics. This may have been the case when umbrella reviews were initially envisioned as part of the Cochrane Library to offer quick, comprehensive overviews (Grant and Booth, 2009). However, the umbrella review presented in this thesis is aimed at informing policymakers. Umbrella review is a suitable method for evidence-informed policy and so a suggested update to the framework is outlined in Table 9-3.

In line with Table 9-3, when sufficient time and resources are available, a systematic review provides the most comprehensive and authoritative synthesis of a body of evidence at a particular point in time and can support major policy or programme decisions. The HRB evidence review that motivated this thesis reflects this role, providing a rigorous synthesis of the literature on healthcare regionalisation to inform national policy discussions. However, its length, resource intensity, and limited treatment of contextual factors highlighted some of the practical and interpretive constraints associated with this approach for complex system reform.

Umbrella review is most useful when there is already a considerable body of research, including multiple existing systematic reviews, on a particular topic. The umbrella review undertaken as part of this thesis provided a structured and time-efficient means of synthesising the international evidence on regionalisation. When shared with policymakers, it offered a clear and accessible overview of current knowledge, supporting its inclusion in the framework as a method that can effectively inform evidence-informed policy within time-constrained environments.

The rapid realist review offered distinct and additional utility. It supported not only a synthesis of what the evidence suggests, but a deeper exploration of *how*, *why*, *for whom* and *under what conditions* healthcare regionalisation may produce particular outcomes. Stakeholder engagement was central to this process. Policymaker interviews (Chapter 6) and consultation with stakeholders during

analysis and interpretation of the rapid realist review (Chapter 8) strengthened the relevance, resonance and explanatory power of the findings. Policymakers, many of whom had not previously encountered a rapid realist review, engaged positively with the material and provided constructive feedback that was subsequently incorporated into the thesis.

In contrast to systematic and umbrella reviews, rapid realist review more actively requires stakeholder involvement and iterative engagement with context. This feature, experienced directly in this thesis, enhances its policymaking relevance, particularly in complex system-level reforms such as regionalisation. As a result, rapid realist review is positioned within the updated framework as a method with particularly strong utility for evidence-informed policy in dynamic and complex health system environments.

Beyond producing external evidence, evidence synthesis can create space for policymakers to reflect inwardly on their own objectives, assumptions, and institutional contexts. In this thesis, engagement with policymakers suggested that the process of reviewing evidence was itself valuable, as it prompted reflection on what the reform was intended to achieve, how success was defined, and which contextual constraints might shape implementation. The rapid realist review was particularly well suited to supporting this reflective function, as its focus on context-mechanism-outcome configurations encouraged policymakers to consider how their own system characteristics, governance arrangements, and priorities might interact with proposed reforms, rather than treating evidence as directly transferable from other settings.

Table 9-3 Utility of different forms of evidence synthesis and their primary audience

	Systematic review	Umbrella review	Rapid-realist review
Suggested primary audience	Professionals, and all other evidence users	Researchers/academics, policymakers	Researchers/academics, policymakers

When is it useful?	When time and resources are available, this provides the most comprehensive and authoritative summary of a body of evidence at a particular point in time, to underpin policy decisions or programme designs	When there is a considerable body of research and a number of research reviews in a particular area	To understand the workings of a complex programme or intervention when time is limited

Key: Text in blue is additional to the Wickremasinghe et al. framework

9.6.3 Technical characteristics

Table 9-4 provides a summary of the main technical characteristics of the evidence synthesis methods. Each technical characteristic is discussed in more detail in section 9.6.3.1 to 9.6.3.3.

Table 9-4 Technical characteristics

	Systematic review	Umbrella review	Rapid realist review
Quality appraisal	Essential	Essential	Limited
Evidence usually presented as	Narrative and tables	Narrative, graphics and tables	Narrative, graphics and tables
Systematic documentation of evidence	Comprehensive	Comprehensive	Comprehensive
Replicable	High	High	Low
Periodic update	Essential	Essential	Possible

Key: Text in blue is additional to the Wickremasinghe et al. framework

9.6.3.1 Quality appraisal

Quality appraisal of studies identified for inclusion is a resource-intensive component of evidence synthesis, particularly when conducted in duplicate, and may not be feasible under constrained conditions (Wickremasinghe et al., 2016).

This was clearly evident during the umbrella review conducted as part of this thesis, where the application of AMSTAR-2 required significant time and methodological judgement.

Formal quality appraisal is a core component of systematic review methodology and is also generally expected within umbrella reviews. In contrast, for rapid-realist reviews there remains less clarity and consistency regarding the role and scope of formal appraisal. In this thesis, the rapid-realist review prioritised relevance to programme theory and the credibility of inferences over formal scoring of individual studies. This decision reflected a fundamental epistemological difference between aggregative and explanatory synthesis approaches. Accordingly, rapid realist reviews prioritise explanatory power over formal scoring, and the application of standardised appraisal tools is therefore generally unnecessary and potentially inconsistent with the aims of this method.

As part of the research for this thesis, the AMSTAR-2 tool was used to quality appraise studies included in the umbrella review (chapter 5). However, while valuable, appraisal tools such as AMSTAR-2 do not properly account for mixed methods studies or emerging synthesis methods in the systematic reviews identified, and thus systematic reviews using these synthesis methods are likely to be unfairly penalised in appraisal. Additionally AMSTAR 2 has been acknowledged to be of more limited use in evaluating reviews without a formal synthesis and those on non-standard interventions (Perry et al., 2021; Puljak et al., 2023). Despite these constraints, there is a lack of robust alternative tools tailored to newer synthesis designs, which reinforces the continued use of AMSTAR 2.

A further distinction between realist and more traditional forms of evidence synthesis concerns how certainty in findings is communicated. Systematic reviews commonly apply formal approaches such as GRADE to assess the certainty of effect estimates, providing policymakers with a clear and familiar indication of the strength of the evidence. GRADE can also be applied to umbrella reviews; however, this is more complex than in primary systematic reviews, as reviewers must synthesise certainty assessments across multiple reviews that may differ in

scope, methods, and quality. In contrast, realist reviews, including rapid realist reviews, do not offer an equivalent summary measure of certainty. Their purpose is not to estimate effects but to develop and refine explanatory theory.

Confidence in realist findings is therefore derived from the plausibility, coherence, and empirical grounding of context-mechanism-outcome configurations rather than from graded certainty ratings. While this limits the ability to express conclusions in probabilistic terms, it reflects a different epistemological orientation, prioritising explanatory insight over statistical inference. For policymakers, this represents an explicit trade-off between quantified certainty and contextual understanding, which should be made transparent when selecting an evidence synthesis approach.

9.6.3.2 Evidence presentation

All evidence synthesis methods typically use some combination of narrative description, tables and graphics to present evidence (Wickremasinghe et al., 2016). Systematic and umbrella reviews often rely on standardised, quantitative approaches with well-established reporting frameworks like PRISMA and PRIOR, which facilitate the clear presentation of findings (Gates et al., 2022; Page et al., 2021). However, rapid-realist review is a more recent approach and the qualitative and iterative nature of the method complicates results presentation (Saul et al., 2013). While reporting guidelines for realist synthesis do exist, (Wong et al., 2013a) they are less explicit than the PRISMA statement for systematic review. The RAMESES standards for reporting of realist synthesis specifies three items (document flow diagram, document characteristics, main findings) to be considering when drafting a results section whereas the PRISMA statement specifies eleven items including subitems. Issues with presenting are particularly problematic when considering context-mechanism-outcome (CMO) configurations, the core analytic units in realist review. Visualising these interrelated elements is inherently complex, as they must capture dynamic interactions across varying contexts and outcomes. Existing visual formats often fail to adequately convey the nuanced, layered reasoning behind the configurations, leading to oversimplification or confusion for end users. The need for clearer guidance and consensus on best practices in presenting realist synthesis results is increasingly evident to ensure their utility in policymaking and practice.

9.6.3.3 Systematic documentation of evidence, replicability and periodic update

All three evidence synthesis methods employ systematic approaches to identifying relevant evidence. However, the degree of replicability varies across methods reflecting different epistemological assumptions and purposes. In traditional systematic reviews, replicability is considered a central methodological strength, supported by structured protocols, transparent search strategies, predefined inclusion criteria, and standardised procedures for data extraction and quality appraisal. These features allow other researchers to reproduce the review process and verify the results.

Umbrella reviews share many of these characteristics, as they increasingly adopt methodological standards derived from systematic reviews. While the original framework suggests only moderate replicability for umbrella reviews, my experience in conducting the umbrella review for this thesis indicates that their replicability can, in practice, be considered relatively high. This is because contemporary umbrella reviews increasingly follow systematic review standards, including protocol development, comprehensive search strategies, transparent selection processes, and structured data extraction and appraisal procedures. In addition, the umbrella review method is now more established and methodologically mature than at the time the original framework was developed. On the basis of this experience, a change to the level of replicability for umbrella reviews has therefore been recommended in the updated framework presented in Table 9-4.

However, the emphasis placed on replicability within systematic review traditions may be less directly applicable when evidence synthesis is intended to inform complex policy decisions. In such contexts, the usefulness of a review may depend not only on whether the process can be reproduced, but also on whether the synthesis meaningfully engages with contextual factors that shape how interventions operate in practice.

Rapid realist reviews illustrate this distinction particularly clearly. Rapid realist reviews are less concerned with procedural replicability in a traditional sense, as they are inherently iterative, theory-driven and interpretive, meaning that the synthesis process evolves as programme theories are developed and refined. In this thesis, conducting the rapid realist review involved ongoing engagement with the evidence, interpretation of emerging context-mechanism-outcome configurations, and reflexive judgement regarding the relevance of different sources. As a result, the process was less easily reducible to a fully standardised, protocol-driven procedure.. However, this is not a methodological weakness, but rather a defining feature of realist approaches. It reflects the different aims of realist synthesis, which seeks to explain how and why interventions work in particular contexts rather than to produce a fully reproducible aggregation of findings.

Indeed, in policy-oriented research, strict procedural reproducibility may sometimes be in tension with contextual relevance. Reviews designed for a specific policy audience may need to adapt their scope, evidence sources, and analytical focus in response to emerging understanding of the policy problem. Rapid realist review explicitly encourages the use of prior knowledge and expert input to accelerate the search process and refine emerging programme theories. While such practices reduce strict procedural replicability, it enhances explanatory power, contextual sensitivity, and policy relevance.

Similar considerations arise when discussing generalisability. Systematic reviews often aim to produce findings that are broadly generalisable across settings. However, for complex health system interventions such as regionalisation, outcomes are often highly dependent on institutional structures, governance arrangements, and local implementation conditions. Realist synthesis approaches generalisability differently, seeking to develop transferable explanations about how mechanisms interact with particular contexts. In this sense, the theories generated through rapid realist review may be applicable to other settings that share similar contextual characteristics, even if the specific findings are not universally generalisable.

Regarding periodic updates, systematic reviews are widely recognised as requiring regular updates to ensure relevance for decision-making, though this process can be resource intensive. Umbrella reviews can also be updated, but Wickremasinghe et al. (2016) suggest that such updates may not always be essential. For rapid realist reviews, updates are possible; however, unless a significant new body of evidence emerges, findings are unlikely to change meaningfully. This is because rapid realist reviews are configurative and interpretive, aiming to explain mechanisms and context rather than aggregate outcomes. In contrast, even a single new study, particularly one with a large sample size or treatment effect, can shift the conclusions of a systematic review with meta-analysis, given its summative and quantitative nature.

9.6.4 Limitations

This section expands on previously reported limitations through reflections from this thesis. The main limitations of the synthesis methods are outlined in Table 9-5.

9.6.4.1 Systematic review

During the conduct of the HRB systematic review, I identified two additional limitations of systematic reviews that are particularly relevant to policy interventions. First, the method is not well-suited to complex interventions as it typically focuses on narrowly defined research questions. Second, systematic reviews often prioritise randomised controlled trials or other quantitative comparative studies, frequently excluding qualitative research, theoretical work, and epidemiological studies, all of which can provide valuable insights for policy development.

9.6.4.2 Umbrella review

Throughout this thesis, additional limitations of umbrella reviews were identified, and they are added to the evidence synthesis framework (additions in blue in Table 9-5). Each review included in an umbrella review must be assessed for quality, which can pose challenges for both resources and synthesis (Wickremasinghe et al., 2016). Carid et al. (2015) highlight that quality assessment involves two levels:

evaluating the methodological quality of each included review and assessing the quality of the evidence within those reviews. Since the quality assessment of primary studies varies across reviews, this second level is often more difficult, especially when time and resources are limited. Handling mixed-quality reviews is also challenging; including low-quality reviews may introduce uncertainty, while excluding them risks biasing the overall evidence. The limitations of appraisal tools such as AMSTAR-2, as already discussed, are also an issue.

Umbrella reviews are only feasible when sufficient systematic reviews exist on a topic (Grant and Booth, 2009; Mallidou, 2014), limiting their applicability in emerging fields. They rely heavily on the data and interpretations reported in included reviews, which may require time-consuming additional extraction from primary studies. Due to the volume and diversity of primary research covered, umbrella reviews face greater challenges than standard systematic reviews in selecting data for synthesis and understanding the limitations of previously extracted data (Caird et al., 2015). This dependence also increases the risk of inheriting biases from previous reviewers. In this thesis, the umbrella review (Chapter 5) identified limited data on the impact of healthcare regionalisation on patient-centred care. However, interviews with policymakers in Ireland, identified patient-centred care as an important outcome. This was a prompt for undertaking a rapid-realist review on that topic.

Findings from systematic and umbrella reviews can become outdated quickly because of the lag between the primary research and its inclusion in the reviews (Caird et al., 2015). They also cannot capture emerging concepts or topics not suitable for systematic review methodology. Given the limitations of systematic reviews on complex interventions, umbrella reviews on complex or non-health interventions may also be limited. Since frequent updates are necessary to keep umbrella reviews relevant, researchers should design their search strategies, extraction tools, and reports to facilitate easy updating, especially if publishing in peer-reviewed journals. However, in slower-moving fields like healthcare regionalisation, update searches may yield few or no new studies.

9.6.4.3 Rapid-realist review

The limitations of realist review are well documented in the literature. Realist reviews face challenges related to methodological complexity, limited transparency, subjectivity in interpretation, difficulty in defining core concepts, reliance on diverse but often insufficient data, and a lack of standardisation, making them resource-intensive, difficult to reproduce, and potentially inaccessible to non-experts. The limitations of rapid realist review are less well described.

The rapid-realist review methodology, as defined by Saul et al. (2013), offers a potentially more time-efficient alternative to traditional realist reviews by streamlining the search and synthesis process. However, this speed can introduce bias, particularly due to the risk of omitting relevant evidence. To address this, Saul et al. recommend involving both an expert panel (comprising researchers and practitioners familiar with the topic) and a reference group (made up of the intended end-users, including funders) to ensure relevance and credibility. In this thesis, an expert panel was not convened, as doing so would have delayed the start of the project. Instead, the researcher's prior experience and subject-matter knowledge of healthcare regionalisation were used to fill this gap. While this approach enabled timely completion, it also highlights a limitation: teams without comparable contextual expertise may struggle to maintain the same depth and balance of interpretation. Thus, rapid-realist review, though potentially cost-effective, still demands significant cognitive and analytical resources within a condensed timeframe, which may not always be feasible in policy or governmental contexts.

A further challenge identified through this research was the steep learning curve associated with realist methodology. Unlike the Cochrane approach, which emphasises accessibility and encourages novice participation in systematic reviews, realist methods are less standardised and more interpretive, making them less accessible to non-experts. The iterative and purposive nature of rapid-realist reviews, though theoretically beneficial, may also reduce transparency and reproducibility. This makes it easier for researcher bias to influence findings, and

harder for audiences to trace the derivation of conclusions (Dixon-Woods et al., 2005; Sheldon, 2005; Tricco et al., 2016).

Defining and consistently applying key realist concepts, particularly the distinction between context and mechanism, proved to be one of the most significant methodological challenges in this study. This issue has been documented in the literature (Petticrew et al., 2013; Tricco et al., 2016). This was an area of particular difficulty for this researcher. To address this, stricter operational definitions of 'context' were developed and applied throughout the review in an effort to impose greater conceptual discipline and analytical consistency. While this strengthened internal coherence, it also highlighted the extent to which the realist process is shaped by reflexive decision-making and ongoing negotiation of meaning, especially in a rapid, time-pressured environment.

Although more methodological guidance has emerged over time (e.g., from the RAMESES project), the literature continues to emphasise the importance of involving expert consultants to maintain quality. However, the limited availability of detailed, step-by-step procedural guidance still hampers accessibility.

Another concern is the inherent subjectivity of rapid-realist reviews. Findings are often shaped by the research team's interpretations. These reviews typically offer tentative recommendations rather than definitive conclusions. The use of expert opinion as evidence, while valuable, adds another layer of subjectivity, especially when such input is not directly gathered or transparently integrated into the synthesis process.

Finally, applying realist methods beyond their original social science context presents additional challenges. In fields where established theoretical frameworks may be lacking, rapid-realist reviews tend to focus more on theory building than theory testing. This can make the approach more exploratory and less structured, as was the case with the rapid-realist review presented in Chapter 8.

Table 9-5 Limitations of synthesis methods

Systematic review	Umbrella review	Rapid realist review
• Resource intensive (time, human, financial) • May have a narrow clinical question or set of questions - <i>the method does not lend itself to complex interventions</i> • Has a history of use in health and education; yet to be fully tested in other development areas, e.g. governance and climate change • Typically, systematic reviews would focus on randomised controlled trials, or quantitative comparative studies excluding qualitative studies, theoretical work, and epidemiological studies, which have relevant to policy interventions.	• Does not include research outside existing reviews • Because reviews are of variable quality, each needs to be assessed for how systematic and comprehensive it is • <i>Umbrella reviews rely entirely on existing systematic reviews, which limits their feasibility in emerging or under-researched topics and excludes evidence outside of these reviews, thereby narrowing the scope of included research.</i> • Quality assessment in umbrella reviews is complex because it requires evaluating both the methodological rigor of the included reviews and the quality of the primary studies within them, which is often inconsistently reported; deciding how to handle mixed-quality reviews can introduce uncertainty and bias. • These reviews depend heavily on the data and interpretations provided by the included reviews, making them susceptible to inherited biases and conceptual limitations, and sometimes requiring additional, time-consuming extraction of primary data. • The large volume and diversity of data across multiple reviews increase the complexity of synthesis compared to standard systematic reviews, posing challenges in selecting and	• Expedited search strategies may miss relevant evidence, introducing bias. • Resource-intensive to conduct within a short timeframe; often requires external expert support. • Effective execution depends on a review team with strong understanding of realist methodology. • The iterative and interpretive nature of the method reduces transparency and reproducibility. • Flexible and purposive processes for data selection and extraction increase the risk of researcher bias. • Difficulty in clearly distinguishing between mechanisms and context, especially for novice teams. • Lack of detailed, step-by-step guidance, particularly in fields outside the social sciences. • Findings are context-specific and can be considered subjective. • Use of expert opinion as evidence introduces subjectivity and may lack transparency if not clearly documented.

Systematic review	Umbrella review	Rapid realist review
	interpreting relevant evidence. • Due to the time lag between the publication of primary studies, systematic reviews, and umbrella reviews, the findings can become outdated quickly, particularly in fast-moving fields. • Umbrella reviews are limited in their ability to address emerging topics and complex or non-health-related interventions, as these areas may not yet have sufficient systematic reviews or may not be amenable to review methodology. • Frequent updating is necessary to maintain the relevance of umbrella reviews, but this process can be resource-intensive and requires careful planning of search strategies and data management.	

Key: Text in blue is additional to the Wickremasinghe et al. framework

9.6.5 Resources required

Consideration of resources can help to determine what is a feasible and relevant scope for the synthesis output within the time available (Wickremasinghe et al., 2016). As outlined in Section 9.4.1, the three approaches examined in this thesis differed substantially in terms of time, team composition, and specialist expertise required.

The HRB mixed-methods systematic review (motivation for this thesis) took sixteen months to complete and was conducted by a team of three researchers working full-time, supported at key points by an information specialist/librarian. The scale of resourcing reflected the breadth of the research questions, the volume of

material screened, and the requirement for detailed quality appraisal and mixed-methods synthesis. This experience confirms that systematic reviews of complex, system-level interventions require substantial investment in both time and personnel.

In contrast, the umbrella review conducted as part of this thesis was completed over approximately eighteen months by a single researcher working part-time, with intermittent support from others when double screening or appraisal was required. Although this appears longer in absolute terms than some figures cited in the literature, the actual time spent actively working on the review was considerably less than the HRB project, and the study could almost certainly have been completed more rapidly with a larger, dedicated, full-time team. Experience on the umbrella review in this thesis would indicate that the length of time an umbrella review takes is dependent on the depth of analysis undertaken and the experience of the team. By relying on existing systematic reviews and synthesising their findings, the scope of searching, screening, and data extraction was substantially reduced. In practical terms, this made the umbrella review less resource intensive, easier to bound, and more achievable for a single researcher operating within the constraints of a PhD. My experience with previously conducting systematic reviews and working on regionalisation also made the process go faster. Umbrella review methods are very similar to systematic review methods and so conducting the umbrella review was straightforward. Doing the umbrella review first also meant that studies were already available for the rapid realist review, and I was already very familiar with the topic.

The rapid realist review was the most difficult to plan and resource with certainty. While it was ultimately completed over approximately twenty-two months by one researcher working part-time, also supported intermittently by others during key stages (see Section 9.4.1), the core challenge was not simply the length of time required but the difficulty in predicting duration at the outset. The iterative, theory-building nature of the method meant that the scope and direction of the work evolved as understanding deepened, making it harder to impose clear boundaries in advance. Additionally, preliminary steps including interviews with

policymakers and a scoping review were required in advance of the rapid-realist review. These are not accounted for in the 22-month time to complete estimate.

Although the supervisory team had experience of realist methods, the primary researcher did not, and this learning curve likely contributed to slower progress in the early stages. At the same time, deep familiarity with the topic of healthcare regionalisation helped to offset this to some extent by supporting the development and refinement of programme theories. Importantly, the interpretive and theory-driven character of the method meant that adding additional reviewers without realist expertise would not necessarily have resulted in greater efficiency. In this respect, the main constraint for rapid realist review in practice was not simply time, but access to appropriately skilled and experienced personnel.

Taken together, the findings from this thesis suggest that:

- Systematic reviews are the most resource-intensive, requiring extended timelines and multi-person research teams
- Umbrella reviews are more feasible for smaller teams and individual researchers and are easier to bound, while remaining methodologically robust and replicable
- Rapid realist reviews are less predictable in their resourcing needs and are constrained less by team size than by access to specific methodological expertise

This variation in resourcing requirements represents a critical practical consideration when selecting an evidence synthesis method for complex system-level policy questions, and it supports the inclusion of more guidance within the revised synthesis selection framework suggested in Table 9-6.

Table 9-6 Resources required

	Systematic review	Umbrella review	Rapid realist review

Indicative production times	18 months	3 months	6 months (18 months part-time)
Skills of the team	Familiarity with the topic area will speed up the process	Familiarity with the topic area will speed up the process	• Familiarity with the topic area will speed up the process • Expectation that at least one team member will have experience of conducting realist review

Key: Text in blue is additional to the Wickremasinghe et al. framework

9.7 Implications for researchers and policymakers

9.7.1 Implications for researchers and research/policy units

The literature suggests that realist review should be conducted by an experienced team with realist review expertise. In reality, there are limited opportunities to gain experience. Those reviewers working with policymakers will often be presented with a research question without a significant lead-in time, and expected timelines for delivery do not lend to researchers getting expert advice on a method before they begin. Researchers are tasked with two options, attempt the methods with limited practical guidance or find budget to employ an expert advisor.

For researchers, there is a clear imperative to develop and apply more sophisticated evaluative tools that can account for complexity and heterogeneity. While developments in qualitative and mixed-methods systematic review approaches (including qualitative evidence synthesis and integrative review designs) have expanded the ability of traditional reviews to engage with experience, meaning and process, these approaches do not explicitly operationalise context-mechanism-outcome configurations in the way that rapid-realist review does, nor are they designed to build and test programme theory. As such, although they can provide valuable complementary insights, they do not offer the same explanatory architecture as a realist approach.

In practice, rapid realist review may not always be a practical method of synthesising evidence for policy researchers, particularly when methodological expertise or appropriate support structures are lacking. The learning curve is steep, and the methods poorly defined. A well-tailored systematic review question that also incorporates qualitative data could also present similar findings.

As outlined in section 9.6.5, systematic reviews, including those incorporating qualitative evidence, can be undertaken in a fairly tight timeframe in specialist research centres. This may mean that, for some organisations, more conventional synthesis approaches remain more attractive in practice than newer methods with additional caveats and limitations.

9.7.2 Implications for policymakers

This thesis compares two newer evidence-synthesis methods: umbrella review and rapid-realist review. In preparation for the rapid-realist review, in-depth interviews were conducted with policymakers to ensure the review addressed relevant concerns and to inform the scope. When working under time constraints, early and close collaboration with decision-makers is essential to ensure that pragmatic limitations, necessary to make the workload manageable, are acceptable to those who will use the findings. However, my experience on this thesis aligns with my earlier work from the HRB (Quigley et al., 2019), where we observed that policymakers are often hesitant to narrow the scope of a review, particularly when they are accountable for decisions based on its results. This tension can result in broad, resource-intensive reviews, reducing the likelihood that a truly in-depth or nuanced understanding can be achieved within limited timeframes.

Policymakers should clarify their main interests at an early stage of the review process i.e. whether they are focused on whether an intervention works (efficacy), its unintended consequences, or how and why it works under specific conditions, as different evidence synthesis methodologies are suited to each of these questions. Engaging policymakers in evidence synthesis remains an evolving area of research (see Chapter 2). In this thesis, the rapid-realist review of regionalisation

was shaped by the findings from the policymaker interviews, and the findings validated by a group of relevant stakeholders. Policymakers also contributed to the HRB systematic review by helping to establish the scope of the research questions and identify priority outcomes for inclusion. However, the level of iterative engagement required for rapid-realist review is not typically embedded to the same extent within umbrella reviews and many traditional systematic review processes, where policymaker involvement is often more limited in scope and timing.

The interview process was time-consuming, particularly in analysing the transcripts, and narrowing the scope was not feasible for two main reasons: interviews were conducted during the COVID-19 pandemic, limiting participant availability, and one-to-one interviews encouraged more candid responses. Despite this comprehensive consultation, additional preparatory work was required for the rapid-realist review, specifically, a scoping review on patient-centred care to identify outcomes for the rapid realist review. This was necessary because Irish policy documents lacked a clear definition of the term, and its meaning varies across fields. The absence of well-defined concepts in policy documents can significantly hinder research.

While systematic review methods are well understood and widely accepted by policymakers, emerging methods such as rapid-realist review are less familiar. Umbrella reviews synthesise existing systematic reviews and may be more accessible to, and readily understood by, decision-makers. In contrast, rapid-realist reviews introduce theory-driven analysis, which can be more complex to explain and interpret. For these reviews to inform decisions effectively, those commissioning them must feel confident engaging with the underlying logic and communicating the findings to stakeholders.

When evidence is needed urgently, researchers and policymakers must agree on pragmatic limitations. It is the researcher's role to ensure that these are clearly communicated and understood. As described in Chapter 8, the findings of the rapid-realist review were validated through consultation with a group of Irish

stakeholders, who also provided feedback on the relevance and usability of the method for policy contexts. Key insights included:

- Only CMOCs (context-mechanism-outcome configurations) relevant to the Irish context should be presented to policymakers.
- Stakeholders expressed interest in knowing which CMOCs were most certain, though rapid-realist methods are not well suited to assessing certainty in the same way as traditional systematic reviews.
- Presenting CMOCs in outcome-based tables was seen as an effective and accessible format for policymakers.

Additionally, interviews described in Chapter 6 revealed significant reform fatigue in the Irish healthcare system, a challenge likely shared by health systems internationally. Continuous reform cycles make it difficult to assess the impact of any one initiative through evidence synthesis, as the effects may not be fully realised before the next round of changes begins.

9.8 Strengths and limitations of this thesis

The strengths and limitations of each of the results sections in this thesis have already been discussed in their respective chapters. Therefore, this chapter focuses on the strengths and limitations associated with the overall comparative analysis presented in this thesis and the study as a whole, particularly in relation to the selection, application and evaluation of evidence synthesis methods.

A key strength of this thesis is its explicit and theoretically informed comparison of several evidence synthesis approaches. While many typologies of evidence synthesis exist, there remains limited practical guidance on which methods are most appropriate for different types of research questions, particularly when those questions relate to complex, system-level interventions such as healthcare regionalisation. Existing guidance documents tend to focus on single-method approaches, often distinguishing only between quantitative or qualitative

paradigms, with very limited attention given to mixed-methods synthesis. This thesis addresses that gap by applying, comparing and critically examining an umbrella review, a traditional systematic review and a rapid realist review, using the Wickremasinghe et al. (2016) framework to structure the comparison. New learnings generated through this work were then used to expand the framework, with the overall purpose of supporting researchers and decision-makers to select the most appropriate evidence synthesis method for their specific purpose. The revised framework offers a practical contribution to the field of health services and policy research.

An additional strength of this thesis is that it represents, to the best of the researcher's knowledge, the first empirical application of the Wickremasinghe et al. (2016) evidence synthesis selection framework within a single research programme. The framework was originally developed through literature review and expert consensus as a conceptual tool to guide the selection of synthesis approaches for policymaking contexts. However, it had not previously been tested through the practical implementation and comparison of multiple evidence synthesis methods addressing the same policy issue. By applying the framework to compare systematic review, umbrella review and rapid realist review approaches within the case study of healthcare regionalisation, this thesis provides an opportunity to examine how the framework performs in practice. This empirical application enabled the identification of additional methodological and practical considerations relevant to policy-focused evidence synthesis, thereby informing the proposed refinements to the framework presented in this chapter.

Interviews with policymakers were instrumental in identifying the core aim of the healthcare reform - improving patient-centred care. This thesis presents a novel understanding of how regionalisation impacts patient-centred care with relevance to Irish health system reform. However, the interviews were conducted during the COVID-19 pandemic, which posed significant challenges. Many key policymakers involved in designing the reform had either been redeployed to respond to the pandemic or had since retired, making it difficult to access those with direct knowledge of the reform's development. Institutional memory is essential for

stakeholder interviews to effectively inform evidence synthesis, but policymaking roles are often transient, particularly following changes in government.

The practical realities of conducting this research during the COVID-19 pandemic also represent an important limitation. The disruption to normal working practices, combined with increased professional and personal pressures, affected both the pace and process of the research. COVID-19 most likely contributed to delays in the overall delivery of the thesis and meant that certain chapters, particularly Chapter 2 and Chapter 5, required multiple updates as the evidence base continued to evolve over the duration of the study. In addition, the work was carried out within a relatively small supervisory and research team, under tight and at times unpredictable timelines, particularly in relation to the rapid realist component. While the supervisory team had experience of realist approaches, the primary researcher did not, resulting in a significant learning curve when applying this method. However, the researcher's familiarity with the topic of regionalisation helped to offset this to some extent, supporting interpretation, theory development and contextual understanding.

There appears to be few studies which have compared umbrella reviews to realist review. The review provides a comparison of an umbrella review and a rapid-realist review on the same topic, both of which can be compared to a previously published systematic review. This researcher was able to provide insights on conducting all three methods, the comparative strengths and limitations of each and the feasibility for use in health policy research.

A further limitation of this thesis is that the same primary researcher was involved in conducting the umbrella review and rapid realist review and had previously contributed to the HRB systematic review that forms the basis of comparison. This may introduce a degree of researcher influence in how the methods were applied and subsequently interpreted in the comparative analysis. An alternative approach would have been to compare independently conducted reviews undertaken by separate teams. While this might reduce the potential for individual researcher bias, it would introduce other limitations, as differences in team expertise,

resources, timelines, and interpretation could make it difficult to attribute differences in findings to the methods themselves rather than to variations in how the reviews were conducted. Similarly, a purely retrospective comparison of separately published reviews on the same topic might increase independence but would reduce the ability to examine methodological decision-making and practical implementation in detail. Conducting multiple synthesis methods within the same research programme therefore provided a consistent topic focus, shared contextual understanding, and comparable decision-making processes across the reviews, although the potential influence of the researcher's perspectives and methodological learning across the studies should be acknowledged when interpreting the comparative findings.

9.9 Considerations for future research

As noted above when newer evidence synthesis methods are applied in a new field, care should be taken in the publication to describe the methods used, adaptations required, and limitations of the method in that field. While guidance exists on which quantitative or qualitative method to select, guidance for mixed methods is lacking and out of date. This area would benefit from additional published guidance.

In addition, the revised evidence synthesis selection framework proposed in this thesis would benefit from further empirical testing in other policy contexts. While the framework has been applied here to compare systematic review, umbrella review and rapid realist review approaches in the context of healthcare regionalisation, additional studies applying the framework across different policy areas and research questions would help to assess its broader applicability and robustness. Such work would allow researchers to further refine the framework and validate whether the additional considerations identified in this thesis are consistently relevant when selecting evidence synthesis methods for evidence-informed policymaking.

9.10 Conclusions on healthcare regionalisation

This chapter has compared different evidence synthesis methods, specifically, a rapid realist review (Chapter 8) and an umbrella review (Chapter 5), to examine their suitability for informing health policy and system-level decision-making. Using healthcare regionalisation as an illustrative case, the thesis has generated insights not only on the relative strengths, limitations, and practical considerations of these synthesis approaches, but also on the mechanisms and contextual factors through which regionalisation may influence patient-centred care and generate both intended and unintended outcomes. Collectively, these findings highlight that healthcare regionalisation should be understood as a complex, contextually contingent intervention rather than a singular or uniformly applied policy reform, and they provide a foundation for reflecting on how evidence synthesis methods can be applied, adapted, and developed to better inform future health system research and policy decisions.

The umbrella review revealed significant challenges in synthesising existing evidence on the effects of regionalisation. Across the nine included systematic reviews, there was limited definitional coherence, and substantial heterogeneity in both the design of regionalisation reforms and the outcome measures employed. Very few reviews, aside from the realist review by Abimbola et al. (2019) and a context-specific synthesis by Rakmawati et al., (2019) were able to draw definitive conclusions, largely due to the limitations of primary data and a lack of methodological rigour in review design. This aligns with the findings of the realist review in this thesis, particularly in regard to the difficulties associated with capturing and interpreting the dynamic and context-sensitive effects of regionalisation.

The findings from the rapid realist review underscore the nuanced and multifactorial ways in which regionalisation can influence patient-centred care. Seven key mechanisms were identified, including ‘responsiveness to local needs and preferences’, ‘when all key providers, including GPs, are included within the RHO structure, they perceive themselves as jointly responsible for the patient

pathway’, and ‘regions function better when they serve the optimal population size’. These mechanisms interact with a range of contextual factors, such as fiscal constraints, rural-urban dynamics, and regional wealth disparities. The identification of these mechanisms highlights how regionalisation may generate both enabling and constraining effects on patient-centred outcomes, depending on how it is implemented and in what context. Notably, these findings build upon and extend theoretical contributions from prior realist work, such as Abimbola et al.’s notions of “voting with feet” and “close to ground,” by demonstrating how similar dynamics are embedded within decentralised health restructuring efforts.

The findings from both reviews converge on several important points. First, regionalisation should not be evaluated through methods derived from clinical trials of pharmaceutical interventions such as randomised controlled trials, as these overlook the complexity and contextual variability inherent in regionalised system. The lack of suitable methodological tools for synthesising evidence on large-scale system interventions, as observed in the reliance on tools such as AMSTAR 2, underscores the need for evaluation frameworks that are better attuned to complexity and context sensitivity. Second, the variation in regionalisation design across jurisdictions, often shaped by distinct political, historical, and fiscal legacies, complicates efforts to draw generalisable conclusions. Indeed, both the realist and umbrella reviews point to the necessity of adopting theory-driven, context-aware approaches to both the implementation and evaluation of health system reforms.

These findings have several implications for policymakers. First, the evidence suggests that any regionalisation effort must be underpinned by careful consideration of contextual factors, particularly local needs, existing infrastructure, and equity dynamics, to ensure alignment with desired patient-centred outcomes. Moreover, regional health organisations must be adequately resourced and empowered to respond to local variation, while also maintaining coherence with broader system-level goals.

In conclusion, this thesis has demonstrated that regionalisation is neither inherently beneficial nor detrimental to patient-centred care or broader health system performance. Its impacts are mediated by an interplay of mechanisms and contextual factors, many of which remain under-theorised and under-evaluated in the current literature. Future work should prioritise longitudinal, mixed-method studies that can trace the evolution of regionalisation efforts over time, and should aim to empirically validate the mechanisms proposed in this thesis. Only through such theoretically informed and empirically grounded research can we advance a more precise and actionable understanding of how, and under what conditions, regionalisation can contribute to more responsive, equitable, and sustainable health systems.

In the Irish context, as outlined in Chapter 2, health system reform has also been marked by fluctuating commitments to regionalisation. Historically, Ireland moved towards regionalisation, most notably through the establishment of Health Boards, but later moved towards centralisation through the establishment of the Health Service Executive. The most recent planned restructure, proposing six new regional health areas (as outlined in the Sláintecare) has been slow to materialise, with regions finally operating in 2025, eight years after the Sláintecare report was published. The findings of this thesis suggest that for regionalisation in Ireland to succeed, attention must be paid not only to governance structures, but also to the enabling mechanisms identified herein, including inter-provider cooperation, responsiveness to local needs, and appropriate scale of operation. Without these, regionalisation efforts risk reproducing existing inefficiencies or generating new disparities. Policymakers in Ireland have an opportunity to conduct a comprehensive, in-depth evaluation of regionalisation as it progresses, allowing changes to the programme to be made, and providing an understanding of healthcare regionalisation which can inform health reforms internationally.

9.11 Conclusions

This thesis demonstrates that using evidence synthesis methods, such as umbrella review and rapid realist review, for health policy research is feasible and can yield

valuable insights, but it requires careful consideration of method suitability, available resources, and the policy context. Successful application depends on both a thorough understanding of the health system under study and familiarity with the methodological approach, particularly for newer or less standardised methods such as rapid-realist review.

Drawing on the evidence synthesis selection framework developed by Wickremasinghe et al. (2016), this thesis applied and compared different synthesis approaches within a single policy case study. In doing so, it provides an empirical examination of how these methods perform when used to address complex policy questions in practice. The comparative analysis illustrates key trade-offs between speed, explanatory depth, and consideration of context, highlighting that no single method is universally optimal. In practice, the choice of synthesis method should be guided by the research question, the type of evidence required, and the needs of evidence users, including policymakers.

The findings of this thesis also suggest that while the Wickremasinghe framework provides a useful starting point for selecting evidence synthesis approaches, additional considerations may be required when applying the framework in real-world policy contexts. Drawing on the empirical insights generated through the case study of healthcare regionalisation, this thesis proposes refinements to the framework to better reflect the practical challenges of conducting policy-relevant evidence synthesis, including issues related to contextual complexity, resource constraints, and the need for timely outputs.

Overall, the expanded framework presented in this thesis provides a structured tool to support the selection and application of evidence synthesis methods. While further empirical testing in other policy contexts would be required to validate and refine these proposed updates, the findings of this research offer practical guidance for researchers and policymakers seeking to generate timely, relevant, and credible evidence for health system interventions.

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Appendix A. Interview schedule

Give your full name as researcher.

1 Identify self as researcher from at the University of Glasgow.

Give short explanation of purpose of the study:

Thank you for agreeing to help with this research. The aim of it is to understand the introduction of regional health organisations to Ireland. We are speaking with representatives from both the Department of Health and the HSE.

Do you have any questions about the privacy note, participant information sheet or consent form I sent in advance?

If at any time you want to stop the interview, or have a break, please feel free to let me know.

I will be recording the interview, to capture what we discuss more accurately.

Section	Question	Prompts
Basic background and contextual information	What is the purpose of introducing regional health areas?	Do you agree with this purpose? What problem or set of problems is it designed to correct?
	How will the individual regional health areas be financed?	Are financial resources distributed as a lump sum? Will there some kind of a resource allocation formula in operation?
Outcomes	What do you think are the likely outcomes of introducing regional health areas?	Record list of outcomes
	What impact do you think there will be on staff?	Will staff need retraining? Do you think there will be any impact on staff retention?
	Do you think the restructure will have budget implications (either positive or negative) for the Department of Health or HSE budget?	Will there be efficiency savings?

Section	Question	Prompts
	Do you anticipate any other economic changes at any level of the system?	What about value for money?
	Will the introduction of regional health areas impact the resources available in the health system?	Number of beds, waiting times?
	What changes for the community/Irish people might be expected because of the restructure?	Do you expect an impact on equity? What about patient centredness?
	Are any new activities/processes needed to bring about these outcomes?	What new activities will be required from healthcare staff? Will the HSE be required do anything differently? Will the Department of Health be required do anything differently? What needs are these activities designed to meet?
<i>*Record a shortlist of outcomes for later questions*</i>		

Section	Question	Prompts
<i>*Record a list of activities*</i>		
Inputs/resources	What resources are available to generate or support each of the aforementioned activities?	facilities, equipment, materials, personnel, money, and other resources
	Is there a gap between the resources necessary to operate the restructure and the currently available resources?	What is the size and nature of the gap? How will this gap be filled? If the gap cannot be filled, which restructure activities or components are in danger of being cut or curtailed?
Prioritising outcomes	How important to you is each of the outcomes on a scale ranging from “critically important” to “not very important?”	*note of outcomes from earlier in interview
	What are they HSE/Department of Health’s priority outcomes?	
Context	Are there any contextual factors that could affect the expected outcomes?	Are there likely events or circumstances that could affect the expected outcomes?

Section	Question	Prompts
		Under what conditions or circumstances do you think the restructure will work best? And Worst?
	Do you think the COVID-19 pandemic will have implications for the planned restructure?	In terms of overall design and outcomes to be achieved
Uncertainty	What uncertainties do you have about the regional health areas programme?	
Snowballing question	Can you name another person or people you think should be interviewed as part of this project?	
Close of interview	Are there any issues, you would like to mention which haven't been covered?	
	Thank the participant for their time	

Appendix B. Ethics approval



University
of Glasgow

Dear Professor Neil Hawkins

MVLS College Ethics Committee

Project Title *Evaluating the impact of regionalising healthcare systems*

Project No *200200004*

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study.

We are happy therefore to approve the project, subject to the following conditions.

- Project end date as stipulated in original application.
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research:
(http://www.gla.ac.uk/media/media_227599_en.pdf)
- The participant identifiable data (contact details) should only be held for as long as is needed for this study.
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any in-person research activity should adhere to local infection control guidance and will require authorisation from relevant departmental leads.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- For projects requiring the use of an online questionnaire, the University has an Online Surveys account for research. To request access, see the University's application procedure at
<https://www.gla.ac.uk/research/strategy/ourpolicies/useofonlinesurveystoolforresearch/>
- You should submit a short end of study report within 3 months of completion.

Yours sincerely

Dr Terry Quinn

Terry Quinn

FESO, MD, FRCP, BSc (hons), MBChB (hons)
Senior Lecturer / Honorary Consultant

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The University of Glasgow, charity number SC004401

Appendix C. Search strategies

MEDLINE

Database(s): Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) 1946 to November 20, 2020

Search Strategy:

#	Searches	Results
1	Meta-Analysis as Topic/	18613
2	meta analy\$.tw.	184992
3	metaanaly\$.tw.	2136
4	Meta-Analysis/	122607
5	(systematic adj (review\$1 or overview\$1)).tw.	186125
6	exp Review Literature as Topic/	14836
7	or/1-6	321357
8	cochrane.ab.	89921
9	embase.ab.	99479
10	(psychlit or psyclit).ab.	915
11	(psychinfo or psycinfo).ab.	38723
12	(cinahl or cinhal).ab.	30556
13	science citation index.ab.	3196
14	bids.ab.	548
15	cancerlit.ab.	632
16	or/8-15	162245
17	reference list\$.ab.	18564
18	bibliograph\$.ab.	18724
19	hand-search\$.ab.	7150
20	relevant journals.ab.	1202
21	manual search\$.ab.	4642
22	or/17-21	45071
23	selection criteria.ab.	31074
24	data extraction.ab.	22631
25	23 or 24	51355
26	Review/	2720486
27	25 and 26	29540
28	Comment/	879178
29	Letter/	1108915

30	Editorial/	547637
31	animal/	6705055
32	human/	18846027
33	31 not (31 and 32)	4725144
34	or/28-30,33	6560218
35	7 or 16 or 22 or 27	386028
36	35 not 34	366623
37	*"Delivery of Health Care, Integrated"/ or *"Delivery of Health Care, Economics"/	9587
38	exp *Models, Organizational/	6340
39	*National Health Programs/	20338
40	*Regional Health Planning/	3276
41	health administration.ti,ab.	6599
42	(better care fund\$ or Sustainability Transformation Plan\$ or vanguard\$).ti,ab.	879
43	local health integration network\$.ti,ab.	124
44	regional health authorit\$.ti,ab.	1073
45	local service network\$.ti,ab.	11
46	local service network\$.ti,ab.	11
47	(local health district\$ or local health network\$ or district health board\$).ti,ab.	1023
48	health board\$.ti,ab.	2191
49	health region\$.ti,ab.	2171
50	health authorit\$.ti,ab.	12836
51	care network\$.ti,ab.	2580
52	integrated network\$.ti,ab.	1065
53	integrated delivery.ti,ab.	1090
54	*regional health planning/ or health systems plans/ or *regional medical programs/ or *state health plans/	8742
55	regionali#ation.ti,ab.	3168
56	((regional or local or district or geographic) adj (organi#ation\$ or authorit\$ or network\$ or board\$ or (health adj1 board\$))).ti,ab.	6622
57	(decentrali#ation or devolution).ti,ab.	3312
58	regional operating model.ti,ab.	2
59	(population-based adj1 approach).ti,ab.	551
60	regional health planning.ti,ab.	50
61	Centrali#ation.ti,ab.	3367
62	*Health Care Reform/	22751
63	Health Planning Organizations/	892
64	regional integrated care.ti,ab.	8
65	or/37-64	108790
66	36 and 65	1474

Embase

Database(s): Embase 1947-Present, updated daily
Search Strategy:

#	Searches	Results
1	exp Meta Analysis/	202721
2	((meta adj analy\$) or metaanalys\$).tw.	245078
3	(systematic adj (review\$1 or overview\$1)).tw.	231885

4	or/1-3	410980
5	cancerlit.ab.	733
6	cochrane.ab.	116815
7	embase.ab.	126370
8	(psychlit or psyclit).ab.	1008
9	(psychinfo or psycinfo).ab.	36800
10	(cinahl or cinhal).ab.	36159
11	science citation index.ab.	3721
12	bids.ab.	714
13	or/5-12	197209
14	reference lists.ab.	20041
15	bibliograph\$.ab.	27898
16	hand-search\$.ab.	8780
17	manual search\$.ab.	5633
18	relevant journals.ab.	1436
19	or/14-18	57826
20	data extraction.ab.	27998
21	selection criteria.ab.	38007
22	20 or 21	63723
23	review.pt.	2716825
24	22 and 23	30459
25	letter.pt.	1156185
26	editorial.pt.	677276
27	animal/	1988201
28	human/	22915492
29	27 not (27 and 28)	1508947
30	or/25-26,29	3324892
31	4 or 13 or 19 or 24	491164
32	31 not 30	478268
33	*health care delivery/	60496
34	organizational efficiency/ or organizational structure/	3674
35	*public health service/	26934
36	*health care planning/	37073
37	health administration.ti,ab.	8099
38	(better care fund\$ or Sustainability Transformation Plan\$ or vanguard\$).ti,ab.	1097
39	local health integration network\$.ti,ab.	221
40	regional health authorit\$.ti,ab.	1344
41	local service network\$.ti,ab.	9
42	local service network\$.ti,ab.	9
43	(local health district\$ or local health network\$ or district health board\$).ti,ab.	1725
44	health board\$.ti,ab.	3514
45	health region\$.ti,ab.	2853
46	health authorit\$.ti,ab.	17478
47	care network\$.ti,ab.	3752
48	integrated network\$.ti,ab.	1404

49	integrated delivery.ti,ab.	1389
50	*health care planning/	37073
51	*"organization and management"/ or *decentralization/	63430
52	*regionalization/	1215
53	regionali#ation.ti,ab.	3991
54	((regional or local or district or geographic) adj (organi#ation\$ or authorit\$ or network\$ or board\$ or (health adj1 board\$))).ti,ab.	9325
55	(decentrali#ation or devolution).ti,ab.	3970
56	regional operating model.ti,ab.	2
57	(population-based adj1 approach).ti,ab.	770
58	regional health planning.ti,ab.	67
59	Centrali#ation.ti,ab.	5142
60	regional integrated care.ti,ab.	6
61	or/33-60	243984
62	32 and 61	3634

Appendix D. List of excluded studies

Adinolfi, P. 2014 Barriers to reforming healthcare: the Italian case

Alves 2013 Efficiency and equity consequences of decentralization in health: an economic perspective

Bambra, C., Garthwaite, K. and Hunter, D. 2014 All things being equal: does it matter for equity how you organize and pay for health care? A review of the international evidence

Barasa, E., Mbau, R. and Gilson, L. 2018 What Is Resilience and How Can It Be Nurtured? A Systematic Review of Empirical Literature on Organizational Resilience

Barry, S. P., Diarra-Nama, A. J., Kirigia, J. M., Bakeera, S. and Somanje, H. 2009 Monitoring and evaluation of health sector reforms in the WHO African Region

Borrell, C., Peiro, R., Ramon, N., Pasarin, M. I., Colomer, C., Zafra, E. and Alvarez-Dardet, C. 2005 Socioeconomic inequalities and health plans in the Autonomous Communities of Spain. [Spanish]

Bretas, N. J. and Shimizu, H. E. 2017 Theoretical reflections on governance in health regions

Bywood 2016 Regionalisation of health services: Benefits and impact. PHCRIS Policy Issue Review. Adelaide: Primary Health Care Research & Information Service.

Bywood 2016 Regionalisation of health services: Benefits and impact

Calderon, C. A. A., Botero, J. C., Bolanos, J. O. and Martinez, R. R. 2011 The Colombian healthcare system: 20 years of achievements and problems

Ciccone 2014 "Linking governance mechanisms to health outcomes: A review of the

literature in low- and middle-income countries"

Duarte, C. M. R. 2007 Health policy effects on infant mortality trends in Brazil: A literature review from the last decade. [Portuguese]

Emamgholipour 2018 Analysis of Health System Decentralization Outcomes on Governance and Justice in Health: Updating Regular Review Studies

Galetto 2017 Organised decentralisation, uneven outcomes: employment relations in the Italian public health sector

Ghuman; Singh 2013 Decentralization and delivery of public services in Asia

Herrera, C. A., Lewin, S., Paulsen, E., Ciapponi, A., Opiyo, N., Pantoja, T., Rada, G., Wiysonge, C. S., Bastias, G., Garcia Marti, S., Okwundu, C. I., Penaloza, B. and Oxman, A. D. 2017 Governance arrangements for health systems in low-income countries: an overview of systematic reviews

Hinings 2004 2004 Regionalizing Healthcare in Alberta: Legislated Change, Uncertainty and Loose Coupling

Koornneef, E., Robben, P. and Blair, I. 2017 Progress and outcomes of health systems reform in the United Arab Emirates: a systematic review

Kurji, Z., Premani, Z. S. and Mithani, Y. 2016 Analysis Of The Health Care System Of Pakistan: Lessons Learnt And Way Forward

Maenpaa, T., Suominen, T., Asikainen, P., Maass, M. and Rostila, I. 2009
The outcomes of regional healthcare information systems in health care: a review of the research literature

- Mbau, R. and Gilson, L. 2018 Influence of organisational culture on the implementation of health sector reforms in low- and middle-income countries: a qualitative interpretive review
- Regmi, K., Naidoo, J., Greer, A. and Pilkington, P. 2010 Understanding the effect of decentralisation on health services: the Nepalese experience
- Rockers, P. C. and Bärnighausen, T. 2013 Interventions for hiring, retaining and training district health systems managers in low- and middle-income countries
- Saltman 2007 Decentralization in health care
- Santos, T. B. S., Moreira, A. L. A., Suzart, N. A. and Pinto, I. C. M. 2020
[Hospital management at Brazil's National Health System: challenges in the study of health policies, planning and management]
- Shaikh, B. T. and Hatcher, J. 2007 Health seeking behaviour and health services utilization trends in National Health Survey of Pakistan: What needs to be done?
- Vargas-Lorenzo, I., Luisa Vazquez-Navarrete, M. and Mogollon-Perez, A. S. 2010 Access to health care in Colombia
- Bayat, M.; Kashkalani, T.; Khodadost, M.; Shokri, A.; Fattahi, H.; Ghasemi Seproo, F.; Younesi, F.; Khalilnezhad, R. 2023 Factors Associated With Failure of Health System Reform: A Systematic Review and Meta-synthesis
- Sapkota, S.; Dhakal, A.; Rushton, S.; van Teijlingen, E.; Marahatta, S. B.; Balen, J.; Lee, A. C. 2023 The impact of decentralisation on health systems: a systematic review of reviews
- Pfisterer-Heise, S.; Scharfe, J.; Kugler, C. M.; Shehu, E.; Wolf, T.; Mathes, T.; Pieper, D. 2023 Protocol for the development of a core outcome set for studies on centralisation of healthcare services

Appendix E. Additional data tables

Table A 1 Breakdown of study designs included in reviews

Study ID	N included studies and breakdown of included study designs
Sumah 2016	N=9 all quantitative 6 studies comparative secondary data analysis (survey data) and 3 studies comparative secondary data analysis (survey data) and primary analysis
Cobos- Munoz 2017	N=54 11 qualitative studies, 28 quantitative studies and 15 mixed methods studies. Quantitative; Before and after with control n=4, Cross sectional study n=9, Interrupted time series n=15. Mixed; Document review, analysis of secondary data n=5, Document review, Key informant interview, analysis of secondary data n=4, Key informant interview and analysis of secondary data n=2, Survey, Key informant interview n=2, Survey, Key informant interview and Focus group discussion n=2. Qualitative; Document review n=2, Document review and key informant interview n=3, Key informant interview n=6, Key informant interview and focus group discussion n=1.
Mello 2017	N=26 Analysis of secondary data=2 Qualitative case study=16 Document analysis=1 Document analysis and analysis of secondary data=1 Experience report=1 Quantitative and qualitative case study=5
Zon 2017	N=21 The majority of the publications (16/21) use data from qualitative case studies that combine reports review and qualitative field survey. Other designs used are qualitative field surveys only (3/21), and literature review only (2/21). In the majority of the publications (15/21), the study

Study ID	N included studies and breakdown of included study designs
	population and sampling method are clearly defined. However, in few publications (6/21), the sample size is lacking or is not clearly specified/ defined.
Dwicaksono 2018	N=16 The studies used cross-sectional analysis (n = 3) or longitudinal analysis (n = 13); of the latter, 11 were based on panel data and 2 were based on repeated cross-sectional. Of the 16 studies, 4 employed individual-level analysis using individual or household data from survey data whereas the remaining studies used the ecological analysis approach
Abimbola 2019	N=51 Individual study designs are not reported. Likely due to the method of synthesis. Did include multiple case studies
Rakmatiwati 2019	N=29 Cross-sectional studies were conducted in 21 articles, one study performed modelling predictive method and seven articles did not clearly specify the study design. Although all the selected studies provided research questions relevant to this review, only 21 studies performed quantitative analyses.
Quigley 2019	N=57 Quantitative comparison before and after regionalisation = 14, regression analysis before and after regionalisation = 9, qualitative case study = 5, mixed methods case study = 9, mixed methods = 6, quantitative comparison different regions = 4 qualitative multiple case studies = 1, qualitative = 3, regression analysis between different regions = 1, Quantitative comparison different regionalisation models = 1, Regression analysis before and after regionalisation, and different regions = 1, Quantitative survey = 3
Ramos 2020*	N=39 11 distinct methods were identified. The most frequent method was the regression model, in general, with 58.97% (n = 23). The regression models varied between simultaneous, Poisson, linear, generalized linear equations with Poisson error

Study ID	N included studies and breakdown of included study designs
	structure, logistical, logistical and linear, hierarchical, multiple and Cox multivariate logistics. Ecological and cross-sectional studies [40, 49, 51] add up to 7.69% each (n = 3) and quasi-experimental studies [44, 45] accounted for 5.12% (n = 2). The methods of cost-utility analysis [18], proportional risk survival analysis [28], cost-effectiveness analysis [23], cost analysis [50], Propensity score [41], multiple comparison test [34], cohort [39] and Data Envelopment Analysis [26] totalled 2.56% of the studies, each.

Table A 2 Additional information main findings

Study ID	Countries included	Outcomes studied	Person/patient related findings (including equity)	System related findings
Sumah 2016	high-, low- and middle-income countries	equity	Depending on context, decentralisation could either lead to equity gains or exacerbate inequities. The impact of decentralisation on inequities in health and health care depends on pre-existing socio-economic disparities and financial barriers to access. While decentralisation can lead to inequities in health financing between sub-national jurisdictions, this is minimised with substantial central government transfers and cross subsidisation.	not reported
Cobos-Munoz 2017	low and middle income countries	Six WHO building blocks	23/26 measures for general health found a positive effect with decentralisation. Quantitative studies estimating mortality outcomes consistently reported positive effects of decentralization on adult, child, and maternal mortality. Qualitative studies showed positive and negative outcomes of	There were positive and negative effects of decentralization of health systems in LMICs. Whereas decentralization of governance, financing and service delivery, have been shown to have positive effects on the system; decentralization of resource management has been challenging in several settings. Overall, lessons learned from

			decentralization. Negative aspects identified included corruption at a local level.	LMICs suggest that factors such as adequate mix of technical skills at the local level to perform decentralized tasks, effective decentralization of decision-making to the periphery, and political leadership are key factors for a successful decentralization. Whereas quantitative data consistently showed positive effects, qualitative studies painted a more heterogeneous picture of the impact of decentralization.
Mello 2017	Brazil	Factors that support or hinder regionalisation processes.	N/A	N/A
Zon 2017	Sub-Saharan Africa	Financing and resources allocations, Services organization and management,	Not reported.	Financing and resources allocations: Mixed impact on resource allocation. In some countries lack of financing means some precision of medical care has fallen short of local needs. In some countries, care has moved from primary to secondary care (curative services). Services organization and management:

		Human resources and capacity building, Governance at local level, Use of services	Little evidence on declining attention being paid to primary health care in favour of hospitals or unsustainable civil works. Human resources and capacity building: Greater evidence on the potential benefits of decentralization: improvements in training and capacity building, supervision and attention to primary health services, availability of district funds. Decentralization reforms have resulted in more effective utilization of local information in the recruitment of health workers, ensuring better planning according to need. Governance at local level: Established bodies (local government ward and village decentralization bodies) had been very useful in facilitating community participation in the control of infectious diseases. Provision of the opportunity for the grassroots community to be involved in the planning process There is a better community participation in the improvement of health care quality.

				Use of services Use of curative care was associated with the progression of the decentralization process; there was a general increase in patient attendance in hospital. EPI coverage decreased to <53% compared with the pre-decentralization national average of 80% in the 1990s; decline in the number of EPI supervisory and delivery visits. There is a significant decline in EPI coverage (DPT3) that cannot be clearly attributed to decentralization. There was relatively little impact of decentralization on the utilization of outpatient services.
Dwicak sono 2018	low- and middle-income countries	Quantifiable health indicators: Health system inputs (eg, financial, human, and	The impact of decentralization on health outcomes seemed to show consistently beneficial effects. There were 7 studies whose outcome variables were classified in the health outcomes domain. More than half of the studies reported beneficial effects of decentralization in reducing infant and postnatal mortality. Two studies did	Health system inputs: 2 of the 3 studies showed adverse effects of decentralization on resource allocation, and 1 study did not find significant effects of decentralization on corruption. Potentially beneficial effects of decentralization on health system inputs seem to be substantially

		physical resources), Health system performance (eg, changes in service utilization), Health outcomes (eg, infant mortality rates)	not find significant associations. Interestingly, 2 studies from Brazil and another 2 studies from China reported contradicting results between them.	conditioned by the presence of effective governance mechanisms that enable responsiveness to local needs and values. Health system performance: Investigated in 7 studies and showed mixed findings. Two studies showed beneficial effects, 3 studies showed mixed results 1 study showed harmful effects, and 1 study showed no significant effects.
Abimbola 2019	high-, low- and middle-income countries	Equity, efficiency, resilience	Inter-jurisdiction equity: wealthier sub-national jurisdictions increase their health budget post-decentralisation and poorer jurisdictions less so, or even experience a decline in their health budget. Intra-jurisdiction equity: lower level jurisdiction governments spend closer to home (i.e.) seats of government in more urban capitals) and more on curative than pro-equity preventive services to generate revenue.	efficiency: cross-border movement of patients from poorer to wealthier jurisdictions means that the latter are able to maximise use of their resources, while the former loses out by paying the former to treat their residents. pro-equity spending (e.g. on prevention) lead to efficiency gains, as is the ability to be responsive to local circumstances retention and reduced absenteeism that result from the local hiring of staff.

			equity: generating funds and making spending decision locally leads to more pro-equity spending and greater retention of staff (albeit only low skilled staff) but nepotism can lead to hiring low-quality staff. 'watching the watchers': equity: higher level governments may hold lower level sub-national governments to account for equity	higher level governments may hold lower level sub-national governments accountable for efficiency, and community groups may hold sub-national governments and health providers to account for efficiency. Resilience: difference centres of governance (e.g. community groups and different levels and arms of government) may step in to ensure services are delivered if one centre, level or arm of governance fails.
Rakma wati 2019	Indonesia	Health level, equity, responsiveness, financial protection, efficiency	Health level and equity: inequity in child immunization completeness, inequity in accessing maternal health services, higher maternal mortality rate among the poor, higher infant mortality rate among the poor. Responsiveness: later response from maternal health providers, low responsiveness in malaria referral diagnostics. Financial protection: out of pocket payment still exists among insurance holders, higher financial burden for the poor.	Efficiency: dependency on central government fund

Quigley 2019	OECD countries	Utilisation of resources, Health and care outcomes, Efficiency, Equity, Patient flow, Cost and cost-effectiveness, Staff work experience, Perceived quality of care received and supplied, Public trust	Regionalisation can result in reductions in acute hospital resource use without negatively affecting overall care outcomes such as mortality.	The long-term cost implications are heavily context dependent. There is an indication that a regionalised healthcare system can be an efficient system, however, careful consideration must be given to what resources are provided in each healthcare setting including acute, primary, community and social care settings.
Ramos 2020*	high-, low- and middle-income countries	Primary: any health outcome (mortality rate, infant mortality rate, preventable	-3 studies found that there was increased provision of healthcare at a regional level following decentralisation effect, 1 study found there with mixed evidence on healthcare at a regional level. -Decentralisation allowed users should have full	Decentralisation had the effect of increasing the efficiency of a provincial health organization, i.e. patients coming from other provinces in Italy, inside and outside the region, as they used the inputs that would otherwise be underemployed. (one study)

		mortality rate, ambulatory care-sensitive conditions, quality of life, comorbidity) and secondary: any effect on management (governance arrangements; financial arrangements; service delivery arrangements; implementation interventions)	freedom of choice on whether to be served by public or private service. (one study) -One study found a mixed impact for fiscal decentralisation on infant mortality rate and increase in life expectancy at birth, the study had issues with separating the intervention effect from the regional context. -There was a significant decline in vaccination coverage rates after decentralisation but the study was not controlled for confounding factors.	One study found that decentralisation has a significant negative impact on health efficiency if it does not take into account regional characteristics of the population and structure of the health system.

*Included both whole health system regionalisation and regionalisation of specific health system aspects. Results for whole health system regionalisation only are used when they were reported separately in the original paper.

Table A-4 Recommendation for future research

Study ID	Recommendation
Sumah 2016	• Further research should look at comparative country study of decentralised and centralised national health systems taking into consideration the methodological issues highlighted in this and previous studies. • The findings of this review also highlight that decentralisation does not represent one single process but rather many complex and interconnected set of processes. It should therefore be implemented and evaluated as a complex intervention for which outcomes are neither straightforward nor predictable, but dependent on pre-existing socio-economic and institutional context.
Cobos Munoz et al. 2017	• New evidence be generated using more robust study designs, but the standard approach for medical research would be inappropriate for assessing the impact of health system decentralization for various reasons: ○ The complex nature of decentralization as an intervention and the range of outcomes that interest policymakers would be difficult to capture in quantitative study designs. ○ Health systems interventions are affected by numerous contextual factors and their effects are the result of the dynamic interaction of multiple subsystems. ○ Policy and decision makers would be interested not only in the effects of decentralization, but also in how and why such interventions had this impact
Mello 2017	None reported.
Zon 2017	Future research needs to explore the use of financial resources by local government, factors that drive local decision-making processes and the effects of decentralization on health sector performance. Moreover, our review of the discussions on validity and reliability of the studies presented in the publications, suggest limitations of some study designs and methods, which prevent very specific generalizations based on this review. To enlarge the knowledge base on decentralization in health care, which is particularly absent in Sub-Saharan Africa, and to provide evidence useful for policymaking in this region, attention should be paid to a systematic and rigorous evaluation of related policy

	interventions. Such approach should make use of theoretical conceptualizations of decentralisation, as well as experience with decentralization evaluation in other developing countries.
Dwicaksono 2018	• Future research is still needed to build our understanding of how decentralization can deliver beneficial results. • The findings of this review support the call for developing a more discrete definition of decentralization that focuses on specific processes that are being decentralized and their interactions as opposed to generalized definitions of decentralization. Bossert's "decision space" approach can provide a framework for analyzing decentralization in terms of the range of choice or discretion owned by the local officials over various government functions. This framework can assist researchers to determine key aspects of decentralization that may contribute to changes in performance and outcomes under decentralization. • Future research also needs to build understanding about various institutional and governance conditions that are essential for decentralization to deliver beneficial results. • Decentralization itself may also be viewed as an important background context with future research focused on how institutional designs and changes following decentralization may contribute to outcomes.
Abimbola 2019	• Future studies should adopt a systematic approach to reporting context. • Further research should explore how to build institutional capacity to facilitate positive effects of decentralization, the links between the contextual factors and the mechanisms identified in this review; and the circumstances in which decentralization may work in different settings.
Quigley 2019	• Future primary publications should be designed to mitigate the influence of confounders on their study results. • Need longer follow up in studies. • Social and community setting needs more data.
Rakmawati 2019	• The service delivery, health workforce, and health financing blocks should be prioritized for further research and policy evaluation to improve the overall health system performance at the district level.
Ramos 2020*	• Conducting RCTs would help to more accurately estimating the effects of regionalisation. • These interventions should be investigated in low- and middle-income countries.

- Research is needed on the impacts for system users outside of the hospital.
- Governance and service arrangements should be evaluated in primary studies.

*Included both whole health system regionalisation and regionalisation of specific health system aspects. Results for whole health system regionalisation only are used when they were reported separately in the original paper.

Appendix F. AMSTAR 2 critical appraisal

Item	Ramos 2020	Mello 2017	Quigley 2019	Abimbola 2019	Rakmawa ti 2019	Dwicakso no 2018	Zon 2017	Cobos- Munoz 2017	Suamh 2016
1. Did the research questions and inclusion criteria for the review include the components of PICO?	yes	no	yes	no	no	partial yes	no	no	no
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the	yes	no	no	no	no	no	no	no	no

review and did the report justify any significant deviations from the protocol?									
3. Did the review authors explain their selection of the study designs for inclusion in the review?	yes	yes	no	no	no	yes	yes	no	no
4. Did the review authors use a comprehensive literature search strategy?	Partial yes	no	partial yes	no	No	no	no	no	no
5. Did the review authors perform study selection in duplicate?	yes	yes	yes	no	no	no	no	no	yes
6. Did the review authors perform data extraction in duplicate?	yes	yes	yes	yes	no	no	no	no	no
7. Did the review authors provide a list of excluded studies and justify the exclusions?	yes	no	yes	no	no	partial yes	no	partial yes	no

8. Did the review authors describe the included studies in adequate detail?	no	partial yes	yes	no	no	partial yes	partial yes	partial yes	no
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	yes	no	yes	no	partial yes	yes	no	yes	no
10. Did the review authors report on the sources of funding for the studies included in the review?	no	no	no	no	yes	no	no	no	no
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A	N/A	yes	N/A	N/A	N/A	N/A	N/A	N/A
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A	N/A	yes	N/A	N/A	N/A	N/A	N/A	N/A

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	yes	no	yes	no	no	yes	no	yes	no
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	no	yes	yes	no	no	yes	yes	yes	yes
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A	N/A	no	N/A	N/A	N/A	N/A	N/A	N/A
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	yes	no	no	yes	Yes	yes	yes	yes	yes

[illegible]

Appendix G. Participant information sheet



University of Glasgow | College of Medical,
Veterinary & Life Sciences

PARTICIPANT INFORMATION SHEET

Evaluating the impact of regionalising healthcare systems

You are being invited to take part in a research study. Before you decide whether to take part in the study, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully.

1. What is the purpose of the study?

The Sláintecare Report of 2017 outlined a ten-year strategic plan to transform how healthcare is delivered in Ireland. Major changes in terms of system overhaul, infrastructure development, improved access and increased accountability were mandated. A core component of this health system reform is the regionalisation (moving responsibility to regional bodies) of the Irish healthcare system.

The overall aim of this PhD project is to determine the likely impact of introducing healthcare regionalisation, as described by the Irish policy documents and policymakers, into a healthcare system.

This part of the study involves gaining insights from key individuals involved in the implementation of the regionalisation policy in Ireland. The data gathered through the interviews will help to define regionalisation in the Irish context, so that only learnings from other countries, which are transferable to the Irish setting, will be collected in a subsequent literature review.

2. Why have I been invited to participate?

You are being asked to take part because, in your role, you have responsibility for implementing some part of the regionalisation policy. You will be one of approximately 15 interviewees.

You can only be in this study if you:

- have been working in the Department of Health or HSE for at least one year,
- are working in a division that will be directly involved in planning the restructure such as the Sláintecare office, operations or strategy and planning,
- are in a management level position (at least higher executive office or grade VII level), or
- are from the HSE's central division rather than a hospital group or a community healthcare organisation.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part.

4. What will happen if I take part?

Interviews via Zoom will take place at a time and location convenient for you. We will start by going over the consent form which you received with this leaflet, to ensure that it is signed. We will then start the discussion. This will be recorded, so that a transcription of the discussion can be typed, at which point all identifying details will

be removed. If you do not want the interview to be recorded, the researcher will take written notes instead.

We want to explore your thoughts on how regional healthcare bodies will be introduced in Ireland and identify any factors which may influence the successful implementation of the policy. Overall, we expect the interview to take approximately 1 hour of your time.

5. What do I have to do?

If you do decide to take part, please contact the researcher Joan Quigley (details overleaf), either by phone or email. You will then have the opportunity to discuss the study further, and to make any practical arrangements for the interview or focus group to take place.

6. What are the possible disadvantages and risks of taking part?

This study will require one hour of your time. There are no identifiable risks to you taking part in this study.

7. What are the possible benefits of taking part?

The information that is collected during this study will give us a better understanding of healthcare regionalisation in Ireland. There may be no direct benefit for you from taking part in this study.

8. Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Please note that assurances on confidentiality will be strictly adhered to unless evidence of serious harm, or risk of serious harm, is

uncovered. In such cases, the University may be obliged to contact relevant statutory bodies/agencies.

9. What will happen to my data?

Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).

10. What will happen to the results of the research study?

The information collected will be used to inform the literature review, which will examine the likely impact of introducing healthcare regionalisation, as described by the Irish policy documents and policymakers, into a healthcare system. We plan to publish the results in relevant peer-reviewed journals, so that other researchers can learn from the study. Anonymised quotes may be used to support any such articles. All information used will be anonymised so that any report or journal articles published will not identify you or any other individual taking part.

11. Who is organising and funding the research?

The study is being conducted by researchers at the University of Glasgow. The Health Research Board in Ireland is the sole funder for this study.

12. Who has reviewed the study?

This project has been reviewed by the College of Medical, Veterinary & Life Sciences Ethics Committee.

13. Contact for Further Information

Joan Quigley

Health Economics and Health Technology Assessment

University of Glasgow

1 Lilybank Gardens

Glasgow G12 8RZ

Telephone:

Email: j.quigley.2@research.gla.ac.uk

Thank you for reading the Information Sheet

Appendix H. Consent form



University of Glasgow | College of Medical,
Veterinary & Life Sciences

Title of Project:

Evaluating the impact of regionalising healthcare systems

Name of Researchers: Joan Quigley, Dr Hilary Thomson and Professor Neil Hawkins.

CONSENT FORM

Please initial
box

I confirm that I have read and understand the information sheet dated 28/09/2020 (version 1) for the above study and have had the opportunity to ask questions.

I confirm that I have read and understood the Privacy Notice dated 28/09/2020 (version 1)

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University archiving facilities in accordance with relevant Data Protection policies and regulations.

I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project.

☐

I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study.

☐

I agree to take part in the study.

☐

I agree to my interview being recorded.

☐

I understand that the recorded interview will be transcribed word by word and the transcription stored for up to ten years in University archiving facilities in accordance with Data Protection policies and regulations.

☐

I understand that my information and things that I say in an interview may be quoted in reports and articles that are published about the study, but my name or anything else that could tell people who I am will not be revealed.

☐

Name of participant Date Signature

Name of Person taking consent Date Signature

(if different from researcher)

Researcher Date Signature

(1 copy for participant; 1 copy for researcher)

Appendix I. Privacy note

Privacy Notice for 'Evaluating the impact of regionalising healthcare systems'

Your Personal Data

The University of Glasgow will be what's known as the 'Data Controller' of your personal data processed in relation to interviews conducted for the project 'Evaluating the impact of regionalising healthcare systems'. This privacy notice will explain how the University of Glasgow will process your personal data.

Why we need it

We are collecting your basic personal data such as name, contact details, and your views on the planned Irish healthcare system restructure. We will conduct interviews to determine a theory of change for how moving to regionalised healthcare organisation might work. We will only collect data that we need in order to provide and oversee this function.

Legal basis for processing your data

We must have a legal basis for processing all personal data. In this instance, the legal basis is public task as well as consent.

What we do with it and who we share it with

- *All the personal data you submit is processed by staff at the University of Glasgow in the United Kingdom.*
- *Data will be stored on a secured server only.*
- *All interview transcripts will be anonymised after they are checked for accuracy.*

How long do we keep it for

Your contact data will be retained by the University until the interviews have taken place and the interviews transcribed, at this point the contact information will be destroyed as well as the video recordings. Anonymised interview transcripts will be retained for ten years after study completion in line with University policy. After this time, data will be securely deleted.

What are your [rights](#)*

You can request access to the information we process about you at any time. If at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected or, erased. You may also have the right to object to the processing of data and the right to data portability.

Where we have relied upon your consent to process your data, you also have the right to withdraw your consent at any time.

If you wish to exercise any of these rights, please submit your request via the [webform](#) or contact dp@gla.ac.uk.

*Please note that the ability to exercise these rights will vary and depend on the legal basis on which the processing is being carried out.

Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the University Data Protection Officer who will investigate the matter.

Our Data Protection Officer can be contacted at

dataprotectionofficer@glasgow.ac.uk

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner's Office (ICO) <https://ico.org.uk/>

☐ I consent to the University processing my personal data for the purposes detailed above.

I have read and understand how my personal data will be used.

Signed:

.....
.....

Date:

.....
.....

Appendix J. Patient-centred care search and definitions

Final search

Ovid MEDLINE(R) ALL <1946 to May 11, 2023>

- 1 (concept\$ or definition\$ or dimension\$ or multidimensional or measure\$ or evaluat\$).ti,ab. 8320864
- 2 (Review or overview or synthesis).ti,ab. 3061093
- 3 (Patient centred care or patient centered care or person centred care or person centered care).ti. 2375
- 4 *Patient-Centered Care/ 13704
- 5 3 or 4 14536
- 6 1 and 2 and 5 858
- 7 limit 6 to (english language and yr="2014 -Current") 593

Full definitions

Table A 3

Dimensions	Definition of dimension
<i>Mørup-Lanberg 2019</i>	
Sharing power and responsibility	Sharing power and responsibility are dependent on informing the patient properly and encouraging the patient to take part in medical decisions. This should lead to greater adherence to and, in turn, more successful treatment. An obvious obstacle to complete egalitarianism is the “competence gap” and a built-in knowledge asymmetry between patient and physician. However, egalitarianism is seen as the aspiration to promote “a shift in doctor-patient relations from the ‘co-operation-guidance’ model

	(analogous to a parent-child relationship) to 'mutual participation' (analogous to a relationship between adults), where power and responsibility are shared with the patient.
Therapeutic alliance	The therapeutic alliance in the relationship between doctor and patient has a value of its own. An accommodating and cooperative relationship, the so-called alliance, might increase patient adherence, whereas an unresponsive or negative relationship might reduce the chances of successful treatment.
Patient-as-person	Patient-as-person means that the influence of an impairment of function could have different consequences, depending on the demands the impairment puts on the patient. Therefore, the patient's current life situation is another factor to take into consideration. The patient-as-person dimension embraced the individuality of each patient's different experiences of illness.
Biopsychosocial	The biopsychosocial perspective involved broadening the view of a patient's illness from a strictly biomedical perspective to one that included a wider range of influences, such as social and psychological factors, which the physician should take into consideration when seeing a patient. The biopsychosocial perspective was described as

	affecting illness on three mutually interacting hierarchical levels: biological, psychological and social, and to treat the patient it was necessary to explore all three levels in the consultation.
Doctor-as-person	As with any relationship, both parties influence each other through interaction. This dimension highlights the importance of being aware that the mind-set, mood and personality of the physician affect the ongoing relationship with a patient and the choices made during a consultation.
Coordinated care	It addressed the need for coordination and integration of the different segments of a patient's care-plan. This dimension was described as: "accessibility of care", "coordination", and "continuity". Some authors referred to coordinated care as: "The delivery of services by different care providers in a timely and complementary manner in order to achieve connected and cohesive patient care. Coordinated care was expected to result in a more continuous, healing and hassle-free experience of the care pathway for the patient. Promotion of this dimension was described as reducing unnecessary usage of healthcare resources, thereby making healthcare more integrated and accessible as well as more cost effective

Sturgiss 2022	
1. Sharing power	Between the patient/client and the practitioner
a) Seen as equals	Balance in the consultation; not 'paternalistic'; reduced medical authority; symmetrical relationship; mutual participation-have similar meaning, but the word 'power' is not used
b) Empowerment	Not defined
2. Sharing responsibility	Between the patient/client and the practitioner, includes collaboration, working together on tasks, each person having their own tasks to be responsible for
3. Therapeutic relationship/bond/alliance	Includes factors of empathy, respect, trust, rapport
a) Compassion	Not defined
b) Emotional engagement	Specifically recognises the emotional needs of the individual including emotional support, attending to the emotions of the patient
4. Patient as a person	Concerned with understanding the individual's experience of illness; seeing the patient as more than just their 'disease' or problem; includes the personal meaning that people bring to illness; the importance of eliciting each patient's expectations, feelings and fears about the illness; strive to

	understand the patient as an idiosyncratic personality within their unique context
a) Person as part of a collective	Recognising that an individual is part of a larger community-for example, family, community, cultural group - and that this impacts management
b) Spirituality, cultural needs	Recognising that the patient has spiritual needs that should be considered, these could be related to religious, cultural or other practices
c) Comprehensive care	Includes care of the 'whole person', including 'holistic care'
d) Strengths based	Recognising and building on the strengths of the individual/family/focus of care
5. Biopsychosocial	Considering the complete picture of biological, social and psychological issues; it is about the issue that the patient/person is presenting with, rather than about its management
a) Social determinants of health	Factors such as housing, employment, poverty and minority status influence both the disease and the participation in treatment

6. Provider as a person	The influence of the personal qualities of the provider; recognising that the practitioner is also a person with multiple facets
a) Professional clinical responsibilities	The clinician involved in the encounter has a set of professional responsibilities that need to be integrated into the approach to the patient
b) Advocate for the patient	The clinician has a role outside the consultation to advocate for the needs of the patient
7. Co-ordinated care	Care provided by a broader team that requires coordination
8. Access	This is the ability of the patient to access care and will have different specifics depending on the level of analysis (person/practice/discipline/system): could include physical access to care; appointment systems (level of the practice); consultation specific issues, for example, language and translation
9. Continuity of care	Care provided by a clinician/team/system that is familiar with the patient's story; includes longitudinal care, care provided over time
Scholl 2014	

Essential characteristics of the clinician	A set of attitudes towards the patient (e.g. empathy, respect, honesty) and oneself (self-reflectiveness) as well as medical competency. Definitions of patient-centeredness described various qualities that a clinician should have, e.g., being respectful, empathic, tolerant, honest, accountable, compassionate, and committed to the patient. Furthermore, a patient-centred clinician should be self-reflective (e.g. being aware of own emotional responses) and show limited self-disclosure. These qualities should go hand in hand with professional expertise, commitment to evidence based practice, and knowledge of basic psychological skills.
Clinician-patient relationship	A partnership with the patient that is characterized by trust and caring. In the analysed literature the clinician-patient relationship is described as central for patient-centred care, by building a partnership with the patient through collaboration. The importance of a reciprocal relationship that is characterized by constancy, trust, connection, mutual caring, mutual knowledge, positive rapport building, guidance as well as mutual understanding of roles and responsibilities is highlighted.

Patient as a unique person	Recognition of each patient's uniqueness (individual needs, preferences, values, feelings, beliefs, concerns and ideas, and expectations). Another dimension that emerged from analysing the definitions of patient-centeredness highlights the importance of each patient's uniqueness. This includes eliciting each patient's individual needs, preferences, values, feelings, beliefs, concerns, ideas, and expectations as well as exploring both the patient's disease and illness experience, the impact on functions (e.g. the patient's idea of how the illness affects his or her daily life; effects of the illness on the patient and his or her family), and his or her individual explanatory model. This also entails providing care that is tailored to each specific patient.
Biopsychosocial perspective	Recognition of the patient as a whole person in his or her biological, psychological, and social context. The dimension biopsychosocial perspective involves understanding the patient's illness within a broader framework by exploring the patient with his or her unique biological, psychological, and social context. This means trying to understand the whole person (e.g. life history, personal and developmental issues), the proximal context (e.g., family, employment, social support, financial situation), as well as the distal context (e.g. cultural background,

	community, ecosystem) and focusing on the patient's quality of life. In some definitions this entails that the clinicians also feels responsible for non-medical aspects of problems and is involved in the full range of difficulties that the patient brings up.
<i>Sidani 2014</i>	
Component 1: holistic care	Holistic care refers to comprehensive care that encompasses all domains of health (i.e. biophysical, cognitive, emotional, behavioral, social and spiritual), and addresses health promotion, and illness prevention and management. The goal is to attend to all needs that patients have at the time of a particular healthcare encounter or may experience over time. Holistic care involves the assessment of patients' conditions and the provision of interventions and services that target the totality of patients' conditions.

Component 2: collaborative care	Collaborative care consists of a partnership between the healthcare professional and the patient that aims to facilitate patients' participation in making care-related decisions and in carrying out treatment or self-management recommendations. Collaborative care involves a process of shared decision-making in which healthcare professionals engage patients in a discussion to find a common understanding of the problem or concern requiring remediation, to explore treatment options for the management of the problem or concern, and to implement the agreed-upon treatment option.
Component 3: responsive care	Responsive care refers to the individualization of care, with the goal of maintaining consistency between the intervention or services to be delivered and patients' needs, values and preferences. Responsive care involves assessment of patients' needs and preferences, and customization of interventions and services to the needs and preferences expressed by patients.

Non-specific element of PCC: the therapeutic relationship	Implementation of the three PCC components is facilitated by a non-specific element: the therapeutic relationship or alliance. A therapeutic alliance is characterized by a trusting and nurturing relationship in which healthcare professionals and patients respect each other, and exchange information that guides the planning, implementation and evaluation of care. In this relationship, patients respect the professionals' expertise, and healthcare professionals are personable, open to and respectful of patients' knowledge and experiences. Healthcare professionals have competent communication skills; they listen to patients when exploring patients' concerns and preferences; they share information regarding patients' conditions and treatments in a complete and unbiased way; and they communicate effectively, using simple terms that patients understand. Professionals provide technical and emotional support to patients during the decision-making process
Grover 2022	
Biopsychosocial approach to care	No collated definitions given
Communication	No collated definitions given
Empowerment	No collated definitions given

Empathy	No collated definitions given
Engagement	No collated definitions given
Family/caregiver involvement	No collated definitions given
Implementation through behavior change techniques	No collated definitions given
Patient Individuality	No collated definitions given
Provider Training	No collated definitions given
Respect	No collated definitions given
Shared decision making	No collated definitions given
Systems-level approach	No collated definitions given
<i>Sharma 2015</i>	
Establishing a therapeutic relationship	Establishing a therapeutic relationship between the health-care provider and person receiving care. Three of seven sources referred to this relationship as a partnership
Shared power and responsibility	Among these reviews, authors discussed the need for persons to be active participants in their care. Furthermore, when persons are involved, the care delivered is individualized and based on their needs, wishes and values
Getting to know the person	Healthcare professionals have a responsibility to learn more about the person who is receiving care. Learning more about

	the person is important as it helps professionals view the person uniquely, and not merely an illness or disease
Empowering	Empowering persons to make decisions about their health and the care they receive. The role of health-care professionals is to provide persons with support, resources and their practical expertise so patients are able to make decisions based on what is best for them.
Trust and respect	Recognition of the person as a unique individual with his/her own values, preferences, lived experience and needs. Health-care practitioners need to not only listen to, but also consider the person's individualized needs and incorporate this into their care
Communication	Providing individuals with understandable and accurate information about their care

Appendix K. Search strategy

Database(s): **Ovid MEDLINE(R) ALL** 1946 to September 19, 2023

Search Strategy:

#	Searches	Results
1	"Delivery of Health Care, Integrated"/ or "Delivery of Health Care, Economics"/	10822
2	exp *Models, Organizational/	6496
3	*National Health Programs/	20805
4	*Regional Health Planning/	3306

5	health administration.ti,ab.	8458
6	(better care fund\$ or Sustainability Transformation Plan\$ or vanguard\$).ti,ab.	1063
7	local health integration network\$.ti,ab.	143
8	regional health authorit\$.ti,ab.	1214
9	local service network\$.ti,ab.	12
10	local service network\$.ti,ab.	12
11	(local health district\$ or local health network\$ or district health board\$).ti,ab.	1503
12	health board\$.ti,ab.	2654
13	health region\$.ti,ab.	2514
14	health authorit\$.ti,ab.	16249
15	care network\$.ti,ab.	3375
16	integrated network\$.ti,ab.	1524
17	integrated delivery.ti,ab.	1212
18	*regional health planning/ or health systems plans/ or *regional medical programs/ or *state health plans/	8822
19	regionali#ation.ti,ab.	3619
20	((regional or local or district or geographic) adj (organi#ation\$ or authorit\$ or network\$ or board\$ or (health adj1 board\$))).ti,ab.	8349
21	(decentrali#ation or devolution).ti,ab.	4064
22	regional operating model.ti,ab.	2
23	(population-based adj1 approach).ti,ab.	650
24	regional health planning.ti,ab.	56
25	Centrali#ation.ti,ab.	4180
26	*Health Care Reform/	23235
27	Health Planning Organizations/	902
28	regional integrated care.ti,ab.	12
29	or/1-28	122663
30	(Patient centred care or patient centered care or person centred care or person centered care).ti,ab.	11205
31	Patient-Centered Care/	23056
32	Sharing power.ti,ab.	93
33	Seen as equals.ti,ab.	1
34	Empowerment.ti,ab.	16653
35	Sharing responsibility.ti,ab.	130
36	(Therapeutic adj2 (relationship or bond or alliance)).ti,ab.	6559

37	Compassion.ti,ab.	8951
38	Emotional engagement.ti,ab.	394
39	Patient as a person.ti,ab.	232
40	Person as part of a collective.ti,ab.	0
41	(Spirituality or cultural needs).ti,ab.	8791
42	Comprehensive care.ti,ab.	5217
43	Strengths based.ti,ab.	959
44	Biopsychosocial.ti,ab.	8301
45	Social determinants of health.ti,ab.	8949
46	Provider as a person.ti,ab.	2
47	Professional clinical responsibilities.ti,ab.	0
48	Advocate for the patient.ti,ab.	223
49	Co-ordinated care.ti,ab.	67
50	Coordinated care.ti,ab.	1640
51	((experience or satisfaction or access) adj2 (patient* or citizen* or healthcare or care or service*)).ti,ab.	152547
52	Continuity of care.ti,ab.	9040
53	Communication Skills Attitude Scale.ti,ab.	53
54	(Consultation and Relational Empathy).ti,ab.	129
55	Consultation Care Measure.ti,ab.	3
56	(CAHPS or (Consumer Assessment of Healthcare Providers and Systems Survey)).ti,ab.	608
57	Decisional Conflict Scale.ti,ab.	351
58	(DPC 13 or Doctor Patient Communication).ti,ab.	1342
59	(FPI or Facilitation of Patient Involvement in Care).ti,ab.	1788
60	General Practice Patient Survey.ti,ab.	48
61	(HCCQ or Health Care Communication Questionnaire).ti,ab.	28
62	Individualised care scale.ti,ab.	16
63	(JSPE or Jefferson Scale of Physician Empathy).ti,ab.	237
64	(MPOC or Measure of Processes of Care).ti,ab.	177
65	Observing Patient Involvement in Decision Making scale.ti,ab.	8
66	Organisational Values Questionnaire.ti,ab.	2
67	Partners in Health Survey.ti,ab.	0
68	(PAM or Patient Activation Measure).ti,ab.	9830
69	(PACIC or Patient Assessment of Chronic Illness Care).ti,ab.	231
70	(PFC or Patient Feedback Questionnaire on Communication Skills).ti,ab.	14020

71	(PPPC-14 or Patient Perception of Patient-Centredness).ti,ab.	4
72	(PCBI or Patient-Centred Behaviour Coding Instrument).ti,ab.	26
73	(PCOF or Patient-Centred Observation Form).ti,ab.	23
74	Patient Practitioner Orientation Scale.ti,ab.	90
75	(P-CAT or Person-centred Care Assessment Tool).ti,ab.	48
76	(PCCQ or Person-centred Climate Questionnaire).ti,ab.	33
77	Practices in Self-management Support.ti,ab.	1
78	(QQPPI or Questionnaire on Quality of Physician Patient Interaction).ti,ab.	10
79	(Resources and Support for Chronic Illness Self-management Scale).ti,ab.	1
80	(SEGUE or (Set the stage Elicit information Give information Understand the patient perspective and End the encounter)).ti,ab.	158
81	(SDM-Q-9 or shared decision-making).ti,ab.	13244
82	(DISQ or Doctors Interpersonal Skills Questionnaire).ti,ab.	35
83	or/53-82	42256
84	or/30-52	247660
85	83 or 84	286109
86	29 and 85	6810
87	afghanistan/ or africa/ or africa, northern/ or africa, central/ or africa, eastern/ or "africa south of the sahara"/ or africa, southern/ or africa, western/ or albania/ or algeria/ or andorra/ or angola/ or "antigua and barbuda"/ or argentina/ or armenia/ or azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or "bosnia and herzegovina"/ or botswana/ or brazil/ or brunei/ or bulgaria/ or burkina faso/ or burundi/ or cabo verde/ or cambodia/ or cameroon/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cote d'ivoire/ or croatia/ or cuba/ or "democratic republic of the congo"/ or cyprus/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or egypt/ or el salvador/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or fiji/ or gabon/ or gambia/ or "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or independent state of samoa/ or exp india/ or indian ocean islands/ or indochina/ or indonesia/ or iran/ or iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libya/ or madagascar/ or malaysia/ or malawi/ or mali/ or malta/ or mauritania/ or mauritius/ or mekong valley/ or melanesia/ or micronesia/ or monaco/ or mongolia/ or montenegro/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nepal/ or nicaragua/ or niger/ or nigeria/ or oman/ or pakistan/ or palau/ or exp panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of belarus"/ or "republic of north macedonia"/ or romania/ or exp russia/ or rwanda/ or "saint kitts and nevis"/ or saint lucia/ or "saint vincent and the grenadines"/ or "sao tome and principe"/ or saudi	1304262

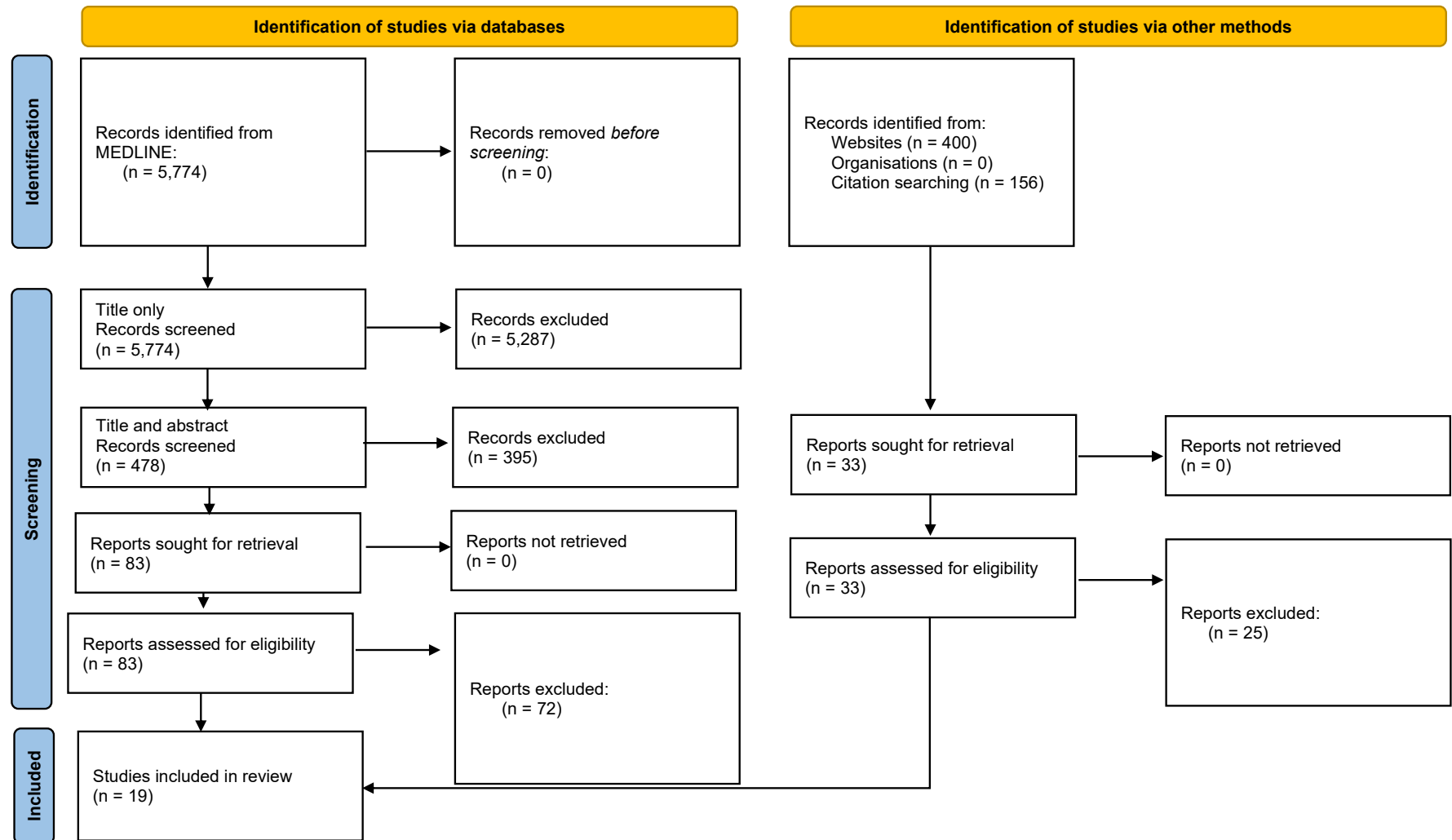
	arabia/ or serbia/ or sierra leone/ or senegal/ or seychelles/ or singapore/ or somalia/ or south africa/ or south sudan/ or sri lanka/ or sudan/ or suriname/ or syria/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or uganda/ or ukraine/ or united arab emirates/ or uruguay/ or uzbekistan/ or vanuatu/ or venezuela/ or vietnam/ or west indies/ or yemen/ or zambia/ or zimbabwe/	
88	"Organisation for Economic Co-Operation and Development"/	560
89	australasia/ or exp australia/ or austria/ or baltic states/ or belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or exp denmark/ or estonia/ or europe/ or finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or exp japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or portugal/ or exp "republic of korea"/ or "scandinavian and nordic countries"/ or slovakia/ or slovenia/ or spain/ or sweden/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/	3505096
90	European Union/	17762
91	Developed Countries/	21407
92	or/88-91	3521135
93	87 not 92	1214452
94	86 not 93	6129
95	limit 94 to english language	5774

Appendix L. Data extraction form

Item for extraction	Details from study
Study title	
Short study identifier (first author and year)	
Study Details	
Country study set in	
Reimbursement system (if known) e.g. fee-for-service, capitation, mixed?	
Year(s) study conducted	
Setting of care (e.g. general practice, outpatient)	
What is the research question or research objective(s)?	
How are participants sampled? (e.g. theoretical, purposive, random)	
How were participants recruited?	
Participants description	
Number of participants	
Age of patient participants	
Gender	
Ethnicity	
Socio-economic status	
Exclusions	
What type of study is it? (e.g. RCT, cohort, qualitative etc.)	
Details of regionalisation	
Timing of regionalisation (e.g. in relation to study measures)	
Aim of regionalisation	
Any suggestion by the authors of mechanisms of action of the chosen intervention strategies?	
Evidence base of intervention? (e.g. any reference to "theory"?)	
Barriers to change identified?	
Details of control conditions (if appropriate)	
RESULTS:	
All measures of PCC	
Losses to follow-up	
Ethical approval sought and obtained?	
How is data collected?	
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?	
Reviewer's notes on 'what is going on here?' 'What are the mechanisms?'	
Other notes	

Appendix M. Study selection flow diagram



Appendix N. Additional study characteristics

Table A 4 Additional study characteristics

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Anton 2014	-	Micro-data from the Health Barometer 1996-2009. This cross-sectional survey, carried out by the Centre for Sociological Research (in Spanish, Centro de Investigaciones Sociológicas), covers a diversity of opinions, attitudes and perceptions of Spanish citizens on the Spanish health care system. The survey is carried out three times a year (with the exception of 2003, with only two waves, and 2001, with only one) and is representative of all Spanish citizens aged 18 and above.	Decentralisation was negotiated case by case by the central government and each of the 17 regions (Autonomous Communities) as part of a long process that took 20 years. It started in 1981, with the transfer of the health competences to Catalonia, and ended in 2001 with the devolution of competences to the last ten regions. The pace of the process was not planned in advanced and was dependent, among other things, on the difficulties found in the negotiations between the parties (the Central Government and the different Autonomous Regions) regarding the conditions in which the transfer was going to take place. According to OECD Statistics, 91.6 % of public health spending in 2010 was in the hands of regional governments. Spanish	Data captured before and after decentralisation, differs by AC.	NR - data collected by a separate organisation	Centre for Sociological Research (Research Grants 2011 edition) and financial support from the Spanish Ministry of Science and Innovation (project CSO2010-16413).

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			decentralisation process is that it has been completely driven by political negotiations, mostly associated with regional identities, so it can be considered reasonably exogenous to health care outcomes. This process was implemented in different stages across different regions, which eases the isolation of the specific effect of decentralisation in the analysis. Among the 17 Autonomous Communities, some are small in size and with few inhabitants (such as La Rioja, with 5,000 square kilometres and a population slightly over 300,000); some are small but very populated (notably Madrid, with 8,000 thousand square kilometres and almost 6.5 million inhabitants), some large and sparsely populated (Castile-Leon, a region with 94,000 square kilometres, approximately the size of Portugal, and 2.5 million inhabitants), etc. The intention has been that all regions could offer almost all kinds of health services and treatments, irrespective of their sizes or demographic and economic characteristics. Patients have the right to be treated in other regions if the			

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			treatment is not available in theirs. Some residual competences are exerted by the Central Government and that the process of devolution included the creation of some coordinating institutions, such as the Interterritorial Healthcare Council.			
Bergevin 2016	Full grey literature report. Bergevin 2016 (Bergevin et al., 2016)	This study used a rapid evidence-based approach consisting of a scoping review of the literature and key informant interviews with 30 senior health leaders from across Canada.	Each Canadian province and territory presents a unique case study in the implementation of regionalisation, reflecting the uniqueness of each province's or territory's peoples, geographies, circumstances and political environments. Provinces have undergone some degree of centralization of local health structures to regional health authorities (RHAs), thus moving to a two-level system consisting of ministries of health and RHAs. This has been achieved by dissolving the boards of local health institutions and placing these institutions under the RHAs. Over time, many provinces have also reduced the number of regions.	Study conducted after regionalisation in all regions	NR	Initiative sur le partage des connaissances et le développement des compétences (IPCDC) and Canadian Foundation for Healthcare Improvement (CFHI)

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Cloutier-Fisher 2006	-	Analyses draw on linked administrative health data from the province of British Columbia for 1990 through 2000 for the population aged 50 and over. Joinpoint regression analyses and t-tests are used to detect and describe trends in the data.	In 1997, in BC the Health Authorities Act established 52 local health authorities made up of 11 Regional Health Boards (RHBs), 34 Community Health Councils (CHCs) and 7 Community Health Service Societies (CHSS) to look after health planning and service delivery across the province. RHBs were given responsibility for metropolitan or urban service provision, while CHCs and CHSSs were jointly responsible for planning and service delivery in rural and remote areas. In 2001, following a change in government, a new round of restructuring resulted in amalgamation of the province's health authorities into five larger regional health authorities and fifteen health service delivery areas, thereby re-centralizing power and authority with the provincial government and reducing local decision making.	1997 and 2001 too major restructures	NR	This research was supported by the Canadian Institutes of Health Research (#765-2000-0146 and #MOP-53070) although this funding agency had no role in the writing of the manuscript.
Costa-Font 2005	-	This study examines the existence of socioeconomic health inequalities within the different Spanish healthcare services, using concentration indices. Data were taken from the most recent Encuesta	Since the approval of the General Health Act in 1986, the Spanish health system has been based on the principles of universal access, efficiency and the decentralisation of health services. The implementation of these principles led to the establishment of a set of seven	Decentralisation started in 1981 and finally, in 2002 all regions were decentralised. This study is from 1997	NR	the Fundacion BBVA funding

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
		Nacional de Salud (Spanish National Health Survey, 1997) and self-perceived health was used to measure health.	regional health services, between 1981 and 1994, and finally, in 2002, to the replacement of the entire centralized network of health services (INSALUD) by ten new regional health services.			
Costa-Font 2009	Preprint Cota-Font 2008 (Costa-Font and Gil, 2008)	Empirical analysis estimates inequalities in three dimensions of health (outcome), healthcare (access) and healthcare payments (financing). Explores the association between three such inequality dimensions alongside other system and socio-economic controls. Examines first wave of asymmetric healthcare devolution which took place in Spain between 1980 and 2001 -whereby health policy responsibilities were transferred to a few region states (autonomous communities [ACs]) - correlates with higher inequalities in health, healthcare and health financing.	Until 2002 a model of asymmetric devolution was in place so that about two-thirds of the Spanish population received healthcare from their own region states who were responsible for healthcare planning, organization and management. Seven out of 17 regional states were politically accountable to their constituents regarding health expenditure. Regional parliaments in those region states empowered with healthcare responsibilities enjoyed a legislative capacity which was only limited by basic legislation of the central state. In contrast, healthcare in the other ten ACs remained centrally managed by the National Institute of Health (Instituto Nacional de la Salud, INSALUD), and regional governments in those regions only had some restricted powers in the fields of primary and community care. In the seven regions, the transfer of healthcare responsibilities	2001 still 10 regions centrally run	NR	authors express gratitude for the 2003 Bayer award and the ministry of health and consumption grant in 2004

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			in Catalonia was completed in 1981, followed by Andalusia (1984), the Basque Country and Valencia (1988), Galicia and Navarre (1991) and the Canary Islands (1994). From 2002 the remaining ACs were empowered with healthcare responsibilities. In 2002 the organization of healthcare in Spain became completely devolved to the 17 different autonomous communities (ACs). However, while the ACs have taken on the responsibility for healthcare delivery, financing is still mainly in the hands of the central government. Decentralised health services in 2001: 1. Andalusia, 2. Canary Islands. 3. Catalunya, 4. Galicia, 5. Valencia, 6. Navarra, 7. Pais Vasco Centrally run health services in 2001: 1. Aragón, 2. Asturias, 3. Baleares, 4. Cantabria, 5. Castilla León, 6. Castilla la Mancha, 7. Extremadura, 8. Madrid, 9. Murcia, 10. La Rioja			
Costa-Font 2018	-	Empirical strategy: before-and-after methodology to examine the prevailing longitudinal regional inequality patterns in outputs and outcomes in both Italian	In both Italy and Spain, healthcare is the main policy responsibility of regional governments and accounts for almost half of total regional budgets. Like in federal states, the central government defines mandatory services to be	The period examined is, as explained above, one during which significant processes of reform took place, leading to the	NR	No potential conflict of interest was reported by the authors.

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
		and Spanish regions from 1998 to 2009, a period in which a second wave of decentralisation took place.	provided across all regions in framework laws, and funding is partly decentralised by the assignment of a share of national taxes and of new taxes to be managed at the local level. The level of autonomy is comparable with most federal states. Both Italy and Spain have gone through two specific waves of decentralisation: a first wave around 1980 (1978 in Italy and 1981 in Spain), and a second wave two decades later around 2000 (1999 in Italy and 2002 in Spain). The first wave began with the transfer of healthcare responsibilities to Catalonia (completed in 1981), followed by Andalucía (1984), the Basque Country and Valencia (1988), Galicia and Navarra (1991), and ended with the transfer of healthcare responsibilities to the Canary Islands (1994). A second wave followed that bridged the gap between the regions with healthcare responsibilities, and the 10 remaining regions were invested with the same level of healthcare responsibilities in 2002.	consolidation of fiscal decentralization in Italy and Spain (second wave of healthcare decentralisation), as testified by the decrease in the share of central government revenue and spending		

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Curtis 2005	-	Retrospective chart audits in secondary and tertiary care sites for ICU data. Data on access taken from Fraser Institute surveys. Patient satisfaction with waiting times taken from survey described by Gregory et al.	All health boards in Newfoundland and Labrador (NL) underwent regionalisation between 1995 and 1997. The largest of the boards (St John's region) also implemented programme-based management, closed hospitals and aggregated services.	Audits were undertaken for patients admitted in 1995 at the beginning of restructuring, in 1999 towards the end of hospital regionalisation, and in 2001 shortly after aggregation of hospitals in St John's had been completed.	yes	This work was co-funded by grants and in-kind support from the Canadian Health Services Research Foundation, Department of Health & Community Services of Newfoundland & Labrador, and the Health Care Corporation of St John's.
Fooks 2015	-	Defined as a commentary by the journal but takes the form of a lit review	NR	Local Health System Integration Act, 2006	not applicable	NR

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Fredriksson 2008	-	To examine the county council's level of support of patient choice, an index is presented. The Patient Choice Index (PCI) shows that there is extensive variation among the CCs. To explain the causes of these variations, a number of hypotheses are tested. The analyses imply that ideology and economy, and more specifically the CCs' governing majorities	The Swedish central government is not involved in the actual production of healthcare. Instead, almost all healthcare in Sweden is administered by regional political authorities called County Councils (CCs). The CCs are governed by democratically elected assemblies and have far-reaching constitutional rights to manage the healthcare sector as well as to levy taxes to finance the provision of healthcare. From a European perspective, the Swedish healthcare system is highly decentralised. The CCs are responsible for the actual healthcare delivery, both private and public, and carry out the planning of regional healthcare functions. Regarding healthcare financing, the main part is funded through local taxation. State grants are the second largest source of funding, partly earmarked for special healthcare reforms and initiatives. Further, since the beginning of the 1990s the Swedish healthcare system has gone through a rather extensive de-regulation and privatization. At the same time,	Further, since the beginning of the 1990s the Swedish healthcare system has gone through a rather extensive de-regulation and privatization. At the same time, gradually, the Swedish state has handed over more and more power to the CCs	NR	Swedish Research Council for funding

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			gradually, the Swedish state has handed over more and more power to the CCs			
Gregory 2005	-	The Employee Attitude Survey questionnaire was sent to acute care providers to assess personal characteristics and perceptions of the impact of reform on workplace conditions, work-related attitudes and turnover intentions. A Patient Satisfaction Survey questionnaire was administered to patients discharged from acute care facilities.	NR	Monitor in 2000, the peak period of worker dislocation in St John's, and 2002 after completion of hospital aggregation.	The Human Investigation Committee of the Faculty of Medicine, Memorial University of Newfoundland, approved the study protocol.	Funded by the Canadian Health Services Research Foundation (CHSRF), Health Care Corporation of St John's (HCCSJ), and the Newfoundland and Labrador Department of Health and

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
						Community Services.
Hanlon 2003	-	Administrative data from the province's hospital discharge data were used to determine how many patients are traveling further than necessary to receive "secondary" level care.	The first stage involved the creation of four regional health boards (RHBs) in 1996. The boundaries of the four RHBs were selected to ensure that each board contained a minimum of 100,000 people, a population size considered sufficient to support a broad range of specialty services. ³ These regional boards were subsequently replaced by nine District Health Authorities (DHA) in 2000.	Pre-RHB era:1992/93 1993/94 1994/95 1995/96 1996/97, RHB era:1997/98 1998/99 1999/00	NR	This research was funded by an operating grant from the Nova Scotia Health Research Foundation (109P).
Jimenez-Rubio 2008	-	Using data from the 2001 Canadian Community Health Survey, we apply a decomposition method of the Concentration Index to explore whether income-related inequalities in health and inequities in the use of health care are more likely to be due to gaps between rich and poor Canadian provinces rather than to differences between rich and poor individuals within them.	Newfoundland, established/changed 1994/2003-2004, current number of RHAS 6/4/2, In 1994, the Government of Newfoundland introduced a parallel structure for institutional and community care through six institutional health boards, four health and community services boards and two integrated boards., population range of RHAs: 295,145-40,516 Prince Edward Island, established/changed 1993-1994/2005, current number of RHAS 0, population range of RHAs: N/A Nova Scotia, established/changed 1996-2001, current number of RHAS 9, population range of RHAs: 398,038-33,165 New Brunswick,	different for each province see details of regionalisation	NR	Financial support from Fundacio' n Ramo' n Areces (Madrid, Spain).

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			established/changed , current number of RHAS 8, population range of RHAs: 18,115-2,441Quebec, established/changed 1989-1992/2003, current number of RHAS 18, population range of RHAs: 1,782,835-9,600Ontario, established/changed 2005, current number of RHAS 14, population range of RHAs: 1,356,500-234,000			
Jovell 2007	-	Data are drawn from nationally representative telephone surveys of the non-institutionalized adult Spanish population (age 18 years and over). The study was carried out in two phases: October-November 2005 (n = 3010) and January 2006 (n = 2101).	Spain has a National Health System organized through 17 Regional Health Services plus the African territories of Melilla and Ceuta. The present health-care model was subsequently laid out in the late 1980s. Budget allocation and planning were decentralised from the central government to 17 regional authorities, known as Autonomous Communities (ACs). Under the previous model, the social security system received 75% of its funding from the working population - as the system was intended for the workers benefit, the employer paid 80% and the employee 20% - and the remaining 25% from the government s tax revenues. As of 1990,	study compares 1991 data with data from 2006, only some regions were decentralised in 1991	NR	The study was funded by Sanofi-Aventis Spain and by the Catalan Department of Health of the Catalan Government.

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			the proportions were reversed such that general tax-based revenue accounted for 72% of expenses. This percentage has grown over time, such that by 1999, public health-care was funded entirely through general tax revenues. Furthermore, during the same time period, public health coverage was also extended to include those who previously could not afford the insurance. The old system was targeted towards workers, who had both an income and an employer to pay for most of the insurance costs. The current system provides health coverage to all who require it, including illegal residents.			
Landi 2020	-	Series of logistic regression models	Since its inception, the INHS has utilized, as most national systems, a decentralised model to respond better to specific need through local authorities, but in the 90s this tendency has been increasing culminating in the 2001 constitutional reform that formalized a hierarchical structure with wide power to regional authorities. The regions have the political and administrative jurisdiction over the health sector (only partially the fiscal power), so they are in charge to	Formalised in 2001. Data used from 2013	NR	The author(s) received no financial support for the research, authorship, and/or publication of this article.

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			organize their own health systems with the constraint to deliver essential levels of care (Livelli Essenziali di Assistenza, LEA) which are decided at the national level and must be guaranteed across the nation.			
Martinussen 2021	-	multilevel logistic and ordinary least squares regression analysis on the seventh and eighth rounds of the European Social Survey (ESS) from 2014 and 2016, including approximately 70 000 respondents from 20 countries.	Used Adolph method of classification of degree of decentralisation for the included countries. This measure classifies level of decentralisation along 2 variables: 1) tasks; framework, legislation, implementation legislation, finance, provision 2) health policy areas: pharmaceuticals, primary care, secondary tertiary care, and public health.	Comparison is degree of regionalisation/decentralisation	This study was exempted from the requirement for approval by the responsible ethics committee because it was a retrospective study of anonymised population surveys	Funding NR, no competing interests declared

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Neville 2005	-	This report therefore presents the qualitative analysis of the interview data for senior Department of Health officials and CEOs/senior administrators	The regionalisation model of governance introduced in Newfoundland and Labrador (NL) resulted in the creation of six health care regions and 14 separate health boards. ⁶ In two regions, Labrador and Northern, integrated boards, governing acute care, long-term care, and community care services were created. In three regions (Western, Central East, and Central West) institutional boards governed acute care and long term care, and separate community health boards were announced. The restructuring in the St John's region (the capital city) resulted in three separate boards governing acute care institutions, long-term care institutions, and community care, as well as one provincially focused board addressing the cancer treatment and research needs of the province. In 1998, the provincial government added social services (child welfare, rehabilitation and corrections) to the mandates of the community and integrated boards.	The interviews were conducted during the winter and spring of 2002. introduction of the regionalisation model in 1993 (and to a lesser extent the addition of social services to the boards in 1998)	NR	This work was funded by the Newfoundland and Labrador Centre for Applied Health Research.

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Rotulo 2022	-	This study performs a fixed-effects panel data analysis of Italian Regions and Autonomous provinces between the years 2001 and 2017, to investigate the effects of health sector-FD on availability, accessibility, and utilisation of healthcare services in Italy.	Over the years, the SSN has experienced a strong decentralisation process, culminating in 2001 with a Constitutional reform enacting health sector FD. The national health system was restructured into several regional services, each one responsible not only for planning of services and allocation of resources, but also for their financing. Although the central government has kept funding responsibilities for some essential levels of care (Livelli Essenziali di Assistenza), all other activities were funded by the regional healthcare budget, financed by (i) two newly introduced regional taxes, (ii) patients' cost-sharing mechanisms, and (iii) fees for carrying out private practices in public facilities (known as intramoenia activity). To expand their budgets, regions acquired the power to introduce, increase, or reduce the share of regional taxes to be levied. They could also determine the amount of co-payments for public provision. Moreover, local authorities became free to outsource the provision of services to private accredited firms, or to directly reimburse private providers for the	Data collected since 2001 when FD was formalised	According to authors: Not applicable: the study employed secondary data for which ethical approval was not applicable.	NR

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			provision of the essential levels of care, where regional system's capacity was insufficient. Similarly, both public and private accredited providers could accept patients from different regions and get reimbursed by the region of origin, based on a system of regional diagnostic related groups. Accordingly, local authorities were also held accountable for any profit or deficit they generated.			
Toth 2014	-	The purpose of this article is to assess the effects that this regionalisation process is having on the rift between the north and the south of the country. Has the gap between the health care systems of the northern and southern regions been increasing or decreasing during the 1999-2009 decade? Three indicators will be	Since the early 90s, regional governments have been granted broad discretion in planning and organising health care services in their own territory. The autonomy enjoyed today by Italian regions is such that it has led to the existence no longer of a single national health service, but rather of 20 different regional systems. The Italian health care system represents a case of political decentralisation. In particular, the last	The time period will be limited to the 1999-2009 decade, essentially due to the lack of uniform data for the years before 1999. Yet, there is another reason: as already anticipated, regional autonomy has been significantly	NR	NR

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
		utilised to answer this question: (1) the level of satisfaction expressed by the citizens towards the regional hospital system; (2) the mobility of the patients among regions; (3) the health care deficit accumulated by the individual regions.	two decades have witnessed the strengthening of the regional level, whose organs of government are elected democratically, holding separate elections from national elections. Despite the previous legislation already provided for a decentralised management of the SSN, the process of health care regionalisation actually started with the coming into effect of the 1992-1993 reform. This reform granted broad discretion to the regions in planning, organising and financing health care services in their own territory. The individual regions have thus been able to choose among various organisation models, differing from each other in a variety of aspects: the size of the local health care authorities, the level of integration between local authorities and autonomous hospital facilities, the involvement of private providers. The strengthening of the regional level was achieved by transferring powers from the national government and by subtracting the management of the local health care units from the municipal governments. This meant that the municipal	enhanced both by legislative decree no. 56 of 2000, and by the 2001 constitutional reform: with 1999 as the starting year, it will be possible to assess the effects of the said significant reforms.		

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			administrations were relegated to a marginal role in terms of health care planning. The local health care units were transformed into public agencies, headed by a general manager appointed by the regional council. Before this, the directors of the local health care units were appointed by the municipal councils, on a mainly political basis. A further step forward in the process of regionalisation was represented by legislative decree no. 56 of 2000. The decree established that financing of the regional health care systems would no longer depend, as in the past, exclusively on transfers from the central government. As from 2000, the regions can rely on a blend of their own resources and central government transfers. The process of regionalisation was further strengthened by a constitutional amendment passed in 2001. On the basis of this amendment, health care has become the object of concurrent legislation between State and regions: this means that the regions have large autonomy in organising and managing health care services on their			

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
			own territory, whereas the State must confine itself to formulating the general rules of the system. The central government has jurisdiction for determining the 'essential levels of care' that must be guaranteed over the entire national territory. The national government must guarantee to the regions the financial resources required to provide the essential levels of care, transferring funds from the wealthier regions to the poorer ones. In the event that a region incurs an operating deficit, it must make it up with its own resources.			

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
Zhong 2010	-	We extend previous studies in two ways. First, to explore the spatial dimension of inequity, we adopt a perfect decomposable inequality measure—the Theil index—in our analysis. Secondly, we conduct a before and after comparison of a change in the degree of decentralisation in Canada—the introduction of the CHST in 1996/1997. We examine the impact of an increase in the degree of decentralisation (the introduction of the CHST in 1996-1997) on inequities in the utilization of three major health care services: general practitioner (GP), medical specialist, and hospital services. We calculate the inequity indices for the indirectly need-standardized utilization of those three health care services at three different time points: 1994-1995, 1998-1999, and 2000-	The paper analyses a change in the degree of decentralisation in Canada. Before 1996-1997, the Canadian federal government used the EPF (Established Programs Financing) to transfer funds to provinces based specifically for postsecondary education and health care expenditures. In 1996-1997, the EPF was replaced by the CHST (Canada Health and Social Transfer) which pooled more programs into a block grant. Consequently, the provinces obtained a greater flexibility to reallocate revenues across service areas.	In 1996-1997 there was an increase in decentralisation in Canada through the CHST. Study uses data before and after this introduction	NR	NR

Study identifier	Associated secondary publications	Study design as described by authors	Details of regionalisation	Timing of regionalisation (e.g. in relation to study measures)	Ethical approval sought and obtained?	How is the study funded? Are any conflicts of interest declared?
		2001, and then decompose those indices into within-in province effects and between-province effects. By adding the 2000-2001 time period into our analysis, we take into account a possible time-lag effect. The changes in inequality in health status over time are also reported in this analysis.				

Table A 5 Participant characteristics

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Anton 2014	Sample representative of all Spanish citizens aged 18 and above.	More than 6000 each year	46.04	51%	NR	Education status: Elementary education 9%, Basic education 47%, Secondary education 28%, Higher education 16%. Employment status: Employed 46%, Unemployed 10%, Retired 22%, Other inactive people 22%.	NR	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Bergevin 2016[™]	Interviewees were senior health leaders from across Canada including: current and former deputy ministers and assistant deputy ministers, current and former CEOs of RHOs, senior academics including a dean, and leaders of key Canadian health organisations.	30	NR	NR	NR	NR	NR	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Costa-i-Font 2005	Spanish National Health Survey participants	6,400	NR	51.5%	NR	NR	NR	N/A
Curtis 2005	NR*	NR*	NR*	NR*	NR*	NR*	NR*	NR*
Fooks 2015	N/A^	N/A^	N/A^	N/A^	N/A^	N/A^	N/A^	N/A^
Fredriksson 2008	NR ^o	NR ^o	NR ^o	NR ^o	NR ^o	NR ^o	NR ^o	NR ^o
Gregory 2005	Employees: Respondents were distributed equally between St John's and other regions,	Employees: The repeat sample consisted of 158 registered	Employees: 44 years of age. Patients: The mean age was 51.7 in 2000	Employees 71% women, Patients:	NR	NR	Employees: name not recorded on an updated mailing list of the professional governing body/council/institutio	N/A repeated sample questionnaire. For

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
	had more than 10 years of work experience, and had been in their current positions for more than five years. Patients' sample characteristics: Respondents were predominantly admitted to an acute care facility in the St John's region (73% in 2000 and 69% in 2002). The percentage of respondents admitted to	nurses, 156 medical doctors, 117 allied health professionals, 93 management personnel and 65 licensed practical nurses. RNs comprised 27% of the sample, MDs 26%, AHPs 20%, MP 16% and LPNs 11%. Patients: accessible	and 52.1 in 2002.	61% women			nal board/licensure board, or no willingness to participate. Patients: younger than 16 years of age; admitted to ICU/CCU, psychiatry or palliative care areas; confused, hard of hearing or terminally ill; previously participated in the survey during a different admission; on isolation precautions; not able to understand and speak English; and	patients Response rates were 82.5% in 2000 and 2002

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
	hospital through an emergency room was similar in both time periods (46% and 48%).	populations were 1741 in 2000 and 704 in 2002. Response rates were 82.5% and 90.2%, respectively.					no telephone number available.	
Hanlon 2003	Population of Nova Scotia and people obtaining general surgical and medical procedures	Total eligible separations 92/93=92,774 96/97=85,021 99/00=93,127	NR	NR	NR	NR	NR	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Jimenez-Rubio 2008	Data are taken from the 2001 Canadian Community Health Survey (CCHS), the first wave of a nationally representative health survey of individuals aged 12 years and over living in Canada	130,880	NR	NR	NR	NR	NR	N/A
Jovell 2007	The data drawn from a study of the attitudes and beliefs of the noninstitutionalized adult Spanish	October-November 2005 (n = 3010) and	NR (all over 18)	NR	NR	NR	NR	N/A - separate panels

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
	population. The study was carried out in two phases using separate surveys with nationally representative samples.	January 2006 (n = 2101).						
Landi 2020	People who have had at least one specialist visit (30,861) or a diagnostic test (29,606) in the latest 12 months	60,467	Specialist 15-24: 7.1%, 25-44: 20.6% 45-64: 34.2% 65-74: 34.2% 74+: 18.6% Diagnostic 15-24: 5.8%	Specialist: 51% diagnostic: 61%	NR	Education: Specialist visits Lower than high school 66.3%, High school certificate 24.0%, and University degrees 2067 (9.7%) Professional qualification	Under 15 years of age	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
			25-44: 24.8% 45-64: 37.0% 65-74: 17.1% 74+:15.3%			Specialist visits Unemployed 68.2%, Unskilled worker 11.4%, Employee, skilled worker 15.2%, Manager, entrepreneur 5.2% Education: Diagnostic tests Lower than high school 59.2%, High school certificate 28.2%, University degree 12.6% Professional qualification Diagnostic tests Unemployed 63.3%,		

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
						Unskilled worker 12.6%, Employee, skilled worker 18.4%, Manager, entrepreneur 5.8%		
Martinussen 2021	NR - data collected by a separate organisation	71,868	49.7	52.9%	NR	Primary education 27.6%, Secondary education 50.1%, Tertiary education 22.4%, Financial strain 20.5%	None reported but data collected by separate group	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Neville 2005	35 individuals participated in the study: 12 senior health ministry officials (including two former Ministers of Health) and 23 CEOs and senior administrators in the health system.	35	Age range Senior ministry officials: 20-39 1 (8%) 40-59 10 (83%) 60+ 1 (8%). Age range CEOs/senior administrators: 20-39 0 40-59 21 (91%) 60+ 2 (9%)	Senior ministry officials: 58% CEOs/senior administrators: 48%	NR	Highest level of education: Senior ministry officials: No undergraduate degree 8%, Undergraduate degree 42%, graduate degree 42%, MD 8%; CEOs/senior administrators: No undergraduate degree 9%, Undergraduate degree 22%, Graduate degree 65%, MD 4%	NR	N/A

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
Rotulo 2022	NR*	NR*	NR*	NR*	NR*	NR*	NR*	not applicable
Toth 2014	Survey based on a statistically representative sample of the resident population	NR	NR	NR	NR	NR	NR	NR
Zhong 2010	The data for the three time points in this study come from the 1994/1995 and the 1998/1999 National Population Health Survey and the 2000/2001 Canadian	128,363	NR	NR	NR	NR	excluded under 12s	Not applicable - repeated cross sectional

Study Identifier	Participants description	Number of participants	Average age of participants	% Female	Ethnicity	Socio-economic status	Exclusions	Losses to follow-up
	Community Health Survey. This analysis is based on the health micro-data file of the household survey of the NPHS. The health micro-data file contains detailed information about health care utilization and the determinants of health care utilization for people aged 12 and over.							

Key: MD –medical doctor, N/A – not applicable, NR – not reported.

[~]Used a scoping review of the literature and key informant interviews

*NR for audits. Survey data collected and published in detail elsewhere.

*High-level aggregate only used, no details provided.

^Literature review style study no specific participants.

^oAnalysis based on rules and regulations only no specific participants

