Ethical problems in performing research on individuals with compromised autonomy - children, the elderly, and the mentally ill

by
Jane Alison Dorothy Freeman B.A., M.B.B.S. (Syd)

Thesis submitted for the degree of
Master of Philosophy by research,
Faculty of Arts,
The University of Glasgow

December, 2001

ProQuest LLC.
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106 – 1346

ACKNOWLEDGMENTS

I would like to thank my supervisor, Professor Robin Downie, for his ongoing instruction and encouragement in the writing of this thesis. His support, both professionally and personally, has been invaluable.

For the contribution to this project of my great-aunt, Mrs Greta Gray, and her ongoing encouragement of my education over the years, I remain very grateful.

I would like also to thank the Faculty of Medicine at the University of Sydney for their generosity in two awards of the Edith Mary Rose Travelling Scholarship, without which this thesis would not have been possible.

ABSTRACT

In this thesis, I explore the range of ethical problems that are seen in research generally, and in research involving individuals with compromised autonomy more specifically - that is, children, the elderly, and the mentally ill.

Chapter 1 deals with reasons why ethical issues surrounding research are becoming more important, and the focus society has on rights, autonomy, and consent. Problems with consent (definition, amount of information to disclose, communication difficulties, and risk-benefit analysis) are explored. The ethical implications of research versus experimentation, and clinical versus non-clinical research are analysed. Problems with clinical research (such as involvement of ill people and conflict or interest) are assessed, as are the problems of non-therapeutic research (use of well people, motivation to participate, and the role of patient consent). This forms the background for an analysis of research on those who have compromised autonomy - children, the elderly, and the mentally ill.

Chapter 2 relates to problems with research on children, assessing the role of parental consent and its advantages (preservation of family relationships and access to benefits of trial) and disadvantages (problems with parental understanding, and the idea that it represents necessarily the views and best interests of the child). The autonomy of the child is also assessed, and seen to be limited by balance of power, difficulties ensuring understanding and voluntary consent, and problems specific to adolescents. Psychosocial research is also analysed, as is the conflict of the doctor's involvement in paediatric research.

Chapter 3 relates to research involving the elderly and why this is important. Autonomy of the elderly may be compromised by a number of factors, such as ambiguity in terminology applied to the elderly, stereotype, extrinsic factors such as poverty and family relationships, and intrinsic factors, such as cognitive impairment, deafness, blindness, and so forth. Problems

obtaining consent relate to the above factors, as well as institutionalisation and the pressures from family. However, research in this group is also important as they have problems which cannot be researched in other groups.

Chapter 4 assesses problems in performing research on the mentally ill, which are particularly highlighted through past exploitation of psychiatric patients. Autonomy in the mentally ill is threatened by a number of factors, such as the wide range of capabilities the mentally ill have; stigmatisation; communication, reasoning, and assessment problems; involuntary hospitalisation and treatment, and the use of psychotropic medications; and deranged interpersonal relationships. Children and the elderly who also have mental illness have extra problems and need careful handling for research. The doctor-patient relationship may also be jeopardised, which is even more significant in a group with fewer social supports.

In summary, there may be seen to be a number of factors which compromise the autonomy of children, the mentally ill, and the elderly. A recognition of these factors, coupled with practical measures to optimise consent and the acceptability of research, can help make such research more ethical. It is important to perform such research, in order to maximise the happiness and well-being of these individuals.

CONTENTS

INTRODUCTION

There is, in recent times, an increasing focus on the ethical issues surrounding research. Much has been written on informed consent and the participation of autonomous individuals in research. There has also been some analysis of the problems of how to deal with people with no autonomous traits, such as those in a persistent vegetative state. Conversely, however, there has been comparatively little written about those potential research subjects who fall somewhere in between - those who have their autonomy compromised in some way, but who cannot be said to be either fully autonomous or fully non-autonomous. In this thesis, I aim to address some of the issues surrounding research on individuals with compromised autonomy.

In chapter 1, I shall discuss a number of points which relate to research in general. Firstly, there has been an increasing awareness of research and its associated problems. Factors which contribute to this are: an increased respect for the rights of the individual and his or her autonomy; increased potential for the range of interventions we can provide; government legislature; the increasing role of the clinician in research; and poor treatment of research subjects, especially vulnerable ones, in the past.

Thus, there has been increasing focus on the rights, autonomy, and informed consent of the individual. However, there are a number of problems with consent, which I shall discuss. These include: difficulties in establishing what constitutes informed consent; difficulties assessing the amount of information that should be disclosed; communication problems; the impact on the doctor-patient relationship and trust; and risks and how they ought to be interpreted.

I shall also contrast experimentation and research, and explore the implications each of these have.

Clinical and non-therapeutic research will also be analysed. Problems with clinical research include conflict of interest for the doctor; involvement of ill people and implications for autonomy; and difficulties about when to stop a trial once some results become apparent. Non-therapeutic research has its own difficulties, such as difficult risk-benefit analysis, the role of patient consent in such studies, the motivation of patients to consent, and the allocation of resources for this kind of research.

An awareness of these issues form a backdrop for an analysis of research involving individuals with compromised autonomy.

The first such group is children, whom I discuss in chapter 2. It is important to perform research on a group such as this, as children have many problems and disease which cannot be adequately assessed thorough research on adults, in order to optimise their well-being. Issues surrounding research on this group will be discussed.

The first main issue relating to research involving children is the role of parental consent. Problems with this include the fact that parental consent does not necessarily involve the best interests of the child or a substitute for their wishes. There are also problems with parental consent relating to lack of parental understanding and the way in which this impacts on parental consent. However, the consent of parents has the benefit of preserving family relationships and allowing children to access benefits.

The autonomy of children themselves needs also to be analysed. It forms a continuum between baby and adult, and problems include lack of understanding, unequal balance of power, parental preference, difficulty of ensuring voluntary consent, and problems specific to adolescents.

Psychosocial research on children causes debate on the subjects chosen, the involvement of well children and risk-benefit analysis, and the long-term outcomes.

The doctor's involvement may also cause problems for research involving children, because it leads to conflict of interest, a change in relationship between parents and doctor, public pressure, and allocation of resources.

In chapter 3, I shall examine issues relating to research involving elderly people. I shall explain why research in the elderly is necessary, and some of the associated problems.

The autonomy of the elderly can be compromised in a number of ways, which will be discussed, and which have obvious implications for research on this group. The ways in which autonomy is affected include ambiguity of terminology applied to the elderly, stereotyping, external factors such as poverty and disturbed family relationships, and internal factors such as dementia, motor and sensory deficits. There are also problems obtaining consent in the elderly, due to factors such as institutionalisation and interactions with the relatives.

However, research may be more acceptable through benefit to the individual or group, satisfaction involved for the subject, previously expressed wishes, and a modification of the research process to optimise autonomy, consent, and ethical research process.

Finally, in chapter 4 I discuss some of the issues which relate to research involving psychiatric patients. I discuss the importance of such research, and reasons why there is increasing concern today (namely, through past exploitation of this group).

Factors affecting the autonomy of this group are also explored. These include: the continuum between normal and 'abnormal', due to varying symptoms and degrees of treatment; stigmatisation; problems with

communication, relationships and assessment of capabilities; involuntary treatment and hospitalisation; and the use of psychotropic medications.

Children and the elderly with mental illness are also discussed, as they face both the problems of having a mental illness, as well as age-related constraints of autonomy.

The doctor-patient relationship may also be affected by difficulties in interaction with the psychiatric patient, and conflict of interest and difficulties recognising these.

In summary, there can be seen to be a number of factors which complicate the autonomy of groups of potential research subjects, such as children, the elderly, and the mentally ill. It is important to develop an awareness of the kinds of factors which are likely to be affecting these potential research subjects, and by focussing on their capabilities, their autonomy may be optimised. It is in this way, coupled with techniques to modify the structure of research, that research involving these groups may be made more ethical and the lives of children, the elderly, and the mentally ill made happier and more healthy.

CHAPTER 1 - ETHICAL PROBLEMS IN RESEARCH

1.1 - Introduction

In this chapter, I shall discuss some of the ethical issues which relate to research in general.

Firstly, I shall discuss factors which contribute to the increasing awareness of research and its associated ethical issues. These include: public concern for autonomy and the rights of the individual; more sophisticated technology; the role of the doctor in research; and the poor treatment historically of research subjects.

The consent of the research subject is usually thought to be of paramount importance for ethical research, and I shall also discuss difficulties relating to consent. Such problems include: defining informed consent; the amount of information to disclose; communication problems in the process of obtaining consent; and trust between doctor and patient.

Experimentation as opposed to research will be discussed, as well as the distinction between clinical and non-therapeutic research. Issues relating to non-therapeutic research also will be analysed. Such problems include: risk-benefit analysis; whether consent overrides risks to well patients; utilitarianism; the involvement of ill people; motivation to participate in such research; and allocation of resources.

Finally, ethical problems relating to the involvement of the clinician and of ill research subjects will also be assessed.

1.2 - The increasing importance of ethical issues relating to research, and factors which contribute to this

Issues surrounding research are becoming increasingly important for a number of reasons.

1.2.1 - Factors which derive from the public and from government bodies

Factors which contribute to an increased awareness of ethical issues in research which derive from public and government bodies include the following: an increased belief in and concern for the rights of the individual; a reaction against paternalistic medicine; a rapidly increasing potential for intervention and techniques for doing this; and a significant increase in new treatments and government regulation of such practices[1].

1.2.2 - Factors which are related to the involvement of clinicians in research

Other factors which contribute to an increased awareness of the ethical problems in research relate to the involvement of clinicians. These include increasing funding available for research; the need for clinicians in particular to demonstrate proficiency in research to advance in their careers; the development of research as a career - for example, clinical pharmacology; increasing emphasis the notion of preventative medicine, rather than on therapeutic treatment of individuals; and the greater capacity for good or harm possible with new treatments and investigations.[2]

1.2.3 - Historical factors

A third reason which has led to concern about research is poor and unethical treatment of research subjects in the past - particularly subjects whose autonomy was compromised in some way, including children, the mentally ill, and prisoners.

In the mid eighteenth century, it was common for orphans and 'foundlings' to be conscripted for research, and children were used for

---

[1]Mason, J.K. and McCall Smith, R.A. (1994), Law and Medical Ethics, Butterworths, London, p. 349.

[2]Beecher, H.K., 'Ethics and Clinical Research', in Kuhse, H. and Singer, P. (eds) (2000), Bioethics - An Anthology, Blackwell, Oxford, p. 422.

autopsies and research on measles and smallpox[3,4]. The nineteenth century saw more experimentation on children (particularly those institutionalised) with a wide range of infectious diseases, such as syphilis[5], scarlet fever, gonorrhoea, and vaccines for rabies and diphtheria[6].

Despite analysis of the treatment of patients and research subjects from very early times historically (ranging from Hippocrates, through to Thomas Percival, William Beaumont, and Claude Bernard in the nineteenth century, and culminating in the Prussian directive and the Reich Circular in the early twentieth century, which give clear directives on ethical research process[7,8]) experiments on x-rays and metabolic diseases, among other things, were conducted on minors well into the twentieth century[9].

Unfortunately, despite the existence of such guidelines and analyses, there continued to occur a range of unethical experiments. A notorious example occurred in Nazi Germany; the practices of Nazi physicians are well known and represent a notorious example of unethical research and inhumane treatment[10].

Nazi doctors conducted a wide range of experiments, including finding antidotes to phosgene gas, limb and bone transplantation with no clinical indication, and injecting subjects' eyes with dye to try to change eye colour permanently[11]. Other experiments included investigating irregular menses in

---

[3]Lederer, S.E. and Grodin, M.A., 'Historical Overview: Pediatric Experimentation', in Grodin, M.A. and Glantz, L.H. (eds) (1994), Children as Research Subjects, OUP, NY and Oxford, p. 4-5.
[4]Grodin, M.A., 'Historical Origins of the Nuremberg Code', in Annas, G.J. and Grodin, M.A. (eds) (1992), The Nazi Doctors and the Nuremberg Code - Human Rights in Human Experimentation, OUP, NY and Oxford, p. 124.
[5]ibid, p. 127.
[6]Lederer and Grodin (1994), op. cit., p. 6-8.
[7]Grodin, M.A., 'Historical Origins of the Nuremberg Code', in Annas and Grodin (1992), op. cit., pp. 124-128, 131.
[8]Perley, S., Fluss, S.S., Bankowski, Z. and Simon, F., 'The Nuremberg Code: An International Overview', in Annas and Grodin (1992), op. cit., pp. 150-151.
[9]Lederer and Grodin (1994), op. cit., p. 9-10.
[10]Zinner, S.E., 'The Elusive Goal of Informed Consent by Adolescents', Theoretical Medicine, 1995; 16; 323-331.
[11]Proctor, R., 'Nazi Doctors, Racial Medicine, and Human Experimentation' in Annas and Grodin (1992), op. cit., p.26.

women who learned of their impending executions[12], and high altitude experiments, the effects of freezing on humans, deliberate infection with malaria and typhus, and poisoning with mustard gas[13].

A more recent example of research abuse is a research project begun in 1932 at Tuskegee, in which 400 black men with syphilis were denied treatment in order to study the natural history of the disease; this project was ceased only in 1972, after public outcry[14]. The individuals involved in this study had no idea that they were infected and that they were being denied treatment[15]. Another more recent example occurred at the Jewish Chronic Disease Hospital in 1963, where 22 chronically ill people were injected with live cancer cells without their knowledge[16].

A combination of these factors has contributed to heightened concern about the ethics of research, particularly on subjects with compromised autonomy.

1.3 - Rights, autonomy and consent

As indicated in the preceding paragraphs, society is increasingly concerned with the rights and freedom of the individual. In terms of research, these central issues are embodied by the notions of autonomy and of consent. Much has been written about the issues of autonomous subjects and about those with no autonomy (for example, those in a coma or a persistent vegetative state).

However, less has been written about the difficulties posed by research on those individuals in whom autonomy may be more borderline. As research

---

[12]Pross, C., 'Nazi Doctors, German Medicine, and Historical Truth', in Annas and Grodin (1992), op. cit., p. 37.

[13]Taylor, T, 'Opening Statement of the Prosecution', Trials of War Criminals Before the Nuremberg Military Tribunals, quoted in Annas and Grodin (1992), op. cit., pp67-93.

[14]Macready, N., 'US to encourage more black people to join research trials', BMJ, 1997; 314: 696.

[15]Katz, J., 'The Consent Principle of the Nuremberg Code: Its significance Then and Now', in Annas and Grodin (1992), op. cit., p. 230.

[16]ibid.

involving these subjects is likely to continue, a discussion of the particular problems they face is necessary.

In summary, problems with research on those with compromised autonomy include: problems in establishing what constitutes informed consent; compromised patient/subject autonomy and associated difficulties with obtaining informed consent; proxy consent for potential research subjects with compromised autonomy; the extent to which the wishes of the individual with compromised autonomy should be taken into account; problems with communicating and understanding information about the research; and risks and benefits, and how much risk is justifiable. These problems will be discussed individually in the following sections.

1.4 - Consent

The exploitation of research subjects, particularly vulnerable ones such as children, led to the establishment of the Nuremberg Code, which states that 'the voluntary consent of the human subject is absolutely essential' in research[17]; research needs 'informed consent' because this reflects the autonomy of the subject, and that they have chosen to participate in the research with understanding of the nature of the project, and possible consequences (risks and benefits).

Given the potential for exploitation of research subjects - particularly those with compromised autonomy - a focus on fully-informed, voluntary consent is understandable. However, there are a number of problems with the notion of consent.

1.4.1 - Difficulties in defining 'informed consent'

[17]Zinner (1995), op. cit., p. 324.

The first problem is that the idea of 'informed consent' is too vague and poorly-defined. In a U.S. legal case (*Salgo* [18]) it was stated that the doctor in question 'should give enough information to form the basis of intelligent consent'; the term 'intelligent consent' was later adapted and used more commonly as 'informed consent'. It has been noted that this is problematic because 'informed consent' is no more than a broad principle and gives no guide to practical aspects (i.e. how much information and what kind of information should be passed on), yet this phrase has become very widely used[19].

1.4.2 - Patient versus professional standard of information disclosure

Further, it is unclear whether the information given to patients/potential research subjects should be 'complete' by the standards of the patient, or whether the doctor or researcher should be allowed to modify and limit the information passed on based on his or her professional judgement.

Thus, a 'patient standard' or a 'professional standard' may be taken as the basis for information disclosure[20]. The patient standard involves disclosure of information to a level determined by the patient, whereas the professional standard is a modified version which leaves scope for clinical judgement - the extent and detail of the information provided is determined by the professional. Most individuals would probably say that they would prefer the patient standard, but there are a number of difficulties with this.

1.4.3 - Problems with the patient standard of information disclosure

Firstly, the information provided to obtain informed consent for therapy or research is generally taken to be the level of information which would be

---

[18] *Salgo v Leland Stanford Junior University Board of Trustees*, 317 P 2d 170 (Cal, 1957).
[19] Mason and McCall Smith (1994), op. cit., p. 238.
[20] ibid, p. 239.

required by a 'reasonable patient', but it is difficult to establish just what this would be. Consent statutes are in use in the U.S., but these serve more to protect the doctor rather than provide adequate guidelines for information disclosure[21].

Further, it is evident that various patients or research subjects want and/or need a very wide range of information in their contact with medicine, or indeed with research. In addition, it is difficult to define the notion of 'fully informed' and the amount of information which should be deemed necessary. As for the term 'reasonable patient', to be 'fully informed' means different things to different people, and it is difficult to ascertain how much an individual patient wants to know, far less be able to establish general principles for information disclosure.

However, there is a trend to interpret a patient standard ('fully informed') to mean *all* information. And although many people would claim that they would want to be given complete information, it is questionable whether many would truly desire this. In fact, a patient in the U.S. sued for damages recently because she felt she had been given *too much* information.

It may be that when patients or research subjects say they want complete information, in reality they want some kind of guarantee against adverse or unexpected events. It is also often the case that individuals claim that they wanted to know more about what they went through, though when questioned prior to a procedure 'only want to know so much'[22] - that is, it is *after* a particular procedure or investigation has been gone through that a person feels able to deal with more information.

1.4.4 - Impact on trust in the doctor-patient relationship

---

[21]ibid, p. 360.

[22]Radley, A., 'The critical moment: time, information and medical expertise in the experience of patients receiving coronary bypass surgery', in Williams, S.J. and Calnan, M. (1996), Modern Medicine - Lay perspectives and experiences, UCL Press, London, p. 130.

Another disadvantage of the 'patient standard' for disclosure of information in obtaining is that the focus on patient autonomy - not just instances of medical negligence - has contributed to the lack of trust between patient and physician, and the decreased role this now plays in a clinical setting. Although this may appear to be less of a problem in research, it is relevant in two ways.

Firstly, the physician often plays a part in research - particularly clinical research - if only as an intermediary between investigator and research subject.

Secondly, the idea of informed consent and its related problems, although important in clinical practice, also has a secondary impact on research, insofar as consent is also an issue in research of all kinds. This focus on patient autonomy has also led to an *expectation* of disclosure of 'complete' information in all situations, even when it is not appropriate for various reasons.

1.4.5 - Advantages of the professional standard of information disclosure

These kinds of difficulties mean that a 'professional standard' for disclosure of information may be more appropriate. There are a number of points in favour of this model.

Firstly, it may function to decrease the stress of research subjects, particularly those who are unwell, by allowing the physician or scientist some flexibility in the amount and type of information they give to the subject. 'Too much' information can be distressing and unhelpful to some individuals, particularly at the time of an illness or procedure; it is in retrospect that more information is usually desired, though the need and want for this is denied at the time[23].

[23]Radley, A., in Williams and Calnan (1996), op. cit., p. 130.

Secondly, it allows a physician or scientist to formulate an explanation, suited to the individual, which maximises that individual's chances of understanding the information to be conveyed.

Thirdly, it also helps to avoid the danger that research subjects may unreasonably misinterpret the information with which they are presented - perhaps in a way which is out of proportion to the 'real' risk.

For example, hormone replacement therapy (HRT) is generally thought to decrease the risk of fractures secondary to decreased bone density by 20% but to increase the risk of breast cancer by 20%. Patients often interpret this information differently from medical personnel - many tend to think that the two (as they both involve a change of 20%) cancel each other out, or that fractures are of minimal significance, or fail to realise that fractures are far more common than breast cancer, and that they are a significant cause of morbidity and mortality. So the risks are interpreted in such a way that the patient may be deterred from trying HRT when its use may be considered acceptable if they actually understood the information more accurately. (Though of course it is difficult to assess when someone 'really' understands something; and it is arguable that they should still be allowed to refuse, even if it does not seem 'reasonable' - particularly when research, rather than treatment, is the issue.)

1.4.6 - Problems with the professional standard of information disclosure

However, there are a number of problems with using the 'professional standard' for information disclosure.

Firstly, although it has been concluded (with respect to therapeutic intervention) that 'a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a respectable body of medical opinion', it is also evident that as choice calls for a decision by the patient on information known to the patient but not to the doctor, it would seem illogical

to hold that the amount of information to be provided by the doctor can be determined from the perspective of the doctor (or medical profession) alone[24].

Secondly, the physician or researcher may be taking into account only medical or scientific aspects of the problem. The patient, or the person giving consent by proxy (for example, a parent) may have a different set of priorities which may affect their decision - for instance, the attending physician may recommend tablets because they are the cheapest, but parents may still want a liquid form of the drug, because (for them) it is worth the extra expense in terms of time and effort saved[25]. More complex factors likely to affect decision-making (in both clinical and research scenarios) include family, social, religious, financial, and even cosmetic considerations, depending on what is involved. The investigator or attending physician may not be privy to such factors, which is another reason why the 'professional standard' may be inappropriate.

A third problem with the professional standard of information disclosure is the risk that the physician or researcher may communicate only that which they believe to be correct, but that they turn out to be incorrect in this belief. This may mean that the patient/research subject is exposed to an ineffective or harmful option which they would not have consented to at the time had they been given more complete information at the time of consent. An example of this is a senior New Zealand doctor, who believed that carcinoma *in situ* of the cervix would not spread and was best left untreated. His patients were denied treatment over 15 - 20 years without being told that they were, in effect, participating in a therapeutic experiment[26]. Thus, the fallibility of investigators is one argument against the professional standard of information disclosure.

Other problems with the professional standard of information disclosure include the possibility that too much information is withheld from the subject -

---

[24]Mason and McCall Smith (1994), op. cit., p. 245.
[25]Forman and Ekman Ladd (1991), op. cit., p. 8.
[26]Mason and McCall Smith (1994), op. cit., p. 361.

or even that an inappropriately large amount of information is given to a particular subject - because the information disclosed to them is dependent on the subjective opinion as to what is 'appropriate information' of the investigator or physician.

The professional may also tend to withhold information because it is less complicated - and less effort - than going through the process of giving a lot of information.

There is also the risk that the process of consent may be altogether bypassed, if the physician or researcher believes that the individual's involvement in the procedure or trial will be to his or her benefit.

A further problem is that an investigator may limit the information he or she gives to a potential participant in order to recruit a sufficiently large number of research subjects.

1.4.7 - Problems in communicating information to a patient or research subject

Even if 'complete' information was desirable, it seems difficult to imagine how this might be communicated in a comprehensible form which still manages to retain a high degree of accuracy.

Complete information often involves a good deal of technical and specialised language which the patient (even when fully mature and competent) may well not understand. Yet even in modifying fairly straightforward information for a lay listener, it is likely that at least some of the accuracy and 'truth' of the information may be sacrificed; it is arguable that in modifying medical and technical language for the benefit of the layperson, a degree of subtlety of meaning is lost.

The physician or researcher has undergone years of study and his or her knowledge has developed to a high level through multiple learning experiences of different kinds, and it is difficult to see how this knowledge can be readily

translated into a neat, concise package accessible to others lacking similar training.

Understanding frequently requires multiple interviews and ways of describing, as well as feedback and questions[27]. It is unlikely that this kind of approach can be used for many areas of research, if only because of time constraints; this kind of information acquisition is seen more often in patients with chronic illness.

Of course, this is not to say that all patients would be unable to understand complex information, nor that no information should be given. However, it is difficult to see how 'all' information relating to a particular procedure or research protocol can be communicated to a patient or research subject, even if this were desirable and something that all research participants truly wanted.

1.4.8 - Misunderstanding in communication between researcher and research subject

The situation is further complicated by the fact that patients and potential research subjects have the capacity to misunderstand and misinterpret the information with which they are presented, regardless of how complete it is from the giver's point of view.

Even in fully autonomous, adult patients, there are often marked problems with understanding. Even after supposedly informed consent, one study found that half the adult subjects receiving placebo in a nonblind, nonrandomised placebo trial still believed they were definitely receiving active medication[28]. Clinical trial subjects have a tendency to believe that investigators

---

[27]Forman, E.N. and Ekman Ladd, R. (1991), Ethical Dilemmas in Pædiatrics - A Case Study Approach, Springer-Verlag, New York, p. 28.

[28]Park, L.L. and Covi, L. 'Nonblind Placebo Trial: An Exploration of Neurotic Patients' Responses to Placebo When Its Inert Contents is Disclosed, Arch.Gen.Psychiatry & Psychology, 1965; 12; 336, cited in Spece, R.G., Shimm, D.S. and Buchanan, A.E. (1996), Conflicts of Interest in Clinical Practice and Research, Oxford University Press, New York and Oxford, p. 362.

are treating them in accordance with Marquis' 'therapeutic obligation'[29], when the nature of the study often precludes this. Another study found that 69% of research participants failed to understand that allocation was random and 40% stated explicitly that they would be allocated to groups depending on their therapeutic need[30], and a third reports that most respondents believe that it is 'the responsible doctor' who allocates them to their group, even when it is explicitly stated that allocation is by chance[31].

In the case of clinical research, patients are often less able to comprehend fully because they are unwell and are suffering associated stress[32]. Although this does not apply to the case in which a proxy consents on behalf of a non-autonomous patient, it is arguable that proxy consent may not overcome this problem, as the stress of seeing the subject ill may compromise the proxy's ability to understand.

Finally, ought one to assume the patient is medically naive, or tell them of 'last chances', or expect them to understand an issue when medicine is itself divided on the issue?[33]

1.4.9 - Risks involved

A final issue relating to consent is the risk to which a research subject is exposed. A large proportion of the function of consent is to allow the patient to assess the probable benefits and risks to which they will be exposed if they participate in the study.

Risk is usually assessed as less than minimal (e.g. giving a urine sample); minimal (e.g. mild side effects such as headache or malaise, or a small risk of a

---

[29]Marquis, D. 'Leaving therapy to chance', Hastings Cent. Rep., 1983; 13; 40, cited in Spece, Shimm and Buchanan (1996), ibid.

[30]Zinner (1995), op. cit., p. 326.

[31]Bjørn, E., Rossel, P. and Holm, S., 'Can the written information to research subjects be improved? - an empirical study', J.Med.Eth., 1999; 25: 265.

[32]Forman, E.N. and Ekman-Ladd, R. (1991), Ethical Dilemmas in Paediatrics - A Case Study Approach, Springer-Verlag, New York, p.28.

[33]Mason and McCall Smith (1994), op. cit., p. 360.

more severe adverse reaction); moderate; or severe. Severe risks are only considered acceptable if: the risk is small compared with the risk from the disease; the disease is serious; there is no other method open to obtain the results; and the patient consents[34]. But one could argue that it is unlikely that the actuality is as straightforward; surely the point of research is that little is known about the compound or procedure in question.

With respect to severe risks, some patients who are particularly unwell may wish to take part in a trial even if it is considered too 'risky' , and it is difficult to decide whether such individuals should be permitted to participate. On one hand, it is arguable that their autonomy should be respected and that they should be able to participate if they so choose. On the other hand, such individuals are at risk of making ill-judged decisions under the stress of being unwell, and may be pressured to participate or exploited in other ways.

With healthy volunteers, it is also debatable whether they should they be prevented from participating in high-(or any) risk studies. Again, it may be that their decision should be respected in order to preserve their autonomy. However, they may have difficulties in understanding the information given as part of the process of consenting. An added complication in this group is that the likelihood of risks is likely to increase when there is inducement (e.g. financial) to participate in a study[35] - but this group do not stand to gain other benefits, such as an improvement in health.

A final point about risks is that it is often difficult to assess both the likely risks and the probability of their occurrence, depending on the experiment.

1.4.10 - Conclusion

---

[34]ibid, pp. 351-2.
[35]ibid, p. 352.

So the issue of informed consent is central in both therapeutic intervention and research, but it can be seen that what constitutes 'informed consent' is not clearly defined, even for mature, competent adult humans. There are a number of difficulties with both the 'professional' and 'patient' standards. The importance that informed consent is generally believed to hold, and the difficulties with implementing it, makes research on individuals with less than complete autonomy - for example, children, the elderly, and less borderline cases such as comatose individuals - even more problematic.

1.5 - Experimentation and research

1.5.1 - Experimentation

There are a number of different areas in science and research and the distinction between these areas can have moral significance. One such distinction is the idea of experimentation, compared with the process of research.

Experimentation may be seen as more *ad hoc* and speculative[36], and therefore not always of obvious immediate benefit to the patient/subject. This may make experimentation more unethical because there is not necessarily an obvious benefit in sight which will justify the risks involved in the experiment.

This lack of obvious benefit and the 'see what we get' approach of experimentation also indicates that research subjects are more likely to be used as means, rather than ends, thereby undermining the entrenched idea that people have intrinsic value, and opening up the possibility of exploitation. (This is particularly the case with non-autonomous subjects.)

However, experimentation gives more scope to modify the conditions of the experiment and take into consideration the individual's response[37].

---

[36]ibid, p. 350.
[37]ibid.

1.5.2 - Research

Research, on the other hand, involves a more clearly defined endpoint and course of action[38]. The parameters of the study are clearer than in the case of experimentation, and the nature of the study, the potential risks and benefits, and other relevant information can be more easily communicated to the research subject. Research, *per se*, seems therefore to be more ethical than experimentation. However, research gives less scope for taking into account the response of the individual, and has a range of other difficulties.

1.6 - Clinical versus non-therapeutic research

Research may be categorised as clinical (or therapeutic), or non-clinical (non-therapeutic). These categories raise different issues.

1.6.1 - Clinical research

Clinical research involves two main consideration which are less an issue in non-clinical research. The first is that the doctor/clinician is more frequently involved in therapeutic or clinical research. The second is that ill patients tend to be involved more often (for obvious reasons) in therapeutic research. The involvement of sick patients raises issues of: exploitation of the patient; compromised ability to consent to high-risk procedures; inappropriate pressure on researchers and compromise of the integrity of the study; and when to cease a study once beneficial or harmful effects become apparent.

1.6.2 - The dilemma of the involvement of the clinician in research

Clinical or therapeutic research raises issues of the involvement of clinicians in research. This is obviously more an issue than in non-clinical or non-therapeutic research as the clinical or treatment setting is much more likely

---

[38]ibid, p. 351.

to involve the treating doctor, or another clinician. This raises several issues about the role and duties of a doctor.

Therapeutic research is aimed at improving the treatment of a patient, or group of patients[39]. This is more in keeping with the traditional (caring/healing) role of the doctor; this form of research may seem to pose less of a dilemma for the attending doctor - who is bound to put the care of his or her patient first - in that the aim is to improve patient care, and at least some of the unwell subjects are being treated.

On the other hand, involvement of one's patients in a trial mean that not all can receive the best therapy; some may receive a placebo or standard therapy, while others gain the advantages of the new treatment. Or there is the risk that the therapy on trial may be less effective than the standard therapy currently available, so that the treatment group receiving the new therapy may suffer ineffective treatment or adverse reactions, while the control group do better. Even if there is no difference between the placebo group and the control group, this could mean that all the subjects in the study may be worse off than non-participants on standard therapy. So - almost by definition - not all patients can be said to be receiving the best therapy at any given time. This is particularly an issue when the research subject has compromised autonomy and their consent in the trial depends on the consent or permission of a proxy.

Hence, there may be problems involving the doctor in research because on one hand they need to be able to say 'the health of my patient is my first consideration' and the structure of research means that the patient may not be receiving treatment which is known to be best. On the other hand, it has been noted[40] that doctors need to be involved at some stage of the proceedings because they still need to care for their patient on a day-to-day basis, their expertise is usually required to interpret clinical signs, they frequently form the

---

[39]ibid.
[40]ibid.

point of contact between the study group and the patient, and they usually enjoy a special and privileged relationship with the patient (which conceivably may be compromised by participation in the study).

1.7 - The involvement of ill individuals in research

1.7.1 - The ill person and consent

1.7.1.1 - The sick role and decreased autonomy

Another problem with therapeutic research relates to the fact that this sort of research necessarily involves subjects who are ill and/or diseased. People who are ill tend to assume a 'sick role', which is difficult to avoid, and of course may represent an important and necessary part of being ill and recuperating.

The difficulty is that while adopting the sick role, such individuals may not function with the same degree of autonomy and assertiveness, and may consent to participate in research which involves conditions the individual might not normally consent to. Even if this is not the case for some ill people, the problem remains, as it would appear difficult to ascertain which individuals are giving their 'real' consent and which are influenced by illness.

1.7.1.2 - The ill person and coercion

There is also the risk that consent may not be wholly valid insofar as subjects in clinical trials are already unwell, particularly if hospitalised, because such individuals may be coerced or pressured (unintentionally or otherwise) into giving their consent to participate in the research.

1.7.1.3 - The ill person and decreased cognitive abilities

Another aspect is that illness may tend to decrease one's cognitive abilities, thereby increasing the risk that the potential research subject will not understand the information they are given. And in the case of proxy consent, although this does not apply directly to the person giving proxy consent for a patient with compromised autonomy, it may be that the proxy, by virtue of their relationship with the patient, is sufficiently distressed that their own decision-making capacity is impaired. An example of this might be the parents of an ill child who are approached to consent to their child participating in a therapeutic trial.

1.7.1.4 - The effect on those consenting by proxy

Issues such as these are in one sense less of a problem for those with compromised autonomy, as it is usually the case that a proxy consents on their behalf. However, one could argue that the difficulty of interpreting the individual's 'real' wishes and thoughts remain, and are merely complicated further by being overridden in favour of the consent of a proxy. (This is particularly the case for children, who - unlike some other groups with compromised autonomy - have not had a chance to specify what they would want done in a particular situation.)

1.7.2 - Very ill individuals and clinical research

1.7.2.1 - Potential for exploitation of patients

Clinical research also creates ethical problems because it can involve very ill patients. Individuals who are seriously ill with a terminal, incurable condition may be open to exploitation in research because they may be sufficiently desperate to consent to high-risk or unethical procedures. An

unethical researcher may also take advantage of this attitude in order to recruit subjects for research.

1.7.2.2 - The right of the seriously ill individual to consent to high risk procedures

It is arguable, of course, that involvement in trials for incurable diseases may be justified because they are likely to benefit future patients - and that such patients should have the right to consent to research if they feel that that is what they wish to do. This is less an issue in autonomous adults (possible illness-induced changes in competence aside) but is a problem for those with compromised autonomy in a number of ways.

Firstly, and most obviously, potential research subjects with compromised autonomy may not be capable of understanding the intricacies of such a situation. That is, they may not be able to comprehend the potential problems of consenting to a high-risk experimental procedure, thereby increasing the risk of exploitation.

Secondly, and conversely, mature minors or elderly people in the early stages of dementia, for example - that is, those who are borderline in terms of autonomy, and who may understand enough to give their consent - may wish to consent to this kind of treatment but have their decision overridden.

Thirdly, cases involving individuals with compromised autonomy may involve proxy consent, and so it may instead be the proxy who seeks desperate solutions, thereby exposing the patient to potential harm. One such example is the parents of a terminally ill child, who may consent to high-risk therapy on behalf of their child. There are a number of problems involved here. It may be unethical to expose the child to suffering when little gain may result from dangerous trials. Or the parents may be acting not out of concern for the child, but out of feelings of guilt, or selfishness, because they fear losing the child[41].

---

[41]Downie, R.S. and Randall, F., 'Parenting and the bests interests of minors', The Journal of Medicine and Philosophy, 1997; 22; 227.

1.7.2.3 - Problems with pressure from/exploitation by seriously ill patients

So on one hand, subjects of therapeutic research may be disempowered by their illness and by their need for the research into that disease[42]. This situation is further complicated by the lack of power and control enjoyed by those with compromised autonomy. But on the other hand, research subjects are capable of exerting a certain amount of power.

This derives partly from the fact that they are human beings with problems which justify research. This is particularly the case when individuals with compromised autonomy are involved. For example, patients with psychiatric problems, or ill children, may be deemed to be particularly deserving of research, for although other groups in the community also have health problems, those with decreased autonomy may be less able to defend their own interests, and so may require outside intervention to have their interests protected. The power research subjects may have may also be exacerbated by the need researchers have to defend what they do[43] (both morally and in practical terms).

This power may manifest itself as pressure exerted on researchers and doctors by patients and their families if the study is known about, particularly if the disease is serious and there is no known cure.

As an example, researchers at Oxford were heavily pressured by the families of patients with ALS (amyotrophic lateral sclerosis) to make available a potential treatment before it was properly trialed, even to the extent that the researchers were harassed at their homes. Eventually, the treatment was released prematurely - and turned out to be ineffective.

A similar situation has been seen with research on HIV/AIDS, where patient lobbying and pressure can so powerful that it can affect decisions

---

[42]Little, M., 'Research, ethics and conflicts of interest', J.Med.Eth., 1999; 25; 259-262.
[43]ibid.

against the judgement and advice of scientists[44],[45]. Many individuals with AIDS believe they should breach trial protocols because they feel they are not 'true' volunteers; a common way in which the trial is compromised is through the treatment group sharing their treatment with those in the placebo group[46].

Thus, pressure from patients or their proxies may jeopardise the entire process of research; if a study is poorly designed, or not followed according to plan, there is the risk that the data obtained will be meaningless, thereby making the study fundamentally unethical. This is of particular importance when the research subjects are individuals with compromised autonomy, as they are not the ones who make the choice to push for premature release of a treatment, despite the fact that this may well expose them to risks. In addition, when the proxies are parents of desperately ill children, for example, the pressure they put on researchers and physicians may well exceed the level of pressure the patient himself would try to exert.

1.8 - When to stop a trial once effects begin to become apparent

Another problem with clinical research arises once a trial is underway. This occurs in a controlled trial because the patients in the treatment group may receive a treatment which, as the trial progresses, shows signs of being beneficial, while the control group are denied this. Conversely, the subjects in the treatment group may receive a treatment which begins to show evidence of being ineffective or more harmful than the control group, and it may appear to be unethical to persist with this course of action.

Thus, it is an issue when to stop the trial when either beneficial or adverse effects become evident. Obviously, it is undesirable that a research subject should have to endure adverse effects for longer than necessary (or at

---

[44]ibid, p. 261.

[45]Mariner, W., 'AIDS Research an the Nuremberg Code', in Annas and Grodin (1992), op. cit., p 286-303.

[46]Schüklenk, U. and Hogan, C., 'Patient Access to Experimental Drugs and AIDS Clinical Trial Designs: Ethical Issues', in Kuhse and Singer (2000), op. cit., p441.

all), nor should the placebo group be denied a treatment which appears to be effective. So there is the issue of when 'enough' good or harm has been demonstrated.

It is clear that this is more likely to be an issue in clinical or therapeutic research as this involves ill people in a trial which offers potential cure or palliation of symptoms. Non-therapeutic or non-clinical research is unlikely to have the same direct effect on ill individuals.

1.8.1 - Neural tube defects: an example

An example is the study which investigated whether folic acid decreased the incidence of neural tube defects (NTDs) in infants[47]. After a time, there was an apparent benefit, but one insufficient to establish with statistical significance that folic acid was actually making a difference. But while waiting for confirmatory data, a number of women (the control group) were denied folic acid - should the control group have been given folic acid immediately?[48] In the case of folic acid and NTDs, the folic acid must be given prior to and in the very early stages of pregnancy to exert its effect - by the fourth week[49], usually before the pregnancy is recognised - and so it is arguable that switching the control group onto therapy would have no effect by that stage. However, this is not the answer for the majority of other situations which involve a similar dilemma.

Firstly, it is arguable that it is not *known* that the results which are seen early in a trial are 'true' *until* statistically significant results are obtained; a study needs to last for a certain length of time in order for the results to be statistically significant[50]. That is, it should be noted that it would not be justified

---

[47]The MRC Vitamin Study Group, 'Prevention of neural tube defects: Results of the Medical Research Council Vitamin Study', Lancet, 1991; 238; 131-137.

[48]Mason and McCall Smith (1994), op. cit., p. 358.

[49]Department of Health, Scottish Office Home and Health Department, Welsh Office, Department of Health and Social Services (Northern Ireland) (1992), Folic Acid and the Prevention of Neural Tube Defects, Health Publications Unit, Heywood, Lancashire, p. 8.

[50]Mason and Mc Call Smith (1994), op. cit., p. 354.

to switch over the control group to receive active treatment until one could be certain that it really was beneficial. However, to be certain of a beneficial effect, it is necessary to continue until the end of the trial, because it is a statistically significant difference which indicates a true benefit - that is the point of doing such studies - to ensure that preliminary findings really are a true or useful result. (Having said that, however, the idea of statistical significance raises the problem of the use and misuse of different statistical systems. It is a comparatively simple matter to manipulate data so that it appears significant (or not), depending on the particular statistical analysis used.)

Secondly, prematurely ending a trial would, in effect, undo the 'good' done by those women who had already participated in the trial - and they would have been exposed to any risks involved in the trial, without any associated gain. In this sense, there is a duty to those women who successfully completed the early stages of the trial, to continue with it in its original format.

Thirdly, it may be that withholding treatment from the control group until a statistically significant result is obtained, is justifiable in that it will provide benefit for all future mothers. However, it could be said that this still impinges on the rights of the control group subjects. Even research subjects who are fully autonomous are problematic in that such an eventuality is unlikely to be the kind of outcome they would consent to.

Fourthly, certain diseases and problems (such as NTD) represent a vast drain on the health care funding and other resources of society, and it could be argued that in a situation such as this, the interests and resources of the community must be considered.

Fifthly, the subjects in the study gave their consent to participate in this kind of trial, knowing the possibility that they might not receive treatment; it is hard to see why this is unethical if the subject is adult, mature and autonomous. However, it must be said that recall rates of information given, and probably levels of understanding at the time of consent, are notoriously poor, even in

those we would call 'autonomous'. In one study involving adults in research, 69% of participants failed to understand that assignment to treatment groups was random - in fact, 40% stated explicitly that they would be allocated to different groups based on their therapeutic need[51]. There is also an obvious difficulty with this defence when one considers the case of those with compromised autonomy who require consent by proxy, such as children, the mentally ill and incapacitated, and so forth.

And finally, continuation of a trial despite preliminary findings might be justifiable in the sense that were the study never embarked upon, the controls who had babies with NTD (as well as the treatment group) would have had that outcome anyway. However, this kind of objection does not work well for trials for a treatment where a reasonably effective, standard treatment already exists, unless the standard therapy is being used for the control group.

1.9 - Non-therapeutic research

There are a number of problems with non-therapeutic research.

1.9.1 - Risk-benefit problem in non-therapeutic research

The first problem to do with non-therapeutic research relates to risk-benefit analysis, which is relevant to a wide range of situations, both clinical and non-clinical research, as well as treatment.

The risk-benefit problem may be argued to be even more significant in the case of non-therapeutic research, as it is more likely to involve well or healthy individuals. If healthy volunteers are used, they are unlikely to have obvious or direct benefits - compared with ill research subjects in clinical research, who may benefit directly.

---

[51]Gray, B.H. (1975) 'Human Subjects in Medical Experimentation', Wiley, New York, cited in Zinner (1995), op. cit., p. 326.

Thus, it is questionable whether the research can be said to be justified in risk-benefit terms; the research subject does not have an obviously direct benefit which offsets the potential risks to which he or she is exposed.

1.9.2 - Degree of risk involved in research may influence its acceptability

However, this argument may depend on the particular research being carried out; a trial with minimal risk may mean that the potential benefits to the entire group to which the subject belongs outweigh the risk, even though no direct benefit is expected for the individual. In addition, some studies may involve less than minimal risk (for example, giving a urine sample) and again, in cases such as these, objections on risk-benefit grounds would not appear warranted.

1.9.3 - A utilitarian defence of the involvement of healthy people in research, and problems with such a defence

Another way in which the lack of obvious direct benefit to the subjects may be justified is on utilitarian grounds - it can be argued that research such as this is justified because, overall, it leads to potential benefits to future individuals.

One problem with this is that it is difficult to ascertain how this degree of goodness should be assessed. Should the 'greater good' be in terms of the absolute number of people who will benefit? or the number of *autonomous* people benefiting? and how should the suffering of some be compared with benefit to others? and so forth. However, having said this, it is arguable that realistically the needs of and cost to the community sometimes need to be factored into the equation. If a particular problem has a significant impact on society and could be reduced by research, then this may help justify the risks research subjects are exposed to.

A second problem with a utilitarian analysis of the situation is that it compromises the idea of the rights and value of the individual.

1.9.4 - The role of patient consent in non-therapeutic research

Therefore, even if strong rights theorists do not accept utilitarianism as a defence for involving people in research, the possible compromise of the rights of the individual in non-therapeutic research may still be defended on the grounds that the research subjects have given their consent to participate. If a study involves risk of harm to participants, it could be argued that their autonomy should be respected and that they should be allowed to participate in the study if they so choose. This, however, raises at least three further issues.

Firstly, this does not hold for cases in which consent or permission is given by a proxy on behalf of an individual with no or compromised autonomy.

Secondly, even in autonomous beings, the notion of consent raises problems, some of which were discussed earlier - learning new information is often a complicated process, and the extent to which someone has understood information is difficult to ascertain with certainty. Although understanding is less likely to be complicated by illness, as in the case of therapeutic research, this lack of illness makes it even more important to ensure that consent is informed, given the lack of therapeutic benefit likely to be experienced by the subject.

And thirdly, a significant proportion of people we would consider autonomous may not understand the intricacies of a number of situations, and it is debatable whether their consent is meaningful when we know it to be less than fully informed. That is, merely having someone agree to participate does not absolve us of our responsibility to ensure they do not endanger themselves.

1.9.5 - The involvement of ill people in non-therapeutic research

With respect to the problem of risks and benefits in non-therapeutic research, it has been argued that it is not justified to use healthy subjects, and that ill patients should be used instead, as they stand to gain something from the study to offset the risks involved.

However, one could argue that it is no less unethical to use ill patients as research subjects, because the potential benefit of the study may not be benefit which relates to their illness; their illness may make them more likely to suffer from the risks involved in the study; they are already ill and to ask them to participate in research which may have nothing to do with helping their condition might be to further increase their suffering; and there is the potential that involvement in the study might make these individuals more unwell as they have fewer reserves than healthy individuals.

Further, it seems evident that there are is a wide range of potential research subjects which do not relate directly to illness. Topics such as social factors, economic and occupational aspects of health and living, preventative medicine, and psychological problems are examples of such subjects. Thus, it is not feasible to use only ill people in research.

1.9.6 - Assessment of probable benefits in research

The issues discussed so far relate to the fact that non-therapeutic research poses an ethical dilemma because it tends to do poorly from a risk-benefit viewpoint. This implies that only research with a clearly defined and probable benefit should be considered ethical.

However, if the outcome (including risks and benefits) of a study could be accurately predicted, there would seem little point in undertaking it. It should also be said that many of the significant scientific discoveries to date

have occurred through chance, which makes it difficult to limit research on the grounds that it is only justified if it is likely to have a benefit.

The issue of serendipity may be less important now in that knowledge in many areas of science and medicine has reached a sufficiently sophisticated level to mean that research is used primarily to refine knowledge, and as a result, the role of chance may play a lesser role and it may be easier to predict whether a study is likely to have a beneficial outcome. However, there are still many burgeoning areas of science and medicine; because so little is known about these topics, it is difficult to predict which studies are likely to benefit the subjects.

But it seems neither possible nor especially desirable to limit research on these grounds (though of course the study needs to be designed carefully in order to minimise the likelihood of problems occurring). In addition, much research may end up proving that the anticipated result does not occur (that is, the null hypothesis); this may still be useful and just as important as positive findings, even though it might be argued that such a study exposes its subjects to risks without direct benefit.

Further, it is arguable that the benefits which result from non-therapeutic research are not so much non-existent as merely less obvious and less direct; clinical, therapeutic research is not the only means of obtaining useful information. In addition, this kind of research is often necessary to develop enough information about a subject for therapeutic research to be possible; therapeutic research is but one end of the range of data which needs to be known about a particular subject. This range includes knowledge about normal, as well as diseased, states. The fact that this kind of research is just as necessary as clinical research counteracts the idea that only research with direct benefit to the subject is justifiable.

1.9.7 - Motivation to participate in research

Another potential problem with non-therapeutic research relates to motivation to participate. Non-therapeutic research is more likely to involve healthy volunteers, for whom material inducements are likely to be important[52] - more so than for unwell patients participating in therapeutic research. The chance of beneficial therapy or cure is more likely to be a stronger motivating factor in this latter group.

Although it would seem that subjects (particularly healthy volunteers) should be compensated for time spent participating in the study, too large a sum of money on offer, or too great a need on the part of the subject for the money on offer, could mean that subjects might ignore excessive risk or have their decision affected in some other respect. This is particularly an issue when the potential research subject has compromised autonomy, and there is the risk that the person giving permission or consent on their behalf may be influenced by financial or other inducements, thereby exposing the potential subject to a possibly dangerous or otherwise undesirable situation.

1.9.8 - Research subjects in non-therapeutic research

Further, healthy volunteers may not represent a randomised sample because they are a specific subset of the population who chooses to participate in an activity such as this. On the other side of the coin are specific populations who may be targeted for participation because of their availability or predisposition to respond to material inducements.

An example of such a group is a tertiary student population[53],[54]. Students are usually healthy, intelligent, available in large numbers, and financially less well off than many other groups in society. The potential for

---

[52]Mason and McCall Smith (1994), op. cit., pp. 352, 356.
[53]ibid, p. 357.
[54]See also Harling, R., 'Organophosphate pesticides are being tested on students', BMJ, 15 Aug 1998; 317: 430.

exploitation of this group is reflected in the University College London recommendations to students that they should satisfy themselves that any project they engage in is approved by an independent ethics committee and that they are legally covered in case of mishap[55]. Another group is prisoners; the obvious risk for this group is coercion to participate in a study[56].

However, with both these 'at risk' groups, it is arguable that they should be allowed to participate in research if that is their choice. The difficulty is assessing the extent to which they are truly free in their consent. A similar sort of problem applies to potential research subjects who belong to 'borderline' autonomous groups, such as children and the elderly.

1.9.9 - Allocation of resources to non-therapeutic research

It should also be noted that it may not be justifiable to spend resources on research which has no obvious direct benefit. Much research is done which is not unethical in the sense that it is approved by an ethics committee, but the results have little or no use, and it is difficult to see how this justifies the risk to patients, the time spent both by researchers and by research subjects, and the use of funding.

However, as I have noted above, likely benefits in a research project are difficult to predict, particularly in a new field of study; difficulty in perceiving benefits doesn't mean that no benefits exist; unexpected benefits often result from research and although that is not to say that any research should necessarily be permitted, it would seem disadvantageous to restrict the scope of research to include only studies which have a very obvious, predictable benefit as outcome. Even if one considers that therapeutic research is more justifiable, it should be pointed out that therapeutic research is not the only source of important knowledge, and in fact a certain amount of non-therapeutic research

---

[55]Quoted in Royal College of Physicians of London (1990), Guidelines on the practice of ethics committees in medical research involving human subjects, p. 25.

[56]Mason and McCall Smith (1994), op. cit., p. 357..

needs to be done to accumulate enough knowledge to permit therapeutic research.

1.10 - Conclusion

To conclude, in this chapter I have discussed a number of issues relating to research in general.

Firstly, I discussed factors which contribute to the increased awareness of ethical issues relating to research. These factors include: increasing focus on the rights of the individual; increasing capacity for intervention in health and illness; influence from government bodies; the dual role of doctor as researcher; and historical examples of the mistreatment of research subjects.

Secondly, I discussed the increasing focus on rights, autonomy and consent, and outlined a number of problems which pertain to consent. Such problems include: difficulty in defining what constitutes 'informed consent'; different standards of information disclosure, such as professional and patient standards; difficulties in communicating; risks involved; and the role of doctor-patient trust.

Thirdly, I differentiated between experimentation and research, and explained why both have some advantages and disadvantages.

Clinical research and non-therapeutic research were also contrasted. Some of the problems with clinical research include the involvement of the clinician and conflict of interest; the involvement of ill individuals, and the way in which this may cause ethical problems; and the issue of when to stop a trial once benefits become evident. Non-therapeutic research has problems with risk-benefit analysis, the role of consent, involvement of ill people, motivation to participate, and allocation of resources.

These factors set the scene for an analysis of research problems involving sub-groups of the research population with compromised autonomy, namely, children, the elderly, and the mentally ill.

CHAPTER 2 - RESEARCH INVOLVING CHILDREN

2.1 - Introduction

In this chapter, I shall discuss a number of aspects of the role of children in research. Firstly, I shall describe why research on the paediatric subpopulation is important. Secondly, I shall also discuss the notion of parental consent, and arguments in favour of this as well as against it. Thirdly, the autonomy of the child will be described, and their ability to consent for themselves analysed. Fourthly, the special case of adolescents will be mentioned, and various aspects which set them apart from other children will be discussed. Fifthly, psychological and social research will be assessed in terms of the way in which they apply to children. Finally, the role of the doctor in research involving children will be examined. These analyses are important to maximise the possibility of ethical research in children.

2.2 - Research involving children

2.2.1 - The need for research in the paediatric subpopulation

Clearly research on children is necessary, at least to a certain extent. Some medical problems exist only in children (such as retinopathy related to prematurity, neuroblastoma, Wilms tumours, and congenital heart disease, and metabolic disorders which need treatment in childhood to avoid irreversible damage) and mean that other age groups cannot be used for research into these conditions[57]. Children are anatomically and physiologically different from adults[58], and respond differently to drugs and various other therapies that are used for diseases common to both children and adults. Drug handling and side

---

[57]Kauffman, R.E., 'Scientific Issues in Biomedical Research with Children', in Grodin, M.A. and Glantz, L.H. (eds) (1994), Children as Research Subjects, OUP, NY and Oxford, pp. 35, 37.
[58]ibid p. 29-30.

effects are also often different in children[59], either quantitatively or qualitatively. These factors also explain the need for research involving children.

2.2.2 - Lack of research leads to inadequate treatment and increased risks

As a result of the factors listed in the preceding section, a lack of properly conducted trials (particularly for medicines) in the paediatric subpopulation means that safe and effective therapy for children is often not known. Although there is no clear evidence of children having been harmed through lack of 'child specific' testing, this cannot be known for certain[60]. The lack of research involving children means that current practice often involves extrapolation from adult data, and treatment on a case-by-case basis. This exposes children to an increased risk of adverse reactions or suboptimal therapy[61,62].

Thus, it would seem unethical *not* to do research on children[63], provided that care is taken. The National Committee for the Protection of Human Subjects specifies that research on children should only be permitted if the experiment investigates a significant problem, it is a good design, the results are likely to be useable, it could not otherwise be done on adults, and there has been previous testing on animals, adults and older children[64,65]. However, such guidelines represent an ideal situation and are not always practicable, and they do not eliminate a number of ethical problems that arise when children are

---

[59]ibid, p. 38-40.

[60]Warden, J., 'Loophole exposed in testing of child medicines', BMJ, 1997; 314: 698.

[61]U.S. Food and Drug Administration, Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, pages 66631-66672 [FR Doc. 98-31902] OC 98142, Docket No. 97N-0165.

[62]Rutter, T., 'Drugs must be tested for use in children', BMJ, 1997; 315: 445.

[63]Forman, E.N. and Ekman Ladd, R. (1991), Ethical Dilemmas in Paediatrics - A Case Study Approach, Springer-Verlag, New York, p. 69.

[64]ibid, p. 70.

[65]See also British Medical Association (1984), The Handbook of Medical Ethics, BMA, London, pp. 31-32.

used as research subjects, particularly in the context of non-therapeutic research.

2.2.3 - Issues raised by the involvement of children in research

Research involving the use of children as research subjects raises a number of issues which I shall discuss. These include difficulties with parental rights and their limits, parental consent on behalf of the child, the consent of the child himself, psychological and social research, and the involvement of the doctor in research.

2.3 - The issue of parental consent

The first such issue surrounding research involving children is whether parents should be able to consent on behalf of their child.

2.3.1 - Historical basis of parental consent

This revolves around the notion of parental rights and their limits. The rights of parents exist today partly through historical precedent (from antiquity, children were considered property of parent or state[66]) but may also be considered to be socially bestowed, as parents have genetic ties to the child, presumably know him or her best, care about the child, and are usually most directly affected by decisions involving their child[67],[68]. In addition, children often *want* their parents to choose, and to interfere in this process may disrupt the structure of the family and may reflect negatively on parents, implying neglect or abuse[69].

---

[66]Lederer, S.E. and Grodin, M.A., 'Historical Overview: Pediatric Experimentation', in Grodin and Glantz (1994), op. cit., p. 8.
[67]Forman and Ekman Ladd (1991), op. cit., p. 9.
[68]Brock, D.W., 'Ethical Issues in Exposing Children to Risks in Research', in Grodin and Glantz (1994), op. cit., p.94.
[69]ibid, pp 95, 100.

2.3.2 - Shift away from complete control of a child by their parents

However, there appears to be a shift away from complete control of a child by his or her parents, even allowing for the fact that ideal parenting seems difficult to define and impossible to achieve. Certain things are already compulsory - even if they conflict with parents' wishes - such as schooling, life-saving treatment, and vaccinations (at least in the U.S.[70]). Society is increasingly prepared to intervene to protect the child, particularly when it seems clear that parents are putting the child in danger (either unintentionally, or through abuse or neglect), or that they do not have the child's best interests at heart. Lord Fraser, in the case of *Gillick*, stated that '[p]arental rights to control a child exist not for the benefit of the parent but for the child'[71], an echo of an earlier statement by Lord Denning, who said that '[p]arental rights start with the right of control and end with little more than advice'[72].

Thus, over the past few decades, there has been an emerging trend in which the judgement of the child is given increasing weight[73], and although parents continue to be involved and to be able to consent before a child is considered capable of doing so, evidently there are now limits to parental rights over a child. This factor is particularly an issue when it comes to research involving children; as consent is considered of fundamental importance in the process of ethical research, decisions about who is the right person to give consent when a child is involved is a key issue. A shift away from complete parental control implies that parents ought not to have an absolute right to consent on behalf of their child, but on the other hand, a middle ground appears difficult to determine, both legally and morally.

---

[70]Bradley, P., 'Should childhood immunisation be compulsory?', J.Med.Eth., 1999; 25: 330-334.
[71]Gillick v West Norfolk and Wisbech Area Health Authority, 1985.
[72]Hewer v Bryant, 1970, quoted in Mason and McCall Smith (1994), op. cit., p. 223.
[73]Weithorn, L. and Scherer, D.G., 'Children's Involvement in Research Participation Decisions: Psychological Considerations', in Grodin and Glantz (1994), op. cit., p 133.

Research on children in the past has been restricted partly owing to doubt about the legality involved[74]. Legally, children under 18 are considered minors, though those aged between 16 and 18 may consent to therapeutic intervention according to the Family Law Reform Act of 1969[75]. The case of younger minors was less clear until the case of *Gillick*, which found that parental right to choose treatment for the minor 'terminates if and when the child achieves a significant understanding and intelligence to enable him or her to understand fully what is proposed'[76]. Thus, although the issue of consent of minors to therapeutic procedures is fairly clear (at least legally), the situation is less certain when research is involved.

It is generally held that parents may 'volunteer' their child for research when the research is therapeutic and the benefits are obtainable only in the context of the research in question[77]. However, it is not clear that the situation is always so admirably straightforward, and so justification of parental consent on these grounds does not seem valid. However, the Age of Legal Capacity (Scotland) Act 1991[78] states that young people aged between 16 and 18 have the capacity to consent to treatment or a procedure on their own behalf, but also that children under 16 are also capable of giving valid legal consent to a treatment or procedure, *including research*, provided he or she is judged to understand the nature and consequences of the procedure. This applies even when the treatment is not directly for the benefit of the child.

However, one of the main issues remains essentially unchanged, and that is ensuring that the minor does truly understand the implications of their

---

[74]The Royal College of Physicians of London (1990), Research Involving Patients, RCP, London, p. 19.

[75]The Royal College of Physicians of London (1990), Guidelines on the practice of ethics committees in medical research involving human subjects, RCP, London, p. 27.

[76]Gillick v West Norfolk and Wisbech Health Authority, 1985, quoted in Mason, J.K. and McCall Smith, R.A. (1994), Law and Medical Ethics, Butterworths, London and Edinburgh, p. 224.

[77]Forman and Ekman Ladd (1991), op. cit., p. 70.

[78]Quoted in: The Scottish Office - Home and Health Department, Local Research Ethics Committees, Scotland, Dd 0011213 C10 8/92 Ed(203704), p. 13.

consent. Making something legal does not automatically mean it is morally right; as has been noted, 'competency' is often interpreted in the legal sense, with those under the age of eighteen being considered incompetent[79].

2.3.3 - Arguments against parental consent

2.3.3.1 - Parental consent as a substitute for a child's own judgement

Clearly, there are a number of problems with parental consent and whether it can be said to be justified. One way of looking at the situation is to see parental consent as a substitute for the child's own judgement that cannot yet be expressed - that the parents are expressing what the child would want to say, had he or she the ability to do so[80].

This seems an inadequate justification, whether the argument be for therapy or for research. It is clear that children often have an opinion that is at variance with that of their parents, whether we consider that opinion reasonable or not. And if a child genuinely could not express his or her opinion, thereby requiring someone to speak on their behalf, it would seem unclear that anyone could know what that opinion was and be able to conclude that the parents were representing this accurately. Adults may express views on the way in which they would like to be treated in certain circumstances that can be taken into account should those circumstances arise and the patient is unable to speak for themselves. But this seems distinct from the case of children in two ways.

Firstly, the view outlined above implies that the child has not yet reached the stage at which they are able to communicate their judgement; if one allows this, then the child would never have expressed his or her judgement at any stage previously.

---

[79]Brock, in Grodin and Glantz (1994), op. cit., p. 81.
[80]Forman and Ekman Ladd (1991), op. cit, p. 370.

Alternatively, and perhaps more realistically, the child may have the capacity for judgement, but is unlikely to have thoughts previously about what they would do in response to many (or all) medical interventions or research proposals. In either case, the child is unlikely to have given an indication in advance of their wishes. However, it seems unreasonable to conclude that the child (particularly if older) can have no judgement when presented with a choice and the relevant information.

2.3.3.2 - Parental consent in the 'best interests' of the child

It is also often argued that parental consent is justified because it is 'in the child's best interests'. This implies that the child does not know what is in his or her best interests, and that the parents do know.

However, evidently some children, particularly older ones, *do* know what is in their interests, or can at least have a point of view that is reasonable, as I have stated above. Further, it is not clear that parental consent is justifiable on the grounds that they alone know what is in the child's best interests - they may not know, or if they do, the situation may be complicated by duties to other family members, to their jobs, and so forth[81].

And although it is generally assumed that the child's parents will feel strong and unselfish love for the child which will lead them to decide in the best interests of the child[82], it is however arguable that a feeling of love does not necessarily translate into an automatic knowledge of the course of action which is in the child's best interests (although it may be some kind of protection against deliberate harm). Nor is such a love guaranteed, as may be seen by the many cases of child abuse and neglect. In addition, it may be that others (such

[81]Randall, F. and Downie, R.S. (1999), Palliative Care Ethics, Oxford University Press, Oxford, p.59.
[82]ibid.

as the attending doctor) know equally well, or better, what is in the child's best interests[83], particularly in a medical context.

Another point is that the 'best interests' of the child may not be particularly clear. The situation is further complicated by the fact that the interpretation of what represents the child's 'best interests' may be biased, depending on who is doing the interpreting. For example, the child's 'best interests' according to his or her parents may be quite different from the 'best interests' according to the child's doctor. Although it is to be hoped that this kind of complication does not arise often, it is unclear whether the problem is readily soluble; there may be no 'formula' for assessing a child's best interests, thereby making any decision on this point somewhat arbitrary. Thus, on these grounds, it is not clear why parents should automatically be the ones to make decisions about consenting for a child.

2.3.3.3 - The problem of lack of parental understanding

Another problem with parental consent is that the parents may not fully understand the trial to which they are consenting on behalf of their child, perhaps exposing the child to a situation or to risks they or the child would not want to be involved in, were their understanding more comprehensive.

It is arguable that although parents may be in a good position to give their permission for many things in a child's life, it is less ethical for them to consent to research on behalf of their child because they may not fully understand the medical information relevant to the study. This lack of comprehension may be exacerbated by stress if their child is already unwell[84].

Although the signature of the parents on a consent form satisfies legal requirements, it is less clear that this is morally adequate, given that

---

[83]Downie, R.S. and Randall, F., 'Parenting and the best interests of minors', The Journal of Medicine and Philosophy, 1997: 22; 219-231.

[84]Forman and Ekman Ladd (1991), op. cit., p. 28.

understanding at the time of signing is often suboptimal[85], and the level of recall even more inadequate[86]. It is difficult to assess the extent to which the parent has understood, particularly if consent is being sought during the limited time of a consultation.

Further, it may be seen that understanding often develops through multiple interviews and various methods of describing, as well as through feedback and asking questions. This is seen, for example, in parents who have chronically ill children[87], but it is reasonable to assume that this would also apply to information about research, particularly if complicated. However, the time and multiple sessions that may be needed are unlikely to be available, thereby jeopardising parents' understanding.

Thus, lack of understanding is a problem for parental consent because it may lead parents to consent when they would not do so were they to comprehend fully. It may also lead them to refuse their consent even when the trial is in the best interests of the child, and in a situation where they would give their consent, were they to understand the trial more fully. They may be confronted with an outcome which, although a reasonable or expected part of the trial, is not so for them because they had not understood the situation fully. And finally, the child may be harmed if parents consent to a dangerous trial they have not fully understood, though it is to be hoped that researchers and ethics committees would help prevent this eventuality.

It may be seen, therefore, that the researcher has a responsibility to help parents understand the need for research, as children are different from other potential research groups. For example, we can avoid involving prisoners and developmentally-delayed adults in much research, as other, autonomous adults may be used as research subjects instead[88]. This, however, applies less to

---

[85]Bjørn, E., Rossel, P. and Holm, S., 'Can the written information to patients be improved? - an empirical study', J.Med.Eth., 1999; 25: 263-267. (p.266)

[86]Forman and Ekman Ladd (1991), op. cit., p. 28.

[87]ibid.

[88]Brock, in Grodin and Glantz (1994), op. cit., p. 90.

children; in the majority of cases, there is no alternative group who can be used instead. Researchers need also to help parents to evaluate the risks and benefits involved, both social and medical/scientific[89].

2.3.3.4 - Problems with the amount of information to disclose to parents

These difficulties in parental understanding have been outlined on the assumption that although complete disclosure may be difficult to achieve, it is desirable. However, this may not be the case. 'Informed consent' is a problematic idea because many people take it to mean that the patient or research subject should be given *all* information, which is not necessarily the same as enough to make a reasoned, balanced decision in the circumstances; the amount of information to give is difficult to gauge. Giving 'all' information is problematic for a number of reasons. Firstly, it would be too time-consuming in many cases. In addition, it is arguable that much information is changed, not just in form but in content, when it is adapted for a non-medical audience. Thirdly, 'complete' information is difficult to define and may mean quite different things for different people. Fourthly, complete information may not be necessary for an individual to make a reasonable and intelligent decision; and fifthly, a lack of background knowledge may predispose the listener to misinterpret the information and focus disproportionately on benefits or harms - even more so in the case of worried parents of a sick child.

2.3.3.5 - Risks to the child's health resulting from parental consent

A further difficulty with parental consent is that parents can endanger their child by giving their consent to a procedure or drug that is not yet - or never will be - at the stage of being trialed formally.

---

[89]ibid, p. 87.

An anecdotal example is the case of a Sydney mother with an autistic boy who remained non-responsive to the range of medications used for the treatment of this condition. The boy was becoming increasingly difficult to control and physically too powerful for his mother. She approached a number of Sydney doctors and requested that they try a new treatment on her son - the use of the gastrointestinal hormone secretin, which is not approved for any use in Australia - which she had heard about on a current affairs show. There was no scientific evidence to support these claims - merely two anecdotal cases. Despite this, a gastroenterologist eventually agreed to administer the medication, at the request of the mother, despite the risks this untested and unlikely treatment poses to the child.

While it is largely uncontested that a physician ought not to force treatment onto a patient when they do not want it, it is rather less clear what responsibilities the doctor has when a particular treatment is requested[90], especially when the treatment is of doubtful efficacy, or when it is being requested for a third party, such as a child. It may be argued that doctors have a duty to co-operate with reasonable requests, but perhaps only those requests that are obviously reasonable as one has an obligation to 'do no harm', and perhaps not if there are other factors that override the request[91] (e.g. other 'more reasonable' requests). Similarly, parental consent poses problems because it means that a child's wishes can be overridden, even when it seems they are in full possession of the facts, and understand that which they are consenting to, which would appear unethical.

2.3.4 - Arguments in favour of parental consent

There are a number of arguments for parental consent.

---

[90]Jackson, J., 'Unproven treatment in childhood oncology - how far should paediatricians co-operate?: Commentary', J.Med.Eth., 1994; 20: 77-79.
[91]ibid.

2.3.4.1 - Parental consent allows the child to access benefits of a trial

Objectively, participation in the trial may be to the child's advantage, more obviously in the case of therapeutic trials. However, non-therapeutic trials may still be advantageous to the child because such research may benefit overall the group to which the child belongs[92], thereby making the research more justifiable by providing a benefit to balance potential risks involved. Parents may be seen as a socially approved proxy whose consent allows the child to access these benefits.

2.3.4.2 - Parental consent permits development of 'pro-social' traits in the child

Parental consent may also be considered justifiable if it is interpreted as parents fulfilling their duty to society by engaging the child in 'pro-social' activities. It may be argued that parents may not have the right to impose 'selflessness' on their children in this way, but it may serve to breed a sense of altruism in the child which an older child at least may be capable of appreciating[93].

2.3.4.3 - Difficulties in overriding parental consent

Further, even if we do not approve of the parents of a child giving their consent for the child to participate in a trial, it may be difficult to justify intervening to prevent this, as it is unlikely that the child's life is threatened through either choice or neglect[94]. This may be particularly true of involvement in research, rather than therapy, which is comparatively straightforward.

2.3.4.4 - Respecting parental consent allows preservation of family relationships

---

[92]Mason and McCall Smith (1994), op. cit., p. 371.
[93]ibid.
[94]ibid.

A further argument in favour of parental consent is that it contributes to the preservation of intimate family relationship[95]; it has been argued that a good family life is one of the greatest personal values[96]. Thus, one could argue that the parental rights that underlie and justify parental consent are not rights of 'ownership' of the child, or derived from knowing the child's best interests, but the right to have the family structure protected against interference from external bodies[97]. This is one reason why parents should be the ones to give proxy consent, rather than some other person, particularly in the case of very young children or infants, where it is more clear that proxy consent is truly needed. This is, of course, compatible with taking into account the views of both the child and the attending doctor[98]. This would appear to apply equally well to consent to research, as well as therapy. However, it should be noted that protection of the parent-child relationship may not be realistic if the parent makes a decision with which the child does not concur[99].

2.4 - The consent of the child

Traditionally, parents had a great deal of control over children and were able to consent to medical intervention on behalf of their child until that child attained majority. As I have discussed above, there are a number of reasons that are often cited in support of parental consent. 'Parental' reasons for parental consent - most of which are not without problems - include notions of parental rights, the best interests of the child, parental consent as a substitute for the child's own views, and preservation of intimate family relationships. Focusing on the child, on the other hand, the main reason that may be used to justify parental (or other proxy) consent is the idea that children are non-autonomous.

---

[95]Downie and Randall (1997), op. cit., p. 219.
[96]Forman and Ekman Ladd (1991), op. cit., p. 9.
[97]Downie and Randall (1997), op. cit., p. 225.
[98]ibid, p. 226.
[99]Zinner, S.E., 'The Elusive Goal of Informed Consent by Adolescents', Theoretical Medicine, 1995; 16: 323-331.

2.4.1 - The autonomy of the child

However, it is questionable whether children *are* actually non-autonomous.

2.4.1.1 - Autonomy is partly dependent on age

Autonomy is partly dependent on age, and although it is certainly arguable that infants and small children lack the requisite features to be characterised as autonomous, as children get older, many do have the capacity to make reasonable judgements and decisions; the capacity to reason like an adult does not suddenly come into existence on the child's eighteenth birthday[100]. Most children have views on issues and situations they face, and although they may not fully understand some of the complexities of health issues, the same is true of some adults[101].

2.4.1.2 - Children are capable of reasoning and decision-making

In any event, there is good reason to think that many do have a comprehensive understanding of quite sophisticated topics. Decision-making capacity increases through practice, as seen in children with (for example) chronic illness, who have a more mature and knowledgeable outlook[102], but quite sophisticated understanding and decision-making is also seen in well children, to a greater extent as they get older.

Even young children recall things well (though it is more difficult to assess understanding)[103] and it has been found that children aged nine to eleven demonstrated a sophisticated way of evaluating information and asking relevant questions when participating in a classroom discussion about

---

[100]Forman and Ekman Ladd (1991), op. cit., p. 12.
[101]Downie and Randall (1997), op. cit., p. 221.
[102]Forman and Ekman Ladd (1991), op. cit., p. 13.
[103]Zinner (1995), op. cit., p. 329.

research[104]. Similarly, a comparison of 36 minors and 36 adults found that there was no difference in the frequency of agreement to participate in various sorts of studies[105]; generally children will make the same kinds of decisions as 'autonomous' adults, though they may not be able to give such sophisticated reasons for their choices[106]. A further study found that 14-year-olds did not differ significantly from adults in their choices about hypothetical medical situations, and the majority of 9-year-olds in the same trial made the same decisions as adults[107].

Thus, not only are children capable of having reasonable views on treatment and research options, but many - even very young children - make the same kinds of decisions that we would consider reasonable when made by adults, whom we consider autonomous.

2.4.1.3 - Continuum of capabilities and corresponding continuum of ability to consent

So it would seem that we cannot claim that children are non-autonomous, because they possess skills which we consider part of being an autonomous being. Certainly, not all children of all ages can be considered fully autonomous in all respects. But there seems to exist a continuum between a completely helpless and non-autonomous neonate, and a near-adult teenager[108] who appears fully capable of making intelligent decisions, which suggest that a corresponding 'sliding scale' of consent would be more appropriate.

Thus, there is a trend towards permitting minors to take increasing control of the decision-making process. This is reminiscent of Locke, who believes that although parents, to fulfil their duty to society, have the right to limit the liberty of their child in order to bring him or her up in a certain way, the goal of parental guardianship is to nurture the autonomous and rational

---

[104]ibid, p. 328.
[105]ibid.
[106]Forman and Ekman Ladd (1991), op. cit., p. 13.
[107]Zinner (1995), op. cit., p. 328.
[108]Weithorn and Scherer, in Grodin and Glantz (eds) (1994), op. cit., p. 133.

powers of children, so that they can be free from the need for parental supervision at adulthood. This implies that there ought to be an inverse relationship between parental supervision and control, and the increasing maturity of the child. (The validity and usefulness of this of course depend on the age of the child, what is being asked, and the extent to which the child appears to understand the proposition.) However, there are a number of difficulties with this.

2.4.2 - Issues relating to the consent of a child

2.4.2.1 - The practical problem of children consenting

The first problem is that having a theoretical framework is one thing, but implementing it, making it feasible and fair, is more difficult. The very nature of the 'sliding scale' model of consent means that no absolute, clearly defined rules can be firmly implemented to enhance to freedom of children who can consent for themselves, and to protect those who cannot. Guidelines, while useful in the main, cannot cover every eventuality. And although it is to be hoped that guidelines are derived from a thorough analysis of the ethical problems involved, they do not form a substitute for the judgement required in a particular situation of a child giving his or her consent. In addition, guidelines are likely to represent the more common, straightforward situations, whereas it is the 'grey' areas that tend to be problematic.

2.4.2.2 - The validity of a child's consent - autonomy

There are also a number of other problems with children giving consent. One main problem is whether such consent can be considered valid at all. One reason why the consent of a child is argued to be invalid is because children are often thought of as non-autonomous.

However, as I have discussed above, this cannot be said to be true of many, let alone all, children. This is because many possess the characteristics

we consider necessary for autonomy - namely, the ability to reason and to come to rational decisions in the same way adults (most of whom we consider autonomous) do.

Some might contend that children are, by definition, non-autonomous, but this seems inadequate and a way of merely avoiding the issue, given that many children have characteristics consistent with autonomy.

Certainly, not all children are fully autonomous in all situations. But it is arguable that a child, with the potential protection or doctor, parents and ethics committees, should be *encouraged* to make his or her own decisions, including the decision whether or not to participate in research, in order to learn responsible and thoughtful decision-making in a comparatively controlled and safe environment.

2.4.2.3 - The validity of a child's consent - understanding

Secondly, it can be argued that children's consent is invalid because we cannot be sure they understand fully that which they are consenting to - particularly when research is involved, rather than therapy.

Again, as I argued above, there is good reason to believe that children can understand a good deal, simply based on the way they behave. Certainly, merely observing children for signs that they understand (or even conducting more formal research) is not a wholly infallible way of ensuring comprehension. However, to demand some other, more exact means of assessing understanding seems unjustified; the same degree of scepticism is not applied to other groups of potential research subjects[109].

In any event, it is difficult to see exactly *how* a child's knowledge could be assessed otherwise, and there seems no way of establishing 'rules', given the variety both of children and experimental scenarios. The potential problem is that researchers or the attending doctor may not take sufficient care to ensure

[109]ibid, p. 155.

the child understands to a satisfactory level. An unethical or overenthusiastic researcher may also deliberately content him- or herself with what they know to be a sub-standard level of understanding in the child research subject, in order to progress with their research.

In any event, it is arguable that a research subject does not need to understand perfectly in order to be able to participate safely in research, and the majority of adult research subjects are unlikely to have in-depth knowledge of the research they are involved in. In categorising all minors as a single group unable to know enough to give valid consent, we may be making the level of understanding required unreasonably high. Indeed, although most people would say that they would want 'complete' information, it is questionable that this is either possible - or desirable.

The majority of patients and research subjects do not have the training and background knowledge to allow them the level of understanding researchers and clinicians have. This means that in conveying information to research subjects, the scientist or clinician is required to modify the information into a form that the subject is able to understand. I would argue that the fact a research subject has a lower level of knowledge, and lacks the requisite background knowledge to assimilate new information to the same level of complexity as the researcher, immediately invalidates the possibility of 'complete' knowledge in many situations.

Similarly, the specific vocabulary used in medicine in particular has very precise meaning; modifying one's explanation to eliminate 'jargon' is not simply a case of presenting information differently, but often decreases the precision and changes the actual meaning of what is said.

So the capacity to give a potential research subject all the information pertaining to the research is certainly not always possible, even if it were desirable. This is one of a number of reasons why trust between physician and patient (or research subject) is of great importance; the physician has

knowledge that the patient does not, and the patient trusts the physician to do the best thing for the patient using the advantages of expertise. This is even more so the case when the research subject or patient is a child.

However, despite these difficulties with communication and understanding, it is still certainly possible for potential research subjects - including some children in some situations - to have *sufficient* understanding to make their consent valid. The notion of informed consent creates problems because - despite its wide usage and acceptance - it is a general, non-specific principle[110] that may be interpreted by some as implying that the individual should be told everything about their condition/treatment/role in the trial. Yet as I have outlined above, this complete information is either difficult or impossible to communicate, even to adults, and it is unclear whether full information is desirable, from the point of view of both the physician or researcher, and the patient or subject. What should instead be focused on is the capacity to give *intelligent*[111] consent, which is a more meaningful and realistic goal, and certainly one within reach of many children.

2.4.2.4 - The validity of a child's consent - child versus parental consent

Apart from the issues of autonomy and understanding, and the extent to which children possess these, there are further difficulties with children giving consent and the validity of this.

One is that although there are reasons why even young children should sometimes be able to consent for themselves, realistically it is the child's parents who do give consent. This is particularly the case in cases which are 'grey areas'. Similarly, the researcher is likely to give more weighting to the wishes of the parents in trying to recruit a child for research, because the decisions

---

[110]Mason and McCall Smith (1994), op. cit., p. 238.

[111]See the U.S. case of *Salgo*, where the judge found that the attending doctor should give enough information to form the basis of *intelligent* consent. Quoted in Mason and McCall Smith (1994), ibid.

involved are more complicated compared with standard, 'proven' therapy (which renders the child's decision more straightforward for him or her).

The fact that parents do still have a good deal of power to consent on behalf of their child - particularly in research - raises the question of whether it is harmful to consult the child on the matter, and to try to get his or her permission, if the child's choice is then ignored in favour of the parent's decision[112].

However, there are still good reasons for involving children in the decision-making process, even if they do not have the final word. These include: giving the child a sense of control, thereby decreasing levels of anxiety, depression and other psychopathology; allows practice of decision-making; improves compliance and commitment to the research project; and develops a sense of altruism and self-esteem[113].

2.4.2.5 - The validity of a child's consent - the difficulties of ensuring consent is voluntary

Another reason why the consent of children may be invalid is because it is hard to ensure that their consent is voluntary.

Physically, of course, children are weaker than adults and easily overpowered[114]; even if they were not physically forced to receive some kind of treatment, or to participate in a trial, the child would be aware that that kind of potential is there. Children are also psychologically more vulnerable in a number of respects; they have no power to impose their decisions and are aware of this, they may feel an absence of a perception of choice[115], they tend to want to please, and they often fear abandonment[116]. All these factors complicate the consent given by a child, and should be taken into account. (However, it should also be noted that these factors are likely to be more

---

[112]Forman and Ekman Ladd (1991), op. cit., p. 12.
[113]Weithorn and Scherer, in Grodin and Glantz (1994), op. cit., pp135-136.
[114]Forman and Ekman Ladd (1991), op. cit., p. 13.
[115]Weithorn and Scherer, in Grodin and Glantz (1994), op. cit., p. 146.
[116]Forman and Ekman Ladd (1991), op. cit., p. 13.

marked in younger children, when less weighting is given to their consent in any event.)

Finally, for consent to be valid, there must be the possibility of dissent[117], and in the majority of clinical scenarios involving children, this is not possible - parents or the court can override the wishes of the child, if those wishes are not deemed appropriate. Thus, 'consent' obtained from the child, when it is unlikely that the child would be permitted to choose the alternative course of action, is less valid than consent when there is the possibility of dissent.

2.5 - Adolescents

The case of consent of, and research on, adolescents is in certain respects both simpler and more difficult than that involving younger children.

It is clearer that adolescents have an increasing capacity for all sorts of tasks, including making responsible and reasonable decisions about receiving medical treatment or participating in research. Most adolescents aged between sixteen and eighteen can already consent for themselves medically[118]. It is arguable that many teenagers should be able to consent for themselves in a wider range of situations than is currently permitted by law, including research, because many teenagers are clearly capable of reasoning and deciding in a mature way.

This is already partly recognised in that some adolescents who are still under the age of eighteen can consent independently to a number of procedures - for example, treatment of sexually transmitted diseases,

---

[117]ibid.

[118]The Family Law Reform Act 1969 states that consent to medical treatment of a minor who has attained the age of 16 years is as effective as it would be if he were of full age [i.e. 18 years] and it is, therefore, not essential to obtain consent from his parent or guardian. (Quoted in The Royal College of Physicians of London (1990), Research Involving Patients, RCP, London, p. 20.) The Age of Legal Capacity (Scotland) Act 1991 also provides that young people aged 16 and over have full capacity to consent to examination or treatment (including research) on their own behalf. (See The Scottish Office Home and Health Department, Local Research Ethics Committees, HMSO, Scotland, Dd 0011213 C10 8/92 Ed (203704), p. 13.

management of pregnancy, drug and alcohol problems[119],[120], and general medical treatment when the teenager is living independently of his or her parents and is taking responsibility for him or herself[121],[122]. In some areas of the U.K., a child under the age of 16 is also capable of giving valid legal consent to a medical procedure or treatment, including research, provided that he or she is, in the opinion of the attending doctor, capable of understanding the nature and possible consequences of the proposed treatment or procedure[123].

This reflects the perception that adolescents are more clearly competent than younger minors - for whom proxy consent may be more justifiable - and this competence increases closer and closer to an adult level as the adolescent approaches adulthood.

2.5.1 - The competency of adolescents to consent

2.5.1.1 - The capacity of adolescents to reason in a similar way to adults

The notion of competency of adolescents to consent is based primarily on the capacity for understanding that the individual possesses, and there is a good deal of evidence that adolescents are able to reason in the same way as adults and arrive at similar decisions. Although they may be influenced more by their peers[124] than adults, and may lack familiarity with research context[125] and the idea of conflict of interest of the physician and researcher, they have an increased sense of individuation, a greater control over their environment[126], and a greater capacity for reasoning than younger children.

---

[119]Munson, C.F., 'Toward a standard of informed consent by the adolescent in medical treatment decisions', Dickinson L. Rev., 1981; 85; 436, quoted in Zinner (1995), op. cit., p. 328.
[120]Brock, in Grodin and Glantz (1994), op. cit., p. 82.
[121]Zinner (1995), op. cit., p, 325.
[122]Brock, in Grodin and Glantz (1994), op. cit., p. 82.
[123]The Age of Legal Capacity (Scotland) Act 1991, quoted in The Scottish Office, Local Research Ethics Committees, op. cit., p. 13.
[124]Weithorn and Scherer, in Grodin and Glantz (1994), op. cit., pp. 156, 159.
[125]ibid, p. 161.
[126]ibid, p. 156.

2.5.1.2 - Studies which indicate similar reasoning and decision-making to that seen in adults

One study found that in a comparison of individuals aged 9, 14, 18, and 21, the fourteen-year-olds demonstrated understanding and competency levels comparable to that of adults[127]. Another study found no significant difference in decision-making ability between pregnant minors (aged 13-17) and older pregnant women (aged 18-25)[128]. A research team performing a meta-analysis of data on legal minors also concluded that 'at about the age of 14 years...a minor has achieved a level of competence in making decisions that differs from that of an adult only in terms of less experience and information and not in terms of ability to make a judgment'[129]. Similarly, it has been noted that evidence suggests that

> [M]ost adolescents can be seen as capable of understanding research procedures when these are explained, using appropriate examples, and when the adolescents' queries are answered with attention to [their] levels of concrete and abstract thinking. [In consenting] to research...adolescents are not only 'adult-like'; they *are* adults.[130]

Thus, there is evidence that the decision-making capacity of adolescents, particularly those aged about fourteen and above, is in many respects equivalent to that of adults.

It is also not clear why consent to research should be restricted when therapeutic consent is permitted; it has been observed that 'most mid- to late adolescents (ages fourteen and older) are probably competent to provide informed consent for research at a level commensurate with that observed in

---

[127]Weithorn, L. and Campbell, S.B., 'The competency of children and adolescents to make informed treatment decisions', Child Dev., 1982; 53: 1589-1598.

[128]Lewis, C.C., 'A comparison of minors' and adults' pregnancy decisions', Am. J. Orthopsychiatry, 1980; 50: 446-453, quoted in Weir, R.F. and Horton, J.R., 'Genetics, adolescents, and consent', Theoretical Medicine, 1995; 16: 347-373.

[129]Nicholson, R.H. (ed) (1986), Medical Research with Children: Ethics, Law, and Practice, Oxford University Press, Oxford, p.149, in Weir and Horton(1995), op. cit., p. 354.

[130]Lynch, A. 'Research involving adolescents: are they ethically competent to consent/refuse on their own?' In Koren, G. (ed), Textbook of Ethics in Paediatric Research, Krieger Publishing Company, Malabar, 1993; 15: 127-128.

adults'[131]. In addition, research and treatment appear similar in terms of benefits, risks, side effects and alternatives[132]. It seems unreasonable, therefore, to prohibit minors from consenting for themselves on the grounds that their decision-making abilities are below that of adults.

2.5.1.3 - Placing unreasonable restrictions on adolescents that we would not apply to other groups

In any event, even adult patients or research subjects are notorious for misunderstanding or forgetting what they have been told[133], and one could argue that it is unfair to discriminate against adolescents on the basis that they may lack understanding.

This is because in many respects their capacity for understanding is equal to that of adults, and also because adults are fallible when it comes to understanding and remembering information with which they are presented, though they are not restricted in their ability to choose for themselves on these grounds. However, it may be that this weakness in adults may mean that the case of minors consenting for themselves is even more doubtful.

Still, it would seem that many adolescents have a level of understanding and ability to reason similar to that of adults, whom we consider able to consent for themselves. Thus, it is arguable that many adolescents should be permitted to consent for themselves. However, there remain difficulties with this.

2.5.2 - The problem of age-specific values

One difficulty is that although adolescents - and even younger minors - seem able to understand information relating to research, and to make

---

[131]Weithorn, L.A. and Scherer, D.G., 'Children's involvement in research participation decisions; psychological considerations', quoted in Weir and Horton (1995), op. cit., p. 354,
[132]Weithorn and Scherer, in Grodin and Glantz (1994), op. cit., p. 147.
[133]Bjørn, Rossel and Holm (1999), op. cit., p. 265; Gray, B.H. (1975), Human Subjects in Medical Experimentation, Wiley, New York, quoted in Zinner (1995), op. cit., p. 326.

decisions about it which parallel adult decisions, in some respects adolescents differ from other age groups. For example, some decisions made by 14-year-olds differ from those made by 9-, 18- and 21-year-olds, such as refusing medical treatment because of the possibility of unwanted cosmetic side-effects[134].

Thus, although adolescents have a more sophisticated capacity for reasoning and decision-making (compared with younger children, for whom proxy consent seems more clear-cut), it may be argued that adolescents should have their capacity for consent restricted because some of their decisions may not seem 'reasonable'. So although different individuals may have different attitudes and beliefs and choices, there are some values that are specific to certain age groups - such as adolescents - and these have been termed 'age-specific values'. It is probably the existence of these which prompts many to say that the consent of adolescents should be restricted, rather than the suggestion of a lack of actual decision-making ability.

Age-specific values are seen in most members of a particular age-group, are characteristic of that age group and are not universal across groups, change over time, and fulfil developmental needs[135]. The difficulty is that age-specific values will change over time and this raises the problem of whether we should allow certain groups, such as teenagers, to make decisions based on these age-specific values, given that the adolescent's attitude is likely to change in the future. The adolescent may commit him or herself to a particular course of action now, the consequences of which may prove unacceptable at a later stage in his or her life. This is one reason why there is a tendency to discount the views of adolescents (and, indeed, younger minors).

---

[134]Weithorn and Campbell (1982), op. cit., quoted in Ekman Ladd, R. and Forman, E.N., 'Adolescent decision-making: giving weight to age-specific values', Theoretical Medicine, 1995; 16: 334.

[135]Ekman Ladd and Forman (1995), op. cit.,, p. 336.

2.5.3 - 'Reasonable' values

Another problem is the question of what sorts of values are considered 'reasonable' and whether these attitudes are justified. On one hand, it does not seem entirely justified to impose some kind of external definition of 'reasonableness', particularly when dealing with adolescents, who in many respects are mature and competent. On the other hand, however, to say simply that whatever seems reasonable, is reasonable, does not advance matters. Naturally, one's own beliefs and values do seem reasonable to oneself[136], but there are plenty of cases in which people make unreasonable choices (though such decisions are presumably justified for them in some way). There are several ways in which the reasonableness of a value or choice can be assessed.

2.5.3.1 - 'Reasonable' as an objective measure

One way of defining 'reasonable' is from an *objective* point of view. 'Reasonable' based on an objective standard is taken to mean what any reasonable, 'average' person would decide; this kind of approach is used when making decisions on behalf of infants and small children, severely mentally retarded people, and individuals whose personal preferences are not known to the proxy decision-maker[137]. That is, the objective standard is used for individuals whose preferences and views on a particular treatment or procedure are not known, and obviously it would seem inappropriate to apply this to adolescents, who clearly have opinions and values of their own. The objective standard is problematic because it ignores stated preferences, and also because it assumes that adult values are the 'right' ones[138], i.e. the objective standard imposes 'prime of life' values as the most important ones[139].

---

[136]ibid, p. 340.
[137]ibid, p. 335.
[138]ibid.
[139]ibid, p. 340.

2.5.3.2 - 'Reasonable' as a subjective measure

The alternative is 'reasonable' according to a *subjective* standard. This involves deciding for someone based on what the proxy thinks they would decide, were they able. This is also problematic because it implies that the individual in question has fixed values which will not change[140], and this is not true of some values held by adolescents - particularly the values which are likely to cause others to want to intervene.

2.5.4 - 'Real' values

The fact that some adolescent values change over time is another argument against allowing adolescents to consent for themselves. The implication is that a value which changes over time is not 'real'. It makes sense to say that holding a value over a long period of time is evidence of commitment to that value, and the long-term nature of some values suggest their importance in an individual's total lifespan.

However, this viewpoint involves the risk of paternalism towards teenagers because their age-specific values are transient in nature and therefore not 'real'[141]. (In fact, paternalism is a risk for all age-groups, given that prime of life and old-age values are equally age-specific.) It also implies that adolescent age-specific values are not worthwhile or important because of their transient nature.

Another difficulty is that this attitude suggests that it is right to restrict the extent to which the individual acts on adolescent values and to impose adult values on them. This may not be justifiable, given that one cannot assume the universality of adult values. However, it is arguable that although the future values of a particular adolescent are not known with certainty, it is known that the adolescent will outgrow their age-specific values. So in that

---

[140]ibid, p. 335.
[141]ibid, p. 337-338.

sense, it may be valid to assume that the adolescent will hold 'standard' adult values[142]. The difficulty with this is that sometimes the values an adolescent hold may seem to be age-specific, though these may prove to be more long-standing for that individual.

2.5.5 - Ways in which permitting adolescents to consent may put unreasonable pressure on them

Another problem is that allowing all teenagers to consent for themselves may be putting too much pressure on them when they may still sometimes wish to act with the spontaneity and disregard for consequences which are characteristic of younger minors.

However, this perceived problem may simply reflect the attitude - previously prevalent and still extant - that adolescents tend to behave too 'childishly' to allow them to consent on their own behalf, despite evidence to the contrary.

It should also be noted that even younger, pre-teen minors are capable of recognising the serious nature of medical intervention, and that it has the potential to impact significantly on them, even if they are unsure of the way in which this will be manifested. Thus, it would seem unlikely that they would behave in a particularly 'childish' way.

2.5.6 - The need to recognise that not all adolescents are capable of consenting for themselves

The view I have outlined above in favour of adolescents consenting for themselves is also problematic because it implies that all adolescents are capable of consenting for themselves, when (realistically) this is not the case. However, it is fairly evident that the majority of adolescents would be capable

---

[142]Forman and Ekman Ladd (1991), op. cit., pp. 15-16.

of consenting for themselves in a wider range of situations than is currently permitted.

In fact, it is arguable that adolescent consent represents an important means of learning to behave responsibly, and to curb the independence of the adolescent is to hinder his or her satisfactory development. Some kind of continuum of responsibility may be appropriate, with each adolescent assessed on a case-by-case basis. This kind of analysis may pose risks because it involves a subjective judgement on the part of the physician or investigator - though this may still be more desirable than the inflexibility posed by guidelines.

Alternatively, a more appropriate course of action might be to allow the adolescent greater responsibility for him or herself, only overriding decisions when they pose a true threat to the adolescent. There are a number of arguments in favour of respecting an adolescent's values and choices in this way.

2.5.7 - Reasons for respecting adolescent values and choices

It is arguable that even if some adolescent values are age-specific, they are still important for the development of the teenager and should be respected whenever feasible. It is possible to look at adolescence as a series of psychological tasks which must be 'completed' in order to allow the teenager to develop emotionally and socially, and to move into adulthood. These include developing one's self-esteem and separate identity; establishing relationships; and gradually achieving independence from one's family[143].

Early and mid-adolescents, for example, are particularly concerned with body image, which explains their tendency to refuse certain types of treatments and procedures because of the threat of change to their appearance[144]. Thus, it may be reasonable for adolescents to have 'adolescent' values, and to override

[143]ibid, p. 14; and Ekman Ladd and Forman (1995), op. cit., p. 342.
[144]Ekman Ladd and Forman (1995). op. cit., p. 342.

choices made by adolescents based on these age-specific values may have an adverse effect on the development of that adolescent.

Illness also causes a good deal of stress to the individual, and to override the values and choices of the adolescent could contribute further to his or her distress. Additionally, in an adolescent, this stress may derive partly from the interruption of their emotional development[145], which may be grounds for respecting the choices of the teenager. However, it must be noted that there will be some situations in which the adolescent's choices may need to be discounted.

2.5.8 - When it may be appropriate to override adolescent choices

2.5.8.1 - Restricting adolescent choice when it may lead to an adverse future outcome

The first, and most obvious, situation in which it may be appropriate to override the adolescent's choice is when that choice will *seriously* affect his or her future health or welfare[146]. This would appear to be a situation in which it is justifiable to override the wishes of the adolescent, and instead act on the decisions of an appropriate proxy.

One problem with this is that it may in some situations be difficult to know with any certainty what will have an adverse effect on the adolescent.

Another problem is that it is easy to extrapolate from this and conclude that allowing an adolescent to consent for himself is always problematic because it involves a potential restriction of future choices.

2.5.8.2 - Restricting some future options is a normal part of development

However, it is difficult to justify overriding the decision-making of the adolescent on the grounds that they might restrict future opportunities, unless the future restriction is likely to have a serious adverse effect.

---

[145]ibid.

[146]ibid, p. 343.

This is because all adolescents must and do restrict future opportunities to some extent - this is an integral part of shaping one's existence and preparing for a particular course in life. There are in fact many situations in which the adolescent is actively encouraged to pursue a course of action which entails closing off certain future choices - for example, when a young person shows signs of being particularly proficient at a musical instrument, a sport, or academic work, and they are encouraged to devote much of their time to the pursuit of this.

2.5.8.3 - Adolescent choice in a research context

Choosing to participate in research is likely to be perceived as a somewhat different situation - compared with choice in other areas of the adolescent's life - and as a result, it may be contended that these objections do not hold when considering the consent of adolescents.

Firstly, however, it is arguable that participating in research need not involve situations which affect the future welfare and choice of the adolescent.

Secondly, research has a greater number of safeguards in place to protect the welfare of the adolescent than many other situations in which adolescents make important choices. For example, encouragement (or pressure) to pursue a particular course in life (thereby potentially limiting future choices) may have a significant impact on the teenager, yet remains something that is not as objective as other areas of the adolescent's life. An example of this is parents who pressure their adolescent to achieve in a particular pursuit, such as sport or a certain academic course.

A third point about the participation of adolescents in research is that the existence of certain age-specific values may serve to protect, rather than harm, the adolescent. For example, the concern adolescents tend to have about their body image may make them more cautious than other age groups about consenting to research which may have physical and cosmetic side-effects.

Similarly, the need many adolescents have to conform to expectations of their peers may make them less likely to do anything perceived as 'different', such as participating in research. The tendency teenagers have to establish their own identity by 'breaking away' from authority figures such as parents may also make them disinclined to go along with the suggestion of a doctor or scientist to participate in a study. These factors help indirectly to protect the teenager.

2.5.8.4 - Restricting adolescent choice in order to preserve family relationships

Protection of the parent-child relationship is a further reason it may be appropriate sometimes to restrict the choices of the adolescent.

If the parents' preference for their child is overridden in favour of the child's preference, the relationship of the parents with both the child, and the doctor or researcher, may be adversely affected. This may be seen to have a negative impact on the child, as the family usually forms the basis of the child's social support network.

2.6 - Psychological and social research involving children

There are several issues relating to psychological and other 'non-medical' research involving children.

2.6.1 - Risk taking in psychological research

The first such problem is that children, particularly those who are well and are more likely to be used in psychosocial and educational research, rather than those children who are unwell, are readily available as research subjects, compared with potential research subjects of other ages. This tends to decrease the logistical complications, which may lead to increased risk taking on the part of the researchers[147].

---

[147]Koocher, G.P. and Keith-Spiegel, ' Scientific Issues in Psychosocial and Educational Research with Children' in Grodin and Glantz (1994), op. cit., p.48.

2.6.2 - Subjective element of psychosocial research may affect the outcome

Some aspects of this type of research may rely on more subjective assessments by the researchers in interpreting their findings, compared with more 'scientific' or 'medical' research. Thus, investigators' theoretical perspectives may affect the outcome (for example, the mother may be perceived as the 'root of all evil') or the risk assessment (e.g., believing children to be more strong or capable than they really are)[148]. Such factors have obvious implications for the wellbeing of the child involved in research.

2.6.3 - Difficulties with longer studies

Social experiments tend often to be of even longer duration than some clinical trials. This leads to problems both in recruiting research subjects and also in *retaining* them during the course of the trial. This kind of study raises issues in that a research subject leaving the trial can be seen to have a more significantly negative impact on the study. This is of particular relevance when children are involved in the study because children can tend to be somewhat fickle in their decision-making, opting out of decisions with perhaps less thought than one might see in older individuals. This also puts them at risk of 'heavy-handedness' to ensure they do not exit the trial without a 'good' reason[149].

2.6.4 - Results from psychological or social studies

In addition, having completed the study, it can be difficult to know what should be done with the information obtained- that is, how to act on one's findings[150]. This would appear to be a distinct case from medical research,

---

[148]ibid, p.49.
[149]ibid, p. 60.
[150]ibid, p. 70.

where a medical problem is investigated and an answer is found about pathogenesis and often the most effective treatment available.

The findings of this kind of research may also have significant impact on the social circle of the child, given that psychosocial circumstances are interpreted in a different way from 'medical' problems in the following ways.

The child's involvement in a study which looks at the behaviour and development of children may attract unfavourable attention from other children, leading to teasing and bullying.

The child's parents, on the other hand, may also be affected by the child's involvement in the study. They may feel that an invitation to participate implies their child has 'something wrong with him or her'. They may make certain judgements, or receive certain feedback, during the trial which leads them to judge their child in a certain way which may impact negatively on family dynamics. More straightforwardly 'medical' problems do not attract negative value judgements in the same way.

2.6.5 - Non-therapeutic research

It is also arguable that the kind of research discussed in the preceding paragraphs is more obviously non-therapeutic, which raises the issue again of whether the parents' proxy consent to non-therapeutic research can be said to be valid[151].

The need for parental consent also leads to parents frequently requesting feedback on their child's 'performance' during a study[152]; they seem to believe that they are 'owed' this in return for their cooperation. If children are asked their permission for this kind of disclosure and they refuse, it can also be difficult to communicate this to the parents without inviting censure.

---

[151]ibid, p. 50.
[152]ibid, p. 66.

2.7 - Issues when the doctor is involved in research on the child

2.7.1 - The conflict between research and the duty to care for the child

Research on children is again problematic when the doctor who cares for the child is involved in the project. The first and most obvious difficulty is that - as stated in the Declaration of Geneva - the health of the patient must be the doctor's first consideration[153],[154].

However, this is not clearly the case in a research setting. Ideally, if there was an equal chance of either method benefiting the patient, the role of the doctor to put the care of his or her patient first would not be compromised. Unfortunately, however, this is not often the case; the doctor usually has a suspicion that one treatment will prove to be of superior efficacy, and indeed there would be little point embarking on a trial if there was no reason to believe one treatment to be better than the other.

With adult patients, this seems less of a problem in that it is more certain that the patient understands that they may not receive the most effective treatment. However, it is less clear that children may appreciate this, particularly younger ones. Still, it must be said that this objection may not apply to randomised control trials in which the attending physician is blinded to the treatment his or her patient is receiving, because he or she does not *know* a) whether the treatment being trialed is more or less effective than placebo, and b) which group his or her patient will be in.

Further, the care of the child may be compromised if the doctor urges participation in a particular study, or if the trial therapy is prematurely ceased because it does not appear to be effective[155]. In the hope of improving the care of the child and to gain more contact time with the physician, parents may feel

---

[153]Declaration of Geneva (as amended at Sydney, 1968), reproduced in Mason and McCall Smith (1994), op. cit., p. 430.

[154]Kauffman, R.E., 'Scientific Issues in Biomedical Research with Children', in Grodin and Glantz (1994), op. cit., p.31.

[155]Forman and Ekman Ladd (1991), op. cit., p. 78.

pressured to consent[156]. There is some evidence to suggest that patients believe that it is the attending doctor who determines the allocation of treatment, even if they have been given written information to the contrary[157], and this may influence parents to consent for their child if they believe the doctor can determine which treatment their child will receive. Similarly, it is often thought that allocation to groups in a trial is based on therapeutic need, rather than by randomisation.

2.7.2 - The effect of the research on the relationship between doctor and parents

This raises another difficulty - the effects on the relationship between the doctor and the parents when a doctor is involved in paediatric research. Although the doctor may try to assure parents that they are not compelled to participate in the study, if the doctor is viewed as an authority figure the parents may still feel obliged to give their consent.

Alternatively, parents may interpret the involvement of the doctor in the study as an unspoken recommendation, or they may believe that the doctor would not suggest they participate if it could be ineffective or harmful[158].

The doctor-parent relationship may also be altered by the doctor feeling as though he or she owes the parents a favour because they have given one in consenting to the trial; on the other hand, though, the relationship may be affected positively by creating a sense of partnership and by educating parents about medicine and about the uncertainty involved in it[159].

The relationship between the doctor and the parents may also be altered by the fact that the methodology of the study may require a certain number of research subjects to be recruited[160]. The potential anxiety of the parents may limit the possibility of them allowing their child to participate in the study,

---

[156]ibid.
[157]Bjørn, Rossel and Holm (1999), op. cit., p. 265.
[158]Forman and Ekman Ladd (1991), op. cit., p. 78.
[159]ibid.
[160]Kauffman, in Grodin and Glantz (1994), op. cit., p31.

which may impact negatively on their relationship with the doctor - particularly in the current clinical environment, where there is a good deal of pressure on clinicians to undertake research and publish.

The anxiety of the parents (and of the child) may be allayed by a number of methods - for example, by performing research using biological samples which have been obtained for another reason (such as CSF taken during a lumbar puncture with a clinical indication), by using smaller samples, or by using less invasive methods, such as MRI or PET scanning[161] (though children can be afraid of the machinery used, and they are exposed to radiation and isotopes via these imaging techniques).

2.7.3 - The issue of high-risk or alternative trial therapies

Doctors caring for a terminally ill child may also be pressured by parents to use non-standard therapy of doubtful efficacy or possible harm. An example of this might be parents who wish to use, on a trial basis, untested anti-cancer medications which are not recognised by western medicine. The doctors caring for the child may believe that standard therapy will offer no cure for their patient, but be equally convinced that the alternative therapy has no evidence to support its use. This raises a number of ethical dilemmas if the co-operation of the doctor is needed for the implementation of this 'trial' treatment.

2.7.3.1 - Refusal to participate may compromise the care of the child

The first is that refusal to co-operate with the parents may leave the family in a worse position[162]; they may also be forced to 'shop around' for another doctor who may agree to the parents' wishes but who may jeopardise the care of the child. However, agreeing to co-operate with the parents may

---

[161]ibid, p 33.

[162]See: Yeoh, C., Kiely, E. and Davies, H. 'Unproven treatment in childhood oncology - how far should paediatricians co-operate?', J.Med.Eth., 1994; 20: 75-76.

lead to difficulties in the doctor-parent relationship, and may compromise clinical freedom and professional standards.

2.7.3.2 - Difficulty in assessing possible risk in untested therapies

A second problem: if such a decision were patently not in the interests of the child, the doctor would be obliged *not* to co-operate[163], as it is generally held that the care of the child ought to be his or her primary concern. If, on the other hand, co-operation in such a project involved no possibility of harm to the child, but the possibility of some benefit - even if unlikely - then there may be nothing wrong in complying with the parents' wishes[164].

However, it is unlikely that one could reliably exclude the risk of harm when very little is known about the treatment at all. And even some of the relatively straight-forward procedures that might be required - such as insertion of a central line - may pose some risk. It may also be argued that this irregular means of trialing a new therapy is unethical in terms of its risk-benefit analysis.

Thus, by agreeing to use experimental kinds of treatment, the doctor may be party to a form of child abuse, insofar as parents do not always know what is best for their child, and their decisions, if automatically acted on, can put the child in danger.

2.7.3.3 - Public pressure on doctors to be involved in trial treatments

A third problem in this kind of scenario is that public opinion may lead the doctor to give his permission and assistance to parents wishing their child to participate in a trial treatment, even though in different situations (e.g. if the patient were an adult) the use of such a treatment would not be embarked upon.

---

[163]Jackson (1994), op. cit., p. 77.
[164]Yeoh et al (1994), op. cit., p 76.

The public and media generate a highly emotional atmosphere when it comes to children and their health - and may generate much support for interventions that have very little success[165]. Disproportionate representation of the situation means a doctor who refuses to participate in unlikely and unproven trial treatments for children is likely to be branded as unfeeling[166]; it is often easier for the doctor simply to acquiesce.

2.7.3.4 - Difficulties with allocation of resources in trial therapies

A fourth - related - difficulty is that involvement in untried, unreliable and (usually) expensive 'alternative' therapies would appear unequal in terms of allocation of health care resources, particularly if it is not part of a properly conducted trial to assess the efficacy of the treatment.

However, it should be considered why the treatment has little evidence to support it - it may not be reasonable to use it if it is fundamentally implausible, but there may be some justification in trying it if other factors are operating[167] (e.g. expense, poor recruitment rates to the trial).

It could be argued that the disproportionate allocation of resources is justified in the sense that the treatment of a child is more likely to be successful medically[168], though this would, of course, depend on the procedure involved. If the trial treatment really is unfeasible, the child is unlikely to benefit, thereby invalidating this particular defence of the allocation of resources in favour of children.

Another way in which this sort of allocation of resources may be defended is in terms of utility; there is likely to be a greater benefit when young are treated preferentially[169]. This may appear to outweigh the notion that the elderly should have equal rights to health care but (the morality of this aside) it

---

[165]Downie and Randall (1997), op. cit., p. 227.
[166]ibid.
[167]Jackson (1994), op. cit., p. 78.
[168]Downie and Randall (1997), op. cit., p. 227.
[169]ibid.

is arguable that allocation of health care resources to the elderly should be increased; the proportion of the population who is aged is increasing at a rapid rate, and poor health in the elderly is likely to become increasingly costly to society.

Hence, the lack of clear reasons why child health care should have unlimited access to resources means it is unclear that parents should be able to consent to trial treatments of doubtful benefit on behalf of their child.

2.7.4 - The issue of limited parental understanding and the role of the doctor

The involvement of the child's doctor in research is again a problem in that lack of parental understanding raises the question of the extent to which one should intervene in such cases - bringing up the issue of medical authoritarianism, the view that 'the doctor knows best' and should be the one to make medical decisions. Parents may refuse to consent to their child participating in research for a number of reasons, but it would seem that it is only ethical to respect the wishes of parents when such wishes are in the best interests of the child[170].

This creates a dilemma for the attending physician when he or she has reason to believe that participation in the trial will benefit the child, particularly if the parents' refusal derives from a lack of understanding. Clinicians and researchers have often spent years learning about a disease while many parents are unlikely to be trained to the same level and it is obviously difficult for them to develop the same depth of knowledge, particularly in a short period. When this difference in knowledge impacts negatively on the care of the child, there is a case for overriding the wishes of the parents, and certainly this does occur in cases where the child has a life-threatening condition.

Medical authoritarianism is problematic in that it may lead to difficulties such as the breakdown of the relationship between doctor and patient, and the

---

[170]Forman and Ekman Ladd (1991), op. cit., p. 31.

risk that the doctor may be wrong. Another problem is that it assumes that only medical factors are relevant in the decision-making process[171]. Parents may have other, quite valid, reasons for their decision, in which case it would not seem justifiable to override their wishes.

2.8 - Conclusion

In conclusion, research involving children may be seen to be important in order to maximise the health and well-being of children.

Despite historical precedent, there is a shift away from complete control of the child by the parents. Problems with parental consent include the mistaken notion that parental consent necessarily represents the child's own judgement, or that it is automatically in the best interests of the child. Other problems include limited parental understanding and risks to the child from ill-judged or misinformed parental consent.

On the other hand, parental consent does have some benefits, including preservation of family relationships and a socially approved way for the child to access benefits.

The child on the other hand, may be seen to have a good deal of capacity for autonomous action. Evidence suggests an ability to reason like an adult, and a continuum of capabilities is suggested. However, there are problems with a child's consent, including limited understanding, unequal balance of power, parental preference, and the difficulty of ensuring voluntary consent. Adolescents have particular problems, such as age-specific values which need to be recognised.

Psychosocial research raises different problems, such as the subjective element of the assessment, the use of normally well children, difficulties with long-term studies, and the difficulty with what to do with the results.

---

[171]ibid, p. 8.

The involvement of the doctor may also complicate research on children because of conflict of interest, changes in the relationship between doctor and parents, public pressure and allocation of resources.

An awareness of these factors is important to try to ensure research involving children is as ethical as possible.

CHAPTER 3 - RESEARCH INVOLVING ELDERLY PEOPLE

3.1 - Introduction

In this chapter, I shall discuss aspects of the issue of performing research on elderly individuals.

These factors include the ways in which autonomy in the elderly may be compromised, difficulties obtaining consent, institutionalisation, community care and the role of relatives.

A defence of research involving the elderly will also be put forward, emphasising the importance of research in this group, benefit to the individual, methodological modification which may make the research more acceptable, the involvement of autonomous elderly, and economic benefit to the community.

3.2 - Research involving the elderly - an overview

Research involving elderly people raises a number of difficulties. These problems derive not so much from old age itself, but rather from certain factors which tend to be associated with members of this age group, or which are seen more commonly in the elderly than in individuals of other ages.

Some of these problems lead to compromise in autonomy. These include: difficulty in defining who is 'elderly' in an increasingly heterogeneous group; a stereotypic perception of the health and competence of older individuals; an actual decrease in mental capacity due to mental, physical, social and environmental factors; greater dependence on others for care; and increased vulnerability[172]. These factors contribute to decreased competence and compromised autonomy (perceived or actual), and this raises difficulties for research on elderly individuals affected in this way.

---

[172]Oppenheimer, C., 'Ethics and Psychogeriatrics', in Bloch, S. and Chodoff, P. (eds) (1991), Psychiatric Ethics, Oxford University Press, Oxford, p. 365.

Despite the multiple difficulties associated with elderly research subjects, there are a number of reasons why such research is important. The elderly have specific medical and social problems which do not exist in other age groups; many elderly are autonomous and should not be ignored; and the health and well-being of older individuals have a significant impact on economics and resources.

There are a number of factors which may make research on the elderly more acceptable. These include: benefit to individual, group of individuals, family, and society generally; the type of research; and satisfaction for those involved.

3.3 - Ways in which the autonomy of older persons may be compromised

3.3.1 - Ambiguity in terminology applied to older persons

Some basic terminology (for example, 'old age' and 'elderly') and definitions (such as the definition of old age as over sixty-five) give rise to a number of difficulties which are relevant to elderly research subjects. There are at least three such problems. These are: the arbitrary and inappropriate nature of the definition of old age as sixty-five years and over; the use of terms such as 'old age' and 'elderly' to refer to people with an increasingly wide range of ages and capabilities; and the risk that such definitions lead society to see any older person over a certain age as a generic 'old person', rather than as an individual.

3.3.1.1 - Arbitrary classification of 'elderly'

As I have mentioned, the first difficulty with the terminology associated with older persons is that the cut-off point defining 'old age' (usually over sixty-five years) is somewhat arbitrary and may be inappropriate, particularly now that increased longevity, expectation of longevity, and health are enjoyed by a

greater proportion of older individuals[173]. The use of age sixty-five to signify the transition to old age may have been more appropriate in earlier times, when life expectancy was lower, and morbidity more usual from an earlier age. However, an increasingly large number of people are living to ever-greater ages, often with 'compressed morbidity' (that is, fewer years of disability and ill-health). This would indicate that the use of a specific age, such as sixty-five years, as a cut-off point has become a somewhat arbitrary means of defining old age, given that the many people who fit into such a group do not have the characteristic morbidity and short life expectancy one tends to associate with the term 'old age'.

3.3.1.2 - Heterogeneous nature of 'elderly' as a group and the way in which this complicates research

The second problem with classifying 'old age' as any age over an arbitrary point such as sixty-five years, is that the range of ages covered by this blanket term is becoming increasingly broad. Various sub-groups within this category may be quite different from others, making the ≥65 cut-off often meaningless for treatment of, and research on, the elderly[174]. For example, individuals aged over 85 tend to have many more of the problems traditionally associated with old age (such as physical illness and dementia) than people aged 65-75, for example. And it has been noted that the difference between a 65-year-old and a 95-year-old may be as great as the differences between a 55-year-old and a 25-year-old[175]. Therefore, age stratification terms such as '≥65' would be more meaningfully replaced by classification by decade, at least to age eighty-five[176], as grouping together all individuals aged over sixty-five

[173]Mason, J.K. and McCall Smith, R.A. (1994), Law and Medical Ethics, Butterworths, London, p. 267.
[174]Avorn, J., 'Including elderly people in clinical trials', BMJ, 1997; 315: 1033.
[175]Oppenheimer (1991), op. cit., p. 365.
[176]Avorn (1997), op. cit., p. 1033.

tends to give a misrepresentative impression of the health and capabilities of this group. This complicates research in at least three ways.

Firstly, a misrepresentative impression of the characteristics of this age group may lead to misunderstanding and incorrect application of research results. This may adversely affect the way in which the health problems of the elderly are dealt with.

Secondly, the diversity now seen within the group classified as the 'elderly' means that research projects may not differentiate between the different sub-groups within the elderly population. More research subjects may be required to retain the same power in the face of such diversity, making research more complicated, time-consuming, and costly. This adverse effect on the process of research may also lead researchers to exclude the elderly.

And thirdly, certain subgroups (such as the 'old old') may be excluded because they have complicated physiology and comorbidity, which may make the research process difficult and the results unfavourable. Specifying subgroups (such as those aged sixty-five to seventy-five, and so forth) would make research results more meaningful because it would be clear which of the wide range of elderly are included in the research, and to whom the results should apply.

3.3.1.3 - Use of 'elderly' terminology detracts from individuals being seen as such

The third problem with defining old age as over 65 years is that older people then risk being viewed simply as an 'old person', rather than as an individual. This is exacerbated in elderly people who are unable - through physical incapacity or mental decline - to communicate the various factors upon which we usually assess the nature of someone's individual personality and belief system. Relatives may also give inaccurate and conflicting interpretations of the elderly person's personality, beliefs and desires[177]; this

[177]Oppenheimer (1991), op. cit., p. 367.

lack of clear information about the person as an individual thereby reinforces the tendency to view the elderly individual simply as an 'old person'.

3.3.1.4 - Summary of impact of terminology on elderly as a group

Thus, even the basic terminology (including terms such as 'old age' and 'elderly') and concepts (for example, defining 'old age' as over 65 years) create problems in research on older individuals because the cut-off age seems no longer appropriate, and somewhat arbitrary; an increasingly broad range of ages and capacities are covered by the blanket term, 'old age'; and the older person risks being viewed simply as an 'old person', rather than being considered as an individual and assessed on his or her own merits. These factors contribute to the impression that all older individuals over a given age (for example, sixty-five years) are equally infirm, mentally incompetent and, therefore, lacking in autonomy.

3.3.2 - Stereotypic perceptions of the elderly

In the previous section, I outlined three ways in which terminology and definitions associated with research on the elderly may be problematic. A fourth, related, problem is that a stereotypic perception of the elderly may arise through the way in which definitions and terminology are used. As I mentioned, terms and definitions currently in use tend to create the impression that *all* older individuals are generic 'old people' who are physically ill and cognitively impaired and, therefore, lacking autonomy and unable to consent. Were this impression accurate, it would have obvious implications for research involving the elderly. Realistically, however, a large proportion of elderly individuals (particularly the 'young' old) are physically well and cognitively intact. The perpetuation of a stereotypic perception of the health and capabilities of this group may impact negatively on the elderly in a number of ways.

3.3.2.1 - Ways in which a stereotypic perception of the elderly is reinforced and perpetuated

Firstly, it was previously the case that many elderly persons would live for a shorter period of time, and suffer from more disease, than is true of elderly persons today. It may be that historical precedent distorts the way in which current reality is perceived, leading society to believe that the elderly suffer from the same degree physical and cognitive incapacity as the elderly of previous generations. This is the first factor which may contribute the stereotypic perception that the elderly are more ill, disabled, and cognitively impaired than is actually the case.

The second factor which may act to perpetuate the negative stereotype of elderly persons is the way in which most people believe that a decline in health is usual as a person ages. Thus, when we encounter an elderly person who is in good health, we tend to think that such a person is an exceptional case; whereas encountering an older person in poor health or mental decline is often seen as more 'normal', and to be expected. In this way, the impaired elderly are focussed on, while the proportion of the elderly who are healthy are underestimated. Therefore, a stereotypic perception of the elderly may continue to be perpetuated, despite the fact that many elderly are obviously well, self-sufficient and autonomous.

Thirdly, this stereotypic perception of the elderly may also be perpetuated inadvertently by health care professionals, who tend to see, treat and research the more infirm end of the spectrum of older people, and who may, as a result, tend to believe that the impaired individuals they see are representative of all elderly people.

Fourthly, old age may also be perceived as more of a problem than it actually is, and be generally misrepresented, because the majority of literature on the subject is written by younger individuals[178]. It may be that such authors

[178]Oppenheimer (1991), op. cit., p. 366.

hold their own prejudices about the capabilities of the elderly and may lack insight.

Fifthly, another difficulty is that care for the elderly - from low-level, community-based care to high-level care in nursing homes - becomes a public issue insofar as such care is subsidised by public resources. This may lead to the unfair and inaccurate perception that all older people are a 'burden' on society[179], because the stereotypic infirm, institutionalised elderly person is focussed on by the public eye.

3.3.2.2 - Ways in which the stereotypic perception of the elderly may affect them adversely

Firstly, a stereotypic idea that the elderly are all incompetent may lead society to implement guidelines and laws which may impose restrictions on the autonomy of the elderly - for example, by limiting the extent to which they can participate in, or consent to, research. It is in this way that competent, autonomous elderly persons may be restricted, through stereotype, in their choice to participate freely in research.

Secondly, autonomy in competent older individuals may also be compromised in more subtle ways by stereotypic perceptions; if there is an expectation that an elderly person is likely to conform to the stereotypic image of an 'old person', it may be assumed that the individual in question is incompetent and unable to consent, without the likelihood of this being properly explored. As a result, the elderly may sometimes be denied needlessly the benefits of research on the assumption that they are a group from whom informed consent is difficult to obtain.

Thirdly, although relatives are legally unable to consent[180] on behalf of adult patients or research subjects, an assumption that the elderly individual is likely to be incompetent may mean that the opinions and wishes of the relatives

---

[179]ibid., p. 368.

[180]Randall, F. and Downie, R.S. (1999), Palliative Care Ethics, Oxford University Press, Oxford, p. 61.

may be given undue weighting when this is inappropriate. This is another way in which the autonomy of the elderly person may be compromised through the stereotypic perception of that age group.

Thus, it may be seen that the stereotypic perception of the health and ability of older individuals ignores the majority of elderly persons who are in fact in good health and cognitively intact, and has an adverse effect on their autonomy and ability to participate in research.

3.3.3 - Real factors which lead to compromised autonomy in older individuals

Having pointed out that many older persons may be more healthy and competent than the stereotypic image of the elderly might suggest, it is still evident that there are a number of elderly individuals who clearly do have problems other than stereotype which can compromise autonomy.

3.3.3.1 - Endogenous and exogenous factors limiting autonomy

These problems may be 'exogenous' (externally-imposed) or 'endogenous' (arising from within the elderly individual)[181]. Externally-imposed difficulties include poverty and dependence - financial or physical - on others for care, while internally-imposed factors include physical illness or weakness, and diminished mental capacity and cognitive function.

3.3.3.2 - Global impairment of autonomy in the elderly

Some of the afore-mentioned factors, such as compromised mental functioning, may lead to decreased autonomy because the capacities generally held to be a feature of an autonomous person - self-governance through features such as understanding, reasoning, deliberating, and independent choice[182] - may be jeopardised. That is, some of the health problems typically

---

[181]Mason and McCall Smith (1994), op. cit., p. 268.

[182]Beauchamp, T.L. and Childress, J.F. (1994), Principles of Biomedical Ethics, Oxford University Press, Oxford, p. 121.

associated with the elderly more than with members of other age groups (such as dementia, or coma arising at the end of a terminal illness) tend to decrease the autonomy of the elderly person in a much more global and extensive way than some other problems experienced by this age group.

3.3.3.3 - Limited impairment of autonomy in the elderly

Alternatively, however, some problems likely to affect elderly individuals may affect specific *choices* which are usually dependent on autonomy, rather than the fundamental, self-governing characteristics of an autonomous being. That is, even autonomous individuals may sometimes fail to be able to govern themselves in certain circumstances because of temporary constraints, such as illness, depression, ignorance of a given situation, coercion, or adverse circumstances[183].

These are more subtle factors than some of the illnesses in, and problems of, the elderly, and their negative impact on an elderly individual may be underestimated. It is also arguable that these factors may affect elderly individuals more than other age groups, which is again an important reason for being aware of their existence and their likely impact on an individual's autonomy.

3.3.3.4 - Significance of range of limitation of autonomy for research

Thus, it may be seen that although the elderly may appear to have decreased autonomy through problems with stereotype and generalisation, there remain some who have real limitations to their autonomy, whether it be through internal or external factors.

The distinction between the two kinds of difficulties are not necessarily clear-cut and it may be difficult to assess the extent to which they contribute to compromised autonomy in the elderly. For example, it is difficult to be certain

---

[183]ibid.

whether adverse external circumstances prevent the enacting of an autonomous decision, or whether it actually inhibits autonomy at a more fundamental level. However, an awareness that such factors may be operating for an elderly person may allow the compromised aspects of the individual's decision-making process to be minimised.

Thus, these 'real' limits on autonomy may be global or limited to certain situations, and this is important in that an elderly person's autonomy may still be maximised if one recognises that the limiting influences need not be universal in scope for that individual.

Therefore, the participation of the elderly in research may be maximised in an ethical way if one recognises that compromised autonomy in the elderly need not be global (that is, affecting all traits which we would normally associate with an autonomous individual), and if their ability to consent is maximised.

3.4 - Problems with research involving elderly subjects

3.4.1 - Difficulties obtaining consent

Obtaining consent is the first main problem encountered in research involving the elderly. As I have outlined in earlier paragraphs, consent may be problematic because the elderly person may have compromised autonomy, and there are many factors which act to compromise the autonomy of elderly people, such as poverty, dependence, vulnerability, frailty, as well as decreased physical and mental functioning. This restriction of autonomy may be specifically compromised in certain circumstances, such as short-term illness; or compromised autonomy may be more global, through a problem such as dementia.

3.4.1.1 - Diminished mental capacity and its impact on giving/obtaining consent

Diminished mental capacity is usually in the form of dementia and is a major contributing factor to decreased decision-making capacity in the elderly. It is likely to become an even greater problem in the future. It is estimated that the number of elderly individuals aged over 65 will increase by 60% in the next 35 years, but that the increase in those with cognitive impairment will increase by about 90%. Although it is predicted that the change in the number of elderly individuals will then stabilise at about 50% more than 1996, the number of cognitively impaired will stay high, peaking at about twice as many in 50 years' time[184].

Dementia poses problems because many of the factors necessary for autonomy are jeopardised by the disease, such as understanding, deliberating and reasoning. The loss of short-term memory, which is usually the first deficit seen, is problematic because the person is unable to retain information long enough to deliberate on it. Choices may also be affected because the dementing individual is unable to deal with the idea of long-term consequences and benefits. In this sense, the situation of the elderly demented person may resemble the compromised autonomy of the child, although it is arguable that many children have the capacity to reason which the dementing may not.

Similarly, dementia may generate problems which compromise autonomous choice, such as comorbidity (which is more common in the demented), depression, and lack of understanding of many situations. The demented elderly person is also more likely to be institutionalised, creating an increased likelihood of circumstances adverse to free decision-making, as well as creating an increased potential for coercion.

3.4.1.2 - Physical impairment and its impact on giving/obtaining consent

---

[184]Melzer, D., Ely, M. and Brayne, C., 'Cognitive impairment in elderly people: population based estimate of the future in England, Scotland, and Wales', BMJ, 1997; 315: 462.

Secondly, other factors, such as physical disability and impairment, may make the process of obtaining consent more difficult when dealing with elderly potential research subjects.

Problems with sensory impairment makes obtaining consent more difficult. For example, many older individuals suffer from varying degrees of deafness (44% of people aged over sixty-five were offered hearing aids in one study[185]), which has obvious implications for effective communication with this age group. And although 39% of women and 55% of men thought they had some degree of hearing loss, few (10% and 12% respectively) had sought advice or treatment for their problem[186], a further contributing factor to impaired communication. Blindness in an elderly individual may similarly restrict the extent to which communication is effective, thereby compromising the process of obtaining consent.

Knowledge that an elderly individual has sensory impairment may also decrease the extent to which the person seeking consent makes an effort to communicate with the elderly subject. A stereotypic perception of the capacities of elderly people, discussed earlier, may also predispose the person seeking consent to assume that the elderly person has sensory impairment and to employ less effort in obtaining consent.

Physical impairment, such as paralysis after a cerebrovascular accident, may also inhibit the normal process of communication, thereby decreasing the effectiveness of the process. Physical impairment may also lead the consent-seeker to assume - perhaps incorrectly - that there is a corresponding mental deficiency, again creating problems in obtaining consent.

3.4.1.3 - Focus on deficits rather than capabilities

---

[185]Wilson, P.S., Fleming, D.M. and Donaldson, I., 'Prevalence of hearing loss ammong people aged 65 years and over: screening and hearing aid provision', British Journal of General Practice, 1993; 43: 406-409.

[186]ibid., p. 407.

A third problem with obtaining consent in elderly patients and potential research subjects is that there is a tendency to focus on the weaknesses in the elderly person's capacities, particularly if he or she is demented. It has been noted that the first question which tends to be asked when dealing with elderly people is whether they are competent, rather than aiming to maximise the decision-making capabilities of the elderly individual[187],[188]. As compromised autonomy in the elderly is, in the main, neither a complete lack nor due to a single irreversible cause, involving the elderly in research can be made a more ethical process by adapting the structure of research projects, and the way in which consent from older participants is sought.

3.4.2 Problems with institutionalisation

Institutionalisation is also a problem for elderly individuals, including potential research subjects, particularly as it is far more common in this age group than in younger persons. Institutionalised elderly are more vulnerable and dependent than other elderly persons, and this poses problems for research on such individuals. The decreased autonomy associated with this phenomenon may be exacerbated by a number of other factors, of which there are at least eight. These are as follows.

Firstly, in common with other institutionalised persons, such as prisoners and long-term psychiatric patients, the elderly are likely to experience changes in their behaviour and personality, leading them to behave in an 'institutionalised' way. This may be exaggerated by the attitudes of staff who perceive the elderly person in a stereotypic way, and may be more marked in the elderly than younger individuals as they are less likely to be discharged.

Secondly, the elderly person is physically frail and vulnerable, and has much less hope of ever being discharged from the institution than younger

---

[187]Hope, T., 'Aging, research and families', J.Med.Eth., 1997; 23: 267-268.

[188]See also Olde Rikkert *et al* (1997), op. cit., pp. 271-276.

individuals. Thus, there may be less motivation to treat them as though they will return to pre-morbid functioning, and their autonomy underestimated as a consequence.

Thirdly, he or she is also likely to be financially constrained, making it difficult for him or her to make any change in his or her circumstances should they be less than satisfactory.

Fourthly, they may tend to be less assertive than younger individuals for social and cultural reasons, and may 'give up' more than younger persons who are institutionalised because it is considered more 'normal' (perhaps incorrectly) for older persons to be institutionalised.

Fifthly, the elderly person's family may contribute by pressuring them to take up residence in the institution, and may similarly pressure their relative to participate in research.

Sixthly, the health of the older individual tends to become worse once they are institutionalised, which further increases their frailty and dependence, and further compromises their ability to make decisions freely. Their cognitive capacities may tend to decrease through lack of stimulation, and this temporary, reversible state of affairs may persist if no effort is made to overcome it, thereby further compromising the autonomy of the individual.

Thus, it may be seen that the above factors are problematic in that they increase the dependency of the institutionalised individual, and exacerbate their lack of autonomy. They are dependent on the institution to provide them with shelter and care. This may make them prone to consenting to participation in research when they may not do so had they more alternatives open to them. They may feel that their dependence on the institution means that they must comply with requests such as those for participation in research.

Seventhly, the relationship between the older person and his or her doctor may be compromised by institutionalisation; the physician is often the person responsible for admitting an elderly person to high level care, such as a

nursing home, and the resentment the older person may feel may decrease the quality of the relationship. Thus, if the physician responsible for obtaining consent for participation in research, the process of obtaining consent may be complicated by the decreased quality of the doctor-patient relationship. A poorer doctor-patient relationship may also expose the elderly person to risks from research if the person recruiting the elderly individual is *not* the doctor; the elderly person may be less likely (or able) to consult his or her doctor for advice, thereby increasing the potential risks.

Finally, another factor working against the elderly person in an institution is that their dependent state naturally predisposes them to feel obliged to participate in research, and may lead to them receiving an excessive number of requests to participate. Apart from the issues of compromised autonomy and its implications for research, multiple requests to participate may cause problems for research insofar as an elderly person may end up involved in multiple trials simultaneously, possibly without the knowledge of the different research teams[189].

3.4.3 - Problems with community-based care of the elderly and the way in which this impacts on autonomy

Related to institutionalisation are other forms of care for elderly people, such as care of various kinds utilised in order to keep the elderly person in the community. Although attempts to keep elderly persons in their homes have the potential to increase the happiness and independence of such individuals, and would appear to contribute to their autonomy, the kinds of care which may be involved in community living may in fact compromise the autonomy of the elderly. And, obviously, decreased autonomy has implications for research involving the elderly. Thus, claiming that elderly persons living in the

---

[189]Royal College of Physicians (1990), Research Involving Patients, Royal College of Physicians, London, p. 24.

community are sufficiently independent and autonomous to allow their participation in research may be oversimplifying the case.

3.4.3.1 - Family pressures and their impact on the elderly

An escalating need for care at home may create problems because it places increasing pressure on other family members.

In one sense, this is less likely to be an issue nowadays, given that the structure of families have changed, tending to be more fragmented, both structurally and geographically. Thus, it may be community services, rather than family, who provide home care for the elderly.

On the other hand, however, when family members are available to provide care for elderly relatives, the likelihood that they will be fewer in number means that an often unreasonably great burden is placed on these carers.

This situation may create tensions within the family that tend to impact negatively on the elderly individual. The older person may also be pressured to enter residential care, thereby weakening his or her autonomy. In addition, entry into a nursing home or hospital makes the elderly person both less autonomous yet more likely to be approached for participation in research.

3.4.3.2 - Community services and their significance for the elderly

If the family are unable to care for their elderly relative, care in the community tends then to come from community services. This also poses problems for the autonomy of the older person.

Many people, but particularly elderly people, may feel that it is more 'natural' for the elderly to be cared for by their families, and when this cannot be achieved, they may be disinclined to accept help from other agencies. This may lead to a lack of adequate care and medical intervention, perhaps exacerbating physical problems and cognitive decline. A failure to accept care

from community services, and the resulting lack of care, may lead the older person to be institutionalised earlier than they need have been.

If, on the other hand, help is accepted from community services, the older individual may feel guilt that they are being a 'burden' on society, particularly when stereotypes about the capabilities of the elderly prevail. Acceptance of care in this way may also lead the elderly to feel increasingly dependent, and to cease to function as a fully autonomous being unnecessarily.

A final problem with community care is that eventually it fails to be cost effective, and it may be necessary to move the elderly person to higher-level, institutional care, even though they may resist this. The combination of institutional care with pressure to be there may mean the elderly person reacts negatively and may become depressed or decline in other respects, thereby compromising their autonomy.

3.4.4 - Difficulties with relatives of elderly people

The care of elderly individuals in the community raised the issue of family involvement in such care and associated difficulties, and there are a number of other ways in which relatives can create problems for elderly people - including relationships between family members and conflict of interest. Both good and bad relationships between elderly persons and their families have implications for research insofar as both may affect the way in which the elderly person behaves - including how they behave in response to requests to participate in research. Disparity between the interests of the elderly person and those of his or her family may also create problems.

3.4.4.1 - Good pre-existing relationships within the family

The first issue is that if the relationship between the elderly person and their family has been good, hospitalisation is likely to result in stress for both

parties. Such stress may compromise the elderly person's autonomy in a number of ways.

Firstly, the stress itself may directly decrease the individual's ability to make reasonable decisions; similarly, it may lead to related conditions such as depression, which also adversely affect autonomous decision-making. (This is likely to be exaggerated in elderly patients as they tend to be hospitalised for longer, thereby increasing the likelihood that stress and depression will complicate matters when consent for research is sought.) Thus, these kinds of factors are problematic for research on the elderly because they affect the individual's autonomy, thereby complicating the process of obtaining informed consent.

Secondly, in this situation, participation of the elderly person in research may also be complicated by the person's desire to be reunited with supportive family; for example, he or she may agree to participate in research in the hope that this will improve their chances of going home.

3.4.4.2 - Stressed relationships within the family

A second aspect of an otherwise good relationship between the elderly person and his or her family is that even if the relationship has always been good, ongoing illness or decreasing cognitive function may lead to family stress, anger and guilt which cannot be helped by outside intervention[190]. In this case, hospitalisation of the elderly person functions as a relief for family members, and three problems arise in this situation.

Firstly, the elderly individual may be pressured by family to remain in hospital, thereby increasing the likelihood that there will be research problems insofar as the longer an elderly person remains an in-patient, the more likely they are to be approached for recruitment to research. Longer periods of hospitalisation may also complicate research in that the elderly person is more

[190]ibid., p. 378.

likely to develop problems which compromise their autonomy - such as thinking and behaving in an 'institutionalised' way, and by developing comorbidity.

Secondly, the family may also - deliberately or otherwise - misrepresent the extent of the elderly person's illness or disability in order to prolong the break from care they receive while the elderly person is in hospital. This misrepresentation is more of a problem for elderly patients than patients in other age groups because elderly persons do tend to be more likely to be unwell, with a greater number of diseases at work, than younger persons. Thus, a misrepresentative image of an elderly person's health or capabilities is more likely to be accepted as true; and the stereotypic perception of elderly people outlined in previous sections may also contribute further to this problem, particularly when the stereotypic perception increases the tendency to give more weighting to the opinions of the relatives.

Thirdly, stress and guilt on the part of family members may lead them to pressure elderly relatives into participating in research. This is because medical intervention - including research, particularly if the cause of the elderly person's problems are not understood or treatable - implies that there is a medical reason for the person's condition, which serves to alleviate feelings of stress and guilt.

3.4.4.3 - Poor pre-existing relationships within the family

I have discussed the two ways in which *good* family relationships may impact on the elderly person. However, it may also be the case that relationships between older individuals and their families may have been *poor*, even prior to illness or dementia. This also may influence the way in which the elderly person behaves, leading to repercussions for research involving the elderly.

One obvious way in which poor family relationships impact on the elderly is that hospitalisation provides welcome relief for both the elderly person and the relatives. The elderly person may be inclined to agree to participate in research in the hope that their stay will be prolonged, thereby avoiding reunion with his or her family. Conversely, the relatives may pressure the elderly person to participate in research in the hope that he or she will be hospitalised for longer.

Relatives may also hope that involvement in research will reveal some cause for the elderly person's behaviour which will absolve them of responsibility for the poor relationship; or that an underlying medical reason may be discovered which might again be contributing to the problems in the relationship.

Removal of the elderly person from the home environment may also create a new equilibrium into which the elderly person may not be readily accepted[191]; this kind of effect may be exacerbated if the elderly person's absence is prolonged by hospitalisation or participation in research.

Thus, as I have discussed, both good and bad relationships within the family of an elderly person may have consequences for the elderly individual's autonomy and attitude towards participation in research.

3.4.4.4 - Conflict of interest within the family

A further way in which the family of an elderly patient or research subject may affect matters is when the *interests* of the family conflict with those of the patient. As has been noted, it should not be the responsibility of the physician (or indeed researcher) to intervene in such problems[192], but it is impossible to dissociate the role played by relatives, and the impact of the

[191]Oppenheimer (1991), op. cit., p. 380.
[192]ibid., p. 379.

family, from the elderly person as a distinct entity in the clinical or research setting.

Traditionally, it is held that the doctor should pursue the course of action which is in his or her patient's best interests, even when this is in conflict with the best interests of relatives, for example. (This is relevant to research in that the attending doctor often plays a fundamental role in recruiting patients for research and forming the link between the research subject and the research project.) However, there are a number of reasons[193] why this focus on the best interests of the patient alone may not be relevant.

One is that it is already the case that patient's best interests are sometimes overridden.

A second reason is that it does not seem reasonable to impose demands on relatives which would not be expected of other carers, such as health care workers.

Thirdly, the interests of the elderly person and his or her family are often not readily separable; an example might be an elderly person whose family can no longer supply adequate care, but who refuses to go into a nursing home because he or she wishes to leave money to his or her children. One might say that it is in the best interests of the offspring to keep the elderly person at home, but that the best interests of the elderly person would be served by putting him or her into a nursing home. However, it is arguable that it is not clear that the elderly person's best interests are so straightforward; it may be in his or her best interests to be kept at home, given the obvious importance the elderly person attaches to the act of leaving money to his or her children[194].

Fourthly, the preference given to an individual's best interests is usually to protect that individual from harm from 'malign influence'[195]; however, it is arguable that this applies less to families, and certainly not in the majority of

---

[193]Hope (1997), op. cit., p. 267.
[194]ibid.
[195]ibid.

situations in which one might wish to take into account the interests of the relatives.

3.5 - Defending research involving the elderly

3.5.1 The importance of research involving older individuals

The difficulty then, of course, is that all the difficulties discussed above contribute to compromised autonomy in the elderly, or other difficulties for consent, which should mean that the elderly individual cannot give informed consent. Yet informed consent is generally considered to be an essential element of research, without which the research cannot go ahead. It is arguable, however, that research in the elderly is still necessary, for four reasons.

3.5.1.1- Medical problems unique to the elderly population

Firstly, there are special medical problems unique to old individuals, and some medical problems are increasing in the elderly as fewer are dying early of ischaemic heart disease and cardiovascular disease.

It is arguable that medical problems which are common to both older individuals and younger groups should perhaps be researched using younger research subjects because it is less likely that they will have the kinds of factors leading to compromised autonomy that are seen in the elderly. (This is also the case when dealing with diseases common to both adults and children.)

However, research on the elderly might still be necessary to ensure that a given disease takes the same course in the elderly as in younger individuals when the disease is common to all groups (as well as for problems seen only in older age groups), given that conclusions reached in studies of young people cannot be extrapolated to elderly people[196]. Further, research may be necessary,

---

[196]Bell, J.A., May, F.E., Stewart, R.B., 'Clinical research in the elderly: ethical and methodological considerations', Drug Intell.Clin.Pharm., 1987; 21: 1002-1007.

not only on the elderly in preference to younger research subjects, but also on elderly subjects with compromised autonomy rather than unimpaired elderly - as in the case of dementia research, for example.

3.5.1.2 - Different biological responses in the elderly

Secondly, the elderly comprise only 14% of the population, yet consume nearly one third of all medications[197], indicating the importance of research in this age group. They also have different drug metabolism; this is particularly marked if the individual is both elderly and ill[198], and multidrug therapy is also more common, leading to an increased risk of adverse drug reactions[199]. The widespread use of medications in the elderly, as well as the different way in which they are handled by the bodies of the elderly, emphasise the importance of drug trials involving the elderly.

The elderly are not only more likely to have problems with medications they are given, but they are also more likely to be on the receiving end of substandard drug trials. This is because the drug industry is highly competitive, and vast sums of money are involved. However, the elderly are problematic for drug testing, having complicated physiology and existing comorbidity, and so tend not to be recruited because of this. As a result, the elderly tend to be excluded from trials[200] when in fact they should be included.

3.5.1.3 - Social problems specific to older individuals

Thirdly, the ever-increasing proportion of elderly people in society raises many social issues for the elderly, such as problems with housing, community care, institutionalisation, and so forth. Research in areas such as these - less

---

[197]Avorn (1997), op. cit., p. 1033.

[198]Avorn, J., Gurwitz, J.H., 'Principles of pharmacology', in Cassel, C.K., Cohen, G., and Larsen, E. (eds) (1997), Geriatric Medicine, Springer, New York.

[199]Mannesse, C.K. *et al*, 'Adverse drug reactions in elderly patients as contributing factor for hospital admission: cross sectional study', BMJ, 1997; 315: 1057-8.

[200]Avorn (1997), op. cit., p. 1033.

directly medical - are also important. Without research into the particular problems characteristic of old age, improvements in knowledge and care cannot come about; hence the importance of such research. This is important not only in order to maximise the happiness, health, and productivity of older individuals, but also to decrease problems and expenses for families and for society more generally.

3.5.1.4 - Social cost of elderly health

And fourthly, health care for the elderly already occupies a substantial proportion of the health care budget, owing to the comparatively extensive morbidity seen in this group. As the proportion of elderly people in society will continue to increase in coming years[201], it is arguable that research into problems characteristic of this age group is necessary, both for their care and to prevent minimise the drain on resources which we are likely to see in the future.

3.5.2 Why research involving elderly with compromised autonomy may be defensible

Even if researchers are confronted with potential elderly research subjects with compromised autonomy, a number of factors may mean that some research can be considered more justifiable for research subjects with compromised autonomy.

3.5.2.1 - Benefits to the individual may increase acceptability of research

Firstly, research may be considered to be more ethical if there are direct *benefits* to the individual which are likely to result from the research,

[201]This is reflected by a number of statistics. People aged over 60 currently constitute a fifth of of the British population, but will be a third by 2030; in 1951, Brtain had 300 people aged over 100, whereas by 2031, it is estimated that there will be 34 000 people over 100; and those aged over 80 represent the fastest-growing section of the population. Taken from Greengross, S. *et al*, 'Aging: a subject that must be at the top of world agendas', BMJ, 1997; 315: 1029-30.

particularly if these benefits are felt to outweigh the risks incurred and the resources utilised in the research. That is, a favourable cost-benefit analysis obviously is to be preferred, particularly when treatment or research is complicated by compromised autonomy on the part of the patient or research subject.

A related aspect is when no direct benefit is expected for the individual, but when it is anticipated that the research will yield benefit for the group overall. This may be considered defensible for a number of reasons: the individual may still advantage from the benefits conferred on the group as a whole; the elderly research subject with compromised autonomy is more likely to have given some kind of indication in advance of how they would feel about participating in research (compared with the case of children); and many factors contributing to compromised autonomy in the elderly may be comparatively minor and still permit the elderly person to be able to consent quite well and validly (again compared with children, in whom a restriction of autonomy is generally held to be more global).

3.5.2.2 - Types of procedures and research may make involvement of elderly more ethical

Secondly, the *type of procedure* involved in the research is relevant. Research using safer and less invasive procedures such as urinalysis would appear to be more ethical when the research subject has compromised autonomy than invasive and high-risk procedures such as surgery.

Some elderly individuals may have different or unexpected responses; as an example, demented individuals may also have different responses to certain situations - for example, they may be more distressed undergoing a CT scan than cognitively intact individuals - which may affect adversely the extent to which research on such individuals can be considered ethical. Other procedures may, however, be more acceptable to the demented elderly person.

Further, a number of practical measures may be taken to facilitate the elderly person's involvement in research, and to decrease the extent to which their autonomy is compromised. For example, many institutionalised elderly people experience a decrease in cognitive function related to their unstimulating environment. This may in part be reduced by providing a more stimulating environment, and the resulting increase in cognitive function may render the elderly person more able to consent to take part in research.

Similarly, altering the structure of a research project - for example, by 'training' the elderly person in the early stages of the trial[202] - may make it more ethical by increasing the understanding of the potential research subject, and therefore the validity of his or her consent.

In addition, not all *types of research* are the same; many kinds of research which are potentially useful for the elderly - such as social policy research, research on care, and music therapy - obviously are much more acceptable for those with compromised autonomy, given their relatively non-invasive and non-intrusive nature.

3.5.2.3 - Justification of research on elderly with compromised autonomy based on levels of satisfaction involved

Thirdly, research on elderly with compromised autonomy may also be considered justifiable in that it may generate a sense of *satisfaction* for a number of parties involved.

The staff caring for the patient (if the research subject is institutionalised) may derive satisfaction from feeling that the maximum is being done for the elderly person; and if a disease entity is detected or defined through involvement in research, the staff may be better equipped to deal with the patient. In addition, involvement of institutionalised elderly persons in

---

[202]Olde Rikkert, M.G.M., van den Bercken, J.H.L., ten Have, H.A.M.J. and Hoefnagels, W.H.L., 'Experienced consent in geriatrics research: a new method to optimize the capacity to consent in frail elderly subjects', J.Med.Eth., 1997; 23: 271-276.

research may be to their advantage in that health problems may be detected when otherwise the elderly person would not have had contact with medical services.

The family may also derive satisfaction from the fact that their elderly relative is involved in research, in that the person may derive direct or indirect benefit from the research; it also implies that the elderly person is receiving attention and care.

Finally, and most importantly, the elderly research subjects themselves may derive satisfaction from participating in a study; they may feel as though they are doing something positive, contributing both to their health, as well as to society and other people with similar problems. It is important to note that the kinds of problems which potentially can decrease the autonomy of the elderly may be much more subtle and varied than the usually more global decrease seen in many other groups (for example, those in a persistent vegetative state). Thus, while there are many potential problems which one needs to be aware of when dealing with the elderly - such as poverty, family tensions, social differences, physical frailty and illness and impaired cognitive function - there may be a sufficiently small number of factors compromising autonomy to make consent valid.

3.5.2.4 - Defending research on the elderly based on previously-expressed acceptance of research

Fourthly, research on an elderly person with compromised autonomy may be justifiable if the person has *expressed previously* an acceptance of or wish to participate in research - a situation different from that of children as potential research subjects, who are unlikely ever to have expressed any view on this matter. The validity of a criterion such as this for involvement in research is heightened if the research in question involves: little or no risk; a high benefit-to-risk ratio; probable benefit to the individual; and little that

could be considered invasive or intrusive (as in studies of the care of the elderly, epidemiology, and so forth). However, there remain problems with this criterion for inclusion of the elderly in research. These four problems are as follows.

The first problem with using previously-expressed acceptance of research as justification for research on an elderly person with compromised autonomy is that few people are likely to give explicit views on whether they would wish to be included in research were they unable to consent for themselves. This is in contrast with certain other clinical scenarios, such as being in a persistent vegetative state; this latter situation is usually more prominent in the minds of most people than research and, accordingly, they are more likely to have expressed views on the way in which they would want to be treated.

A second problem with using a previously-expressed acceptance of research as grounds for inclusion in a study is that an expression of support for research generally does not necessarily translate into a willingness to participate oneself. And even if there is evidence that the elderly individual had communicated a willingness to participate in research himself, there is no guarantee that such a view will always remain current; the individual may change his or her mind, without the knowledge of the family or friends who are likely to be questioned on the views of the non-autonomous elderly person.

The third difficulty is that even if the elderly person has previously indicated that they would be prepared to participate in research were they to become unable to consent for themselves, it may be the case that they have not understood the nature of research in general. And it is almost certain that it would be impossible for them to understand the specifics of a particular study in advance; it is also unlikely that an individual is able to predict in advance how he or she would feel about involvement in particular kinds of research.

Finally, the situation may be complicated by the involvement of the elderly person's family, who may be unreliable in reporting the previously-expressed wishes of their relative. Family members may substitute their own views for those of the elderly person. Or they may misrepresent the views of the person through ignorance of the person's true views, through a desire to help their relative (either by involving them in research or preventing them from participating, depending on what they perceive to be in the best interests of their relative), or through other factors (such as an inability to cope with an unwell elderly person, and a subsequent desire to pinpoint a 'medical reason' to explain the situation).

Thus, it can be seen that there are a number of objections against using previously-expressed acceptance of research as a criterion for inclusion of elderly research subjects with compromised autonomy. These problems, as I have discussed, include the lack of likelihood that an opinion specific to research has been given in advance; a general support of research may not signify one's own participation; the person may change his or her mind; the person may not understand research generally, and is unlikely to have given views on specific kinds of research; and the elderly person's family may complicate matters by misrepresenting the views of the person.

However, a previously-expressed acceptance of research may still be useful, particularly for potential elderly research subjects with compromised autonomy. This is because compromised autonomy in the elderly is far less likely than other groups to be absolute (except in cases of advanced dementia, coma, and so forth) - as I have discussed - and although the elderly person may lack one or two of the criteria used to assess competence, it is not the case that this makes the elderly person unable to consent meaningfully.

It is likely that many elderly individuals with compromised autonomy may still retain many of the criteria we would consider necessary for competence and consent, and it is in this way that the use of other, minor

factors can be seen. For example, a previously-expressed acceptance of research by an elderly person with compromised autonomy may not be considered sufficient, on its own, to justify involving the person in research. However, a factor such as this may be useful when considered in conjunction with other criteria which indicate that involvement in research may be appropriate.

3.5.2.5 - Summary of factors which may render research on elderly with compromised autonomy acceptable

Thus, in summary, there are a number of factors which may make research on elderly individuals with compromised autonomy more acceptable. These include: benefits (direct and indirect) for the individual; a modification of research procedure and the kinds of research performed to make it less invasive and intrusive; satisfaction on the part of staff, family, and the elderly person himself; and a previously-expressed acceptance of, and willingness to participate in, research.

Although some of these factors would not be considered a satisfactory criterion for including an elderly person with decreased autonomy in research, they may serve as useful factors which can help an assessment of the suitability and ethics of the individual's involvement in a research project. As I have noted above, this is partly because the elderly with compromised autonomy are often borderline cases, rather than completely lacking in autonomy. For example, an elderly person who has a poor relationship with his or her family may consent to participate in research in the hope that this will increase the length of their stay in hospital, away from their family, yet be quite cognitively intact and healthy and not subject to compromised autonomy in any other way. In a case such as this, it may be seen that although it is important to be aware of factors such as poor family relationships, obviously the individual is essentially competent.

It is in situations such as these where some of the factors outlined in this section may be useful - for example, a previously-expressed wish to participate in research may allow inclusion of the person in research insofar as it compensates for the fact that the elderly person appears to be consenting in order to stay in hospital, away from his or her family.

3.5.3 Research involving autonomous elderly

It is of course the case that a good number of elderly persons - particularly the 'young old' - are free from the kinds of factors which may adversely affect autonomous decision-making.

However, the existence of other elderly persons with a decreased capacity to consent to research may lead us to restrict autonomous elderly from participating. This may in part be due to the stereotypic perception that many more elderly people are impaired than is actually the case. Therefore, the capabilities of each individual elderly person to consent may be less likely to be adequately assessed. In addition, stereotypic perception creates the possibility that legislation may be implemented in order to protect the non-autonomous from exploitation in research, thereby preventing the autonomous elderly from participating in research.

However, it is obviously the case that this is undesirable. Elderly persons, as a group, stand to be disadvantaged if research is not carried out into problems affecting them, and it is clearly preferable that research subjects be able to consent when they can. Further, it would appear an unreasonable imposition on the liberty of the individual to prevent autonomous elderly persons participating in research on the basis of their age, when we extend no such prohibition to other autonomous groups. Autonomous elderly are just as likely to have altruism, curiosity and scientific enthusiasm as younger

persons[203], and it does not seem right to prevent them from participating in research when they are in fact autonomous.

3.5.4 - Economic and resource factors in favour of research involving the elderly

A further point in support of some research involving elderly subjects with compromised autonomy has its basis in economics and the problem of resource allocation. The health problems of the elderly already occupy a disproportionate amount of the health care budget, and as the proportion of the population who are elderly will continue to increase in coming years[204], it is arguable that research on the health problems and care of the elderly is desirable in that it will help reduce the resources allocated to the health of this age group.

Research also increases the likelihood that the elderly will receive improved care and quality of life, and it is not clear that they should be denied the possibility of this on the grounds that resources would be better spent elsewhere. It is often contended that health care resources are better spent on younger patients. In one sense, this may be justifiable, in that younger patients tend to do better and any benefits they receive are likely to last longer owing to a longer lifespan. In addition, older individuals may exert considerable pressure - 'grey power' - leading to a potential for misallocation of resources in favour of the elderly. On the other hand, benefits should be assessed depending on existing disability[205], not simply on the basis of age; elderly individuals who do not have existing comorbidity may easily do as well as younger persons.

In addition, it does not seem justified to deny the elderly access to research and care which may greatly improve their quality of life on the grounds that they have already had 'a good innings'. This is only valid if one assesses 'a good innings' simply on the number of years the individual has

[203]Oppenheimer (1991), op. cit., p. 375.
[204]Greengross (1997), op. cit., p. 1029.
[205]Mason and McCall Smith (1994), op. cit., p. 276.

lived. In other senses, the elderly person may not have had such a good innings as many younger people. For example, life as a young person would have been a good deal more difficult for many of the elderly than it is for younger individuals today[206]. It is also worth noting that although the elderly have been alive for longer, they have not had access to sophisticated health care and technology for any longer than younger people, given that many treatments and techniques were developed later in the lives of the former.

A final point in favour of providing resources for research involving the elderly is that we are making a false distinction between the 'elderly' and ourselves - it has been noted[207] that the elderly *are* ourselves, and to designate them as a separate group is simply freezing a thin slice in time, thereby creating a false impression that somehow the elderly are a distinct group.

Thus, it would seem that there are reasons for research on the elderly which render it both necessary, and justifiable in many respects.

3.6 - Conclusion

To summarise, it may be seen that the autonomy of elderly persons is affected in a number of ways.

These include: the terminology applied to elderly people; stereotypic perceptions of the elderly; endogenous and exogenous factors decreasing capacity for consent; the varying degrees of impairment which exist; institutionalisation; community care; and the relatives of elderly people.

However, research is still important in this group of people in order to optimise their management and to improve their quality of life.

The acceptability of research may be increased if: it benefits the individual; leads to satisfaction; there exists a previously expressed desire to participate; the methodology can be modified to optimise the capacities of the

---

[206]Oppenheimer (1991), op. cit., p. 382.

[207]Daniels, N., Am I my parents' keeper? An essay on justice between the young and the old, OUP, Oxford, quoted in Oppenheimer (1991), op. cit., p. 381.

individual; to provide equitable distribution of resources; and to improve the health of the elderly.

CHAPTER 4 - RESEARCH ON PSYCHIATRIC PATIENTS

4.1 - Introduction

In this chapter, I shall discuss a number of factors which relate to performing research on individuals with mental illness.

I shall discuss: the importance of research in this group; past exploitation of the mentally ill and the way in which this affects our attitude towards them now; the factors affecting autonomy in psychiatric patients, such as the continuum between normal and abnormal, stigma, impaired reasoning and communication, difficulty assessing levels of understanding, institutionalisation and involuntary treatment, and the use of psychotropic medications.

I shall also discuss the special cases of children and the elderly who are also mentally ill, as well as issues for the doctor involved in psychiatric research.

Finally, I shall outline ways in which ethical research in the psychiatric population may be brought about.

4.2 - Why research on psychiatric patients is necessary

Obviously, psychiatric patients may also suffer from various medical problems which are seen in other members of the population who do not suffer with mental illness, and it may be argued that for conditions such as these, it may be preferable to use people who do not suffer mental illness as research subjects.

However, as is the case with problems unique to children (such as congenital heart disease, Wilms' tumours, and retinoblastoma) or the elderly (for example, dementia and falls), psychiatric patients have particular problems which are unique to them as a group, and which make some research desirable and indeed necessary.

This is important in that research increases knowledge of various mental illnesses, thereby augmenting understanding of the pathogenesis, symptoms, clinical course, treatments, and impact on the sufferer of such illnesses. This allows more effective diagnosis, a more realistic understanding of such illnesses, and better treatment of such conditions. This in turn ultimately improves the lives of those who suffer mental illness.

4.3 - Past exploitation of psychiatric patients and the implications of this for research

Part of the reluctance to involve psychiatric patients in research stems from the many abuses they have suffered over the years, both in a research context, and more generally in society.

4.3.1 - The mistreatment of minority groups in a research context

Until recent times, experimentation and research were carried out with comparatively little regulation to protect the research subjects. As a result, potential research subjects were often selected from minority groups who had no real protection, and little support.

For example, children, particularly orphans and 'foundlings', were often recruited because they were readily accessible in orphanages, had no family or friends of sufficient influence to protect them, and were considered dispensable[208].

Another major group was of course the mentally ill, who have been treated as either unwell or criminal for much of history. This made them ideal candidates for research purposes, as they too often had little social support to protect them, often had impaired means of communicating any discomfort or

---

[208]Lederer, S.E. and Grodin, M.A., 'Historical Overview: Pediatric Experimentation', in Grodin, M.A. and Glantz, L.H. (eds) (1994), Children as Research Subjects, Oxford University Press, New York and Oxford, pp. 4-9.

discontent, and were viewed as sub-standard members of society. And people who were both children and mentally compromised were doubly vulnerable.

4.3.2 - Exploitation and poor treatment in a research context of subjects who are mentally compromised

An example of exploited research subjects who were both mentally vulnerable and children occurred Willowbrook in the U.S., where mentally retarded children were deliberately infected with hepatitis, to study the disease; parents were given faster admission if they consented to the procedure[209]. Jonas Salk also trailed his vaccine on a child who was mentally retarded[210].

Another example of the exploitation of the mentally compromised is the way in which the notion of mental illness has been misused in some countries, such as the USSR, as a means to control individuals on a personal and political level. This was made possible through social and political pressures, inadequate controls and checks on the clinical process, legislative problems and poor clinical standards[211].

4.3.3 - Nazi Germany: an example of exploitation of psychiatric patients for research purposes

A notable, yet comparatively little-publicised, example of exploitation of psychiatric patients is the way in which psychiatric patients were treated in Nazi Germany. The Nazi state was perceived as being 'organic' (biologisch), and employed biological imagery and the use of Darwinian terminology as its mainstays[212].

---

[209]ibid, p. 17.

[210]ibid.

[211]Fulford, K.W.M., Smirnov, A.Y., and Snow, E., 'Concepts of Disease and the Abuse of Psychiatry in the USSR', British Journal of Psychiatry 1993: 162; 801-810.

[212]Proctor, R.N., 'Nazi Doctors, Racial Medicine, and Human Experimentation', in Annas, G.J. and Grodin, M.A. (eds), The Nazi Doctors and the Nuremberg Code - Human Rights in Human Experimentation, Oxford University Press, New York and Oxford, pp. 19-20.

This generated the idea of racial hygiene, and started a prolonged propaganda campaign that focussed on degrading the 'useless eaters' - namely, groups such as the homeless and psychiatric patients[213]. Under the guise of 'mercy killings' - designed also in part to free up hospital beds for the war wounded - 70 000 people in mental homes were killed by Hitler in 1939, and during WWII, one quarter of psychiatric patients starved to death as they were too low on the ration list[214]. The apparatus used to gas Jewish people was available because it had been designed to kill the mentally ill[215].

Psychiatrists were directly involved in this abuse of German psychiatric patients; leading psychiatrists and anthropologists translated Nazi ideological slogans into supposedly scientific categories as a basis for racial hygiene[216].

Psychiatrists were also involved in experimentation on psychiatric patients under the Nazi regime. The notions of mental illness were greatly exploited for political and social ends; for example, a Nazi psychiatrist, Robert Ritter, studied Asozialen (antisocials and gypsies) and concluded they were of primitive intelligence[217].

This demonstrates the way in which psychiatrists have exploited their role in the past, and the way in which the definition of 'mental illness' may be manipulated for political or other ends.

4.3.4 - Attempts to minimise the exploitation of the mentally ill for research purposes

However, there have been moves in recent years to decrease the probability of abuse or unfair treatment of psychiatric patients.

---

[213]Pross, C., 'Nazi Doctors, German Medicine, and Historical Truth' in Annas and Grodin (1992), op. cit., p. 33.
[214]Proctor, in Annas and Grodin (1992), op. cit., pp. 23-4.
[215]ibid, p. 25.
[216]Pross, in Annas and Grodin (1992), op. cit., p. 38.
[217]ibid, p. 37.

For example, psychiatric patients can now no longer be detained against their will for an indeterminate length of time; there are strict requirements that a patient be seen by several doctors during the early stages of their admission, and their case is heard by a visiting magistrate at the earliest opportunity (usually within a week) who can overturn the decision to schedule a psychiatric patient[218]. Even if a patient needs to be put into seclusion, because he or she is at risk of harming him- or herself, or others, he or she needs to be reviewed on an hourly basis by a medical practitioner, with a view to ending the period of seclusion[219].

In fact, past abuses may lead to problems now in that we may overcompensate when dealing with psychiatric patients. This approach may partly be because of a fear of letting some research subjects with compromised autonomy 'slip through the net', and be damaged by the research process because insufficient care was taken. However, it may be that this fear itself provides a certain degree of protection, in that it creates a heightened awareness of the possibility in the researcher, who will then be vigilant in their interactions with the individual. In addition, even if a psychiatric patient did occasionally have an adverse outcome, it does not seem reasonable to limit the exercise of autonomy for the majority of the mentally ill who do have a sufficient degree of autonomy. This would be a standard that we would not apply to the population more generally - for example, we do not alter our approach to research for autonomous adults on the off-chance that an adult who appears autonomous may not be sufficiently so - so it does not seem right to impose different standards on groups such as the mentally ill.

On the other hand, some writers have claimed that 'we should value liberty more highly than mental health, no matter how [it is] defined'[220], but it

---

[218]Central Sydney Area Health Service, Royal Prince Alfred Hospital Camperdown, NSW, Australia.

[219]Northern Sydney Area Health Service, Manly Hospital, Manly, NSW, Australia.

[220]Szasz, T. (1972), Law, Liberty and Psychiatry, Harcourt Brace Jovanovich, New York, quoted in Downie, R.S. (ed) (1996), Medical Ethics, Dartmouth, Aldershot, p. 402.

has been noted that attitudes such as this may be an overreaction to the fact that psychiatric patients have been ignored or poorly treated in the past, and that in putting liberty above all other considerations, we may be condemning them to another form of imprisonment[221]. This may lead people to erroneously accept the patient's preferences, no matter how they are arrived at, in an attempt to preserve their autonomy and self-determination[222]. It has been noted that freedom is a fundamental value, but there are other values which need to be preserved (such as equity, justice, self-respect, and life itself), and that freedom itself is a hollow value if the individual lacks adequate understanding, an ability to reason, or a reasonable assessment of likely outcomes[223].

It is arguable that for individuals with compromised autonomy, it is negligent and unfair to place too much responsibility on them - by making them consent for themselves, when they may lack the capacity for this - and that the researchers, and society more generally, should take some of the responsibility for this decision-making. Further, given the level of knowledge of the researchers, compared with that of research subjects with impaired autonomy, it may be that it is our duty to use this information, rather than expecting the research subject to deal with this by him- or herself.

4.4 - Autonomy and the psychiatric patient

The autonomy of psychiatric patients is affected by a number of factors, which I shall discuss. These include: the continuum that exists between normal and abnormal; stigma surrounding mental illness; impaired reasoning and communication; difficulties gauging the level of understanding when assessing psychiatric patients; external factors affecting a mentally ill person; the

---

[221]Chodoff, P., 'The Case for Involuntary Hospitalisation of the Mentally Ill', in Downie (1996), op. cit., pp.403, 406.

[222]Brock, D.W. and Wartman, S.A., 'Sounding Board: When Competent Patients Make Irrational Choices', in Downie (ed) (1996), op. cit., p. 408.

[223]Macklin, R., 'Refusal of Psychiatric Treatment: Autonomy, Competence, and Paternalism', in Edwards, R.B. (ed) (1982), Psychiatry and Ethics - Insanity, Rational Autonomy, and Mental Health Care, Prometheus Books, p.332.

possibility of involuntary treatment; institutionalisation; mental illness itself; and the existence of mentally ill individuals who are minimally affected. These impact on autonomy, and affect on psychiatric research in various ways.

4.4.1 - The continuum which exists between the mentally ill and 'normal' individuals

Many psychiatric conditions represent a continuum between normal and the markedly abnormal, and their diagnosis often depends on the subjective (and potentially fallible) judgement of psychiatrists[224].

4.4.1.1 - The continuum of mental illness and the way in which this differs from other groups with compromised autonomy

While psychiatric illness can be said to represent a continuum, this differs from other groups who have compromised autonomy - such as children and the elderly - in certain ways. The notion of a continuum is somewhat true of children and the elderly, in that they represent the extremes of age in the human population, and also in the sense that those groups contain individuals with a wide range of capabilities and capacities.

However, the range of states covered by the blanket of mental illness is much broader, and the capacities and degrees of impairment even more varied; the notion of a continuum appears to be even more prominent with psychiatric conditions and the sufferers of such conditions.

Some psychiatric conditions are very close to 'normal' on the continuum, and as a result may be difficult to segregate these potential research subjects from 'normal' individuals. A good example of this is personality disorder, in which the boundary between 'normal' and 'abnormal' can be difficult to evaluate, as well as quite arbitrary.

---

[224]Chodoff, in Downie (ed) (1996), op. cit., p. 404.

4.4.1.2 - The continuum of mental illness and the way in which this differs from physical disease

It should also be pointed out that some physical illness can be a continuum as well - for example, hypertension is a range of blood pressures, the 'normal' cut-off becoming increasingly low as more is learned about the long-term effects of even mildly elevated blood pressure.

This may be distinct from the case of the mental health spectrum in that having some physical diseases, such as mildly elevated blood pressure when previously the same reading would have been considered normal, does not carry the same negative connotations, emotive power, and associated difficulties for the sufferer.

4.4.1.3 - Neurosis versus psychosis

One way in which the continuum of psychiatric illness is manifested is shown by the way in which the term 'mental illness' encompasses both neurotic and psychotic conditions. Psychosis and neurosis represent a vast clinical spectrum, from mild anxiety, to uncontrolled, violent psychotic episodes.

However, a failure to recognise the existence of this continuum may mean that even sufferers with mild disease, few symptoms, or treated disease may be subjected to the same kinds of prejudices as those with more severe symptoms, by being categorised as 'mentally ill'.

This may lead to problems when research involves psychiatric patients, as the whole group may mistakenly be thought to possess the same capabilities and capacity for consent. There may be a tendency to use the most severe end of the spectrum as representative of the capacities of psychiatric patients, partly because this subset of the psychiatrically ill is most visible, most problematic, has the biggest range of problems, is most likely to benefit from research into their behaviour, and is most vulnerable.

4.4.1.4 - Partially and completely treated mental illness

Further, unlike groups that are classified on the basis of age, psychiatric patients may also be partially or completely treated, thereby further blurring the line between 'normal' and 'abnormal'.

Again, this causes problems when performing psychiatric research, because those potential research subjects with mental illness that is treated may be able to function at a normal or near-normal level, which would make informed, autonomous consent possible. On the other hand, those who are partially treated may be less likely to be able to consent for themselves, but it may be difficult to assess their degree of impairment.

A further complicating factor is that the extent to which a patient is treated may change over time. For example, a mentally ill person whose disease is well managed may give their consent to participate in a research project, but then may deteriorate during the project, making their on-going consent less clear. Conversely, a potential research subject with a psychiatric illness may be limited in their participation, or have a proxy consent on their behalf, but then improve subsequently to the level where they could realistically consent for themselves.

4.4.1.5 - Symptomatic and asymptomatic psychiatric disease

Patients may also be asymptomatic at various stages of their illness as part of the natural course of the disease, which can complicate assessment of their autonomy and their suitability to consent to participation in research.

Bipolar disorder, for example is characterised by episodes of both manic and depressive behaviour, interspersed with often quite long periods of normal behaviour. This, again, raises difficulties when recruiting psychiatric patients for research, as they are classified as having a psychiatric condition (with negative connotations and associated perception that they may be incompetent to consent to participation in research) even during their periods of normal

behaviour. It may also be difficult to assess *how* normal these patients are at a particular time, given the changeable nature of their disorder.

4.4.1.6 - Difficulties in diagnosing mental illness and implications for research

The fact that mental illness represents a continuum with normal (compared with many somatic diseases, where there is a particular, definable, physical abnormality) may lead to difficulties with diagnosis.

On one hand, some individuals with mental illness may be underdiagnosed, their behaviour being insufficiently obtrusive to lead to presentation, diagnosis and treatment. Examples might be people suffering from anxiety or obsessive-compulsive disorder. Others with some psychotic features may not be diagnosed because their symptoms are thought to be 'eccentric behaviour' - that is, not sufficiently abnormal to be classified as formal mental illness. These people may be considered 'normal' and be thought fit to consent, when in fact they may be sufficiently impaired to compromise the consent process.

Conversely, some people may be diagnosed with mental illness when they are in fact comparatively normal - such as some people with borderline personality disorder - and this may have significant impact on the individual, in terms of impairing their autonomy, and exposing them to stigma, which is difficult to avoid. Thus, they may be considered to be incompetent to consent to, or refuse, participation in research.

In addition, once an individual has been labelled as having a psychiatric illness, it is very difficult to overcome such labelling, even if it is incorrect. It also legitimises enormous power over those people who have been labelled[225].

4.4.2 - Stigmatisation and the fear of the mentally ill

[225]Edwards, R.B., 'Mental Health as Rational Autonomy', in Edwards (ed) (1982), op. cit., p. 68.

Psychiatric patients are also different from other groups, such as children or the elderly, in that they are more markedly stigmatised on the basis of their condition (although children and older persons may face preconceptions about their capabilities).

4.4.2.1 - Stigmatisation as a way of reinforcing the difference between normal and abnormal

The existence of a continuum between normal and abnormal in mental illness, compared with most physical illness, may generate fear and negativity. This is partly because mental illness, with its negative connotations, comes uncomfortably close to the normal population. By stigmatising psychiatric conditions, the rest of the population may attempt to broaden the division between the mentally ill and 'normal' people as a way of 'protecting' themselves.

4.4.2.2 - The lack of clearly defined biological basis to mental illness and the way in which this may contribute to stigma

Mental illness may also be feared because it is not obviously biological, or at least purely biological, in its basis. For example, there are a number of conditions which have a recognised organic basis, and although they may lead to similar behavioural manifestations as some 'psychiatric illnesses', they are not classified as such. These include delirium, and aphasia and mental retardation.

It has been noted that such conditions are not classified as mental illnesses *because* they have a biological basis[226]. And although some mental illnesses may ultimately be found to have a corresponding biological basis, at present this is not well understood. It is clear that the terms used in psychiatry do not ascribe pathology - many terms were used prior to the knowledge of

[226]Boorse, C., 'What a Theory of Mental Health Should Be', in Edwards (ed) (1982), op. cit., p. 34.

any underlying organic process[227]. As a result, diagnosis of mental illness does not rely on finding an objective, physical state in a patient; it relies instead on more subjective interpretation of symptoms.

This may contribute to stigmatisation of the mentally ill, again in an attempt to differentiate them from 'normal' people. (Having said that, it is worth noting that both organic and mental illness share a socially constructed negative evaluation, however[228].)

4.4.2.3 - Changes in definitions of mental illness and implications for stigmatisation

In addition, notions of mental illness, and the range of conditions which fall under the banner of psychiatry, have changed with time.

For example, more recent editions of the DSM no longer include excessive smoking or a predilection for too much caffeine as mental illnesses[229], or homosexuality. Conversely, newer editions now include problems such as pre-menstrual syndrome, whereas older editions did not recognise this cluster of symptoms as a clinical entity.

The changing nature of mental illness may also generate fear in people, because it further blurs the division between 'normal' and 'abnormal'. This may exacerbate stigmatisation of psychiatric patients, again with a view to broadening the division between 'them and us'.

4.4.2.4 - Stigmatisation of the mentally ill and portrayal of mental illness in the media

Stigma towards the psychiatrically unwell is likely to have been exacerbated by the negative portrayal and perception of the mentally ill throughout many periods in history, as well as in literature, journalism, film

---

[227]Sedgwick, P., 'Illness - Mental or Otherwise', in Edwards (ed) (1982), op. cit., p. 52.
[228]Veatch, R.M., "The Medical Model: Its Nature and Problems', in Edwards (ed) (1982), op. cit., p. 91.
[229]Edwards (1982), op. cit., p. 74.

and television. Such depictions of mental illness and its supposed treatment do little to eradicate the negative perception of mental illness.

A well-known example is Jack Nicholson's character in One Flew Over The Cuckoo's Nest. This has probably had such a significant impact on the public because it portrays an apparently misdiagnosed free spirit who, once inside a mental institution, cannot convince staff he is in fact not suffering from a mental illness.

In addition, the behaviour of the mentally ill is often shown as being very extreme and alien to usual behaviour, and treatment usually portrayed as barbaric. Examples include unmodified electro-convulsive therapy, which is no longer in use today, or frontal lobotomies; psychosurgery has not been performed in New South Wales for several decades. Representations such as these prey on the fears of many people.

4.4.2.5 - Implications of stigmatisation for the autonomy of the mentally ill

This stigmatisation disempowers the mentally ill, and may weaken their autonomy both at an endogenous and an exogenous level. At an internal (or 'endogenous' level), it may lead the mentally ill person to feel rejected, worthless, and unable to cope, which may affect their ability to consent for themselves. On the other hand, stigmatisation may lead to adverse, external circumstances for the patient, such as poverty, lack of social support, decreased education and job possibilities, and disrupted interpersonal relationships. These may also affect the capacity for autonomous choice and consent-giving.

4.4.3 - Impaired reasoning and communication in psychiatric patients and the implication of this for research

Another main way in which autonomy is impaired relates to abnormal reasoning and communication. Psychiatric patients may have difficulties as research subjects because they may not reason in the same way as other

individuals, particularly when acutely unwell, and as a consequence of this, they may not communicate in the usual way, which leads to a number of problems.

This may be seen to be different from the case of research on children or the elderly, in that although very young children and very demented elderly may not reason in the same way as most other people, in general, the basis of their reasoning has some features in common with others, and their communication to some extent conforms to the normal rules of social interaction.

This problem with reasoning and communication impacts negatively in a number of ways, including impaired interpersonal relationships. The relationship with health professionals may be adversely affected, leading to difficulties in managing the patient, suboptimal treatment, and problems obtaining consent for participation both in treatment and research.

In addition, other relationships, particularly intimate relationships with the patient's family and friends, may also be deranged, leading to isolation of the psychiatric patient, and a lack of support and trust, a phenomenon that is often seen among psychiatric patients. As a result, such patients may lack an ability to understand the implications of agreeing to participate in research, and may not have a sufficient support network to protect them against irrational decision.

4.4.4 - Difficulty assessing the level of understanding in psychiatric patients

Although psychiatric patients demonstrate certain behaviours which we associate with their condition, in general the impact of mental illness on the sufferer is much harder to assess than somatic illness and disease. Even if we have not had a particular illness with predominantly physical manifestations, our personal experience usually allows us to have some insight into the condition, and some appreciation of how it must feel for the patient. However,

it is much harder for outsiders to gain insight into the nature of mental illness, and the way in which it feels for the sufferer.

It should be pointed out that we cannot truly know what it actually feels like to be another person; usually, however, we interpret their behaviour as a basis for our interaction with them. So to say that we cannot rely on the behaviour of psychiatric patients to gain insight into their feelings and wishes may be imposing restrictions on them that we would not usually apply to other individuals.

However, it may be argued that our interpretation of the behaviour of other people usually relies on the assumption that the other person is 'normal' and knows the 'rules' of interaction. This obviously applies on a day-to-day level, as well as for interactions with patients and unwell people. The 'patient role' is a well-known phenomenon, and in the experience of this author, patients who violate these rules - including psychiatric patients - are 'bad' or 'difficult'.

4.4.5 - The impact of mental illness on external factors influencing autonomy

Problematic communication skills, coupled with the often negative perception of the psychiatrically unwell in our community, leads also to other difficulties such as unemployment. This in turn leads to problems with poverty, lack of housing, and decreased self-esteem. All these factors diminish the patient's sense of self and ability to cope. They also may function as exogenous factors which weaken the patient's autonomy, insofar as they may affect the individual's capacity to freely give consent to participate in research.

4.4.6 - Involuntary treatment of the mentally ill and implications for their autonomy

Psychiatric patients can also be treated against their will, which has obvious implications for autonomy.

Obviously, anyone who is behaving in an impaired way who is thought to be incapable of making a rational decision, can in theory have their wishes overridden by appealing to the Guardianship Board. And it may be seen that the wishes of some elderly persons and of some children may be viewed as inappropriate because they do not have the characteristics of an autonomous being, and lack rational judgement.

However, this phenomenon seems to occur far more frequently in the psychiatric population, partly because the very nature of the individual's illness implies that they lack these features we associate with rational decision and autonomy. Subsequently, psychiatric patients are frequently treated against their will, which may further decrease already impaired autonomy by making the patient believe their wishes are unlikely to be regarded. The nature of the treatment (for example, sedatives and antipsychotics) also further impair decision-making and autonomous action.

4.4.7 - Institutionalisation of psychiatric patients and effects on autonomy

Psychiatric patients tend also to be hospitalised for long periods, which makes them prone to becoming institutionalised. This has implications for the autonomy of such patients, and, consequent to this, may impact on the ability of psychiatric patients to consent for themselves.

4.4.7.1 - Institutionalisation and why this is a significant problem for the mentally ill

The negative effect of institutionalisation on autonomy and consent may be even more marked in psychiatric patients than in other hospitalised groups, because the mentally ill tend to be hospitalised more frequently, for longer, and more often against their will than other members of society. They may be aware that they are often unable to function normally in the outside world, whereas a 'normal' person, even if hospitalised for a long period of time, usually would

still believe that he or she had the capacity to function normally in the community.

4.4.7.2 - The effects of institutionalisation on mentally ill persons and implications for consent

These factors may affect the autonomy of the psychiatric patient, making him or her more likely to consent to participation in research against his or her will.

He or she may fear that refusal may lead to either prolongation of the hospital stay (if the patient is unhappy being hospitalised) or premature cessation of the hospitalisation (if the patient fears discharge from hospital).

There may be a perception in the mentally ill individual that he or she may have no medical or psychological option but to agree to participate; he or she may also fear transfer to another, more restrictive facility; and such patients may believe that they have no legal right to refuse to go along with that which they are asked to do[230].

The psychiatric patient may also believe that refusal to participate in research may mean that they will receive sub-standard care, or face further discrimination from the hospital staff, when such staff may already be the patient's only form of social and emotional support.

4.4.8 - The use of psychotropic medications in the psychiatric population and implications for autonomous choice

The autonomy of psychiatric patients may also be affected because such patients are frequently prescribed various psychotropic medications, ranging from hypnotic sedatives and anxiolytics, to anti-psychotic medications, often in significant doses, and sometimes with the aim of sedating the patient to such an extent that he or she may sleep for twenty-four hours or more; this author was

---

[230]Breggin, P.R., 'Coercion of Voluntary Patients in an Open Hospital', in Edwards (ed) (1982), op. cit., p. 240.

once required to sedate a violent psychotic patient, restrained by six members of staff, using 80mg of diazepam and 40mg of haloperidol intravenously, against the patient's will, at the insistence of the staff in the psychiatric unit.

Smaller doses of psychotropic medications are also frequently used on a long-term basis, and while the usefulness and necessity of such medications cannot be denied, the potential negative impact on the psychiatric patient's autonomy is evident.

This is obviously distinct from other potential research groups, such as children or the elderly, in that medications are either infrequently used, or in fact designed to try to enhance the patient's mental function and potentiate characteristics we associate with autonomy. Although medications used for the treatment of mental illness may also be given with the aim of normalising the patient's behaviour, the side effects often compromise their capacity for autonomous choice.

Thus, the use of psychotropic medication in the psychiatric patient population may lead to problems with research, because these medications may affect the way in which the patient reasons and communicates, and the extent to which their decision to participate could be said to be voluntary.

4.4.9 - The effect of mental illness itself on autonomy

A final point is that freedom is not merely defined by a lack of external controls; it has been noted that internal, psychological factors can be just as damaging in 'throttling the spirit' as any external influence[231]. Thus, the direct influence of the mental illness itself may impair thought and behaviour just as forcibly as any other factor that impairs autonomy.

4.4.10 - The impact on the autonomous choice of minimally affected psychiatric patients

---

[231]Chodoff (1996), op. cit., p. 406.

There are, of course, a significant number of psychiatric patients who are either partly or totally treated; who are asymptomatic at a given time; or who have forms of mental illness that do not significantly inhibit their functioning on a day-to-day level (such as comparatively mild anxiety and depression).

Such individuals may also be adversely affected if it is erroneously believed that the impaired members of the psychiatric population are representative of all mentally ill people - a misconception that may be enhanced by negative public perception, a tendency to focus on the floridly unwell mentally ill, and a desire to protect those individuals who are impaired.

Such beliefs may lead to even the comparatively well mentally ill having their freedom to choose inhibited by the attitudes of family, friends, the general public, the medical profession, research bodies, and legislative bodies. This discrimination may manifest itself in a number of ways, including: a reluctance to initiate certain studies; little effort to involve patients in existing trials; excessive focus on the deficits of patients; underestimation of their capacities; insufficient effort taken to elicit their suitability for consent; a tendency to assume incapacity when none may exist; and the implementation of legislation limiting the involvement of the mentally ill as a group in research, irrespective of individual capabilities.

4.5 - Children and psychiatric research

Children who suffer from mental illness pose particular problems when involved in psychiatric research. These include: added constraints on autonomy; underdiagnosis; lack of knowledge of how best to treat them; diagnostic challenges; disrupted family and interpersonal relationships; and misuse of psychiatric diagnoses to explain other problems. These points will be discussed individually.

4.5.1 - Multiple factors affecting autonomy

The first, and most obvious, point is that children with mental illness face twice as many difficulties from the point of view of factors which inhibit autonomy, because they have the difficulties of being a child, as well as being a psychiatric patient.

4.5.2 - Underdiagnosis of mental illness in children

It was also not recognised for a long time that children were affected by mental illness. As a result, many children with psychiatric problems were either not diagnosed, or were not diagnosed for a long period of time. This meant that many adverse behavioural traits and dysfunctional ways of coping could become entrenched, and have a lifelong effect on the individual. In addition, those children who were diagnosed faced added stigma because it was thought to be so unusual to see mental illness in children.

Children can also pose diagnostic challenges, as they pass through stages of certain actions of beliefs which might be problematic were they to persist. However, many little phobias and anxieties are common and transient in children, and as a result it can be difficult to establish which require intervention and which are likely to resolve spontaneously. It can also be more difficult to assess which of these states are problematic and should be treated, because it can be harder to assess the impact - both immediate and more long-term - on children than adults. This is because they can lack the means to communicate their distress in an effective way, and they do not have the same experience as adults which might be helpful to them in assessing factors which are likely to have a negative effect.

4.5.3 - Lack of knowledge of how to treat children with mental illness

There is also a lack of consensus on how to treat children who have mental illness, partly because it is a comparatively new field, and partly because research in children in general tends to be more limited than in the

adult population. This means that research in such groups is even more important, because limited knowledge on how we should treat children with mental illness means they may receive substandard care.

4.5.4 - Disruption of relationships and support network

Although in general children have more support from family and other social contacts than other groups with compromised autonomy, such relationships may be disrupted in children who have a mental illness, which exposes them to the risks of being exploited and poorly treated. Because of the often negative connotations of being mentally unwell, parents may deny that there is a problem, which leads to underdiagnosis, mismanagement, lack on involvement in research, and perpetuation of poor treatment and limited understanding of children with mental illness.

However, the quality of interpersonal relationships may be improved by participation in research, by improving the family's understanding of mental illness and their contact with their child. The family and the patient may benefit directly from the treatment in the research project, and more indirectly from learning more about the condition[232].

4.5.5 - Medicalisation of social problems

Finally, there can be a tendency to overmedicalise children's behaviour, perhaps because medical labelling adds a degree of legitimacy to certain behaviours, and because it takes blame away from others (for example, parents).

An example is ADHD (attention deficit hyperactivity disorder), with which a vast number of children are diagnosed. It is debatable whether the behaviour that the majority of these children exhibit is in fact normal and

---

[232]Osher, T.W. and Telesford, M., 'Involving Families to Improve Research', in Hoagwood, K., Jensen, P.S. and Fisher, C.B. (eds) (1996), Ethical Issues in Mental Health Research With Children and Adolescents, Lawrence Erlbaum Associates, New Jersey, p. 31.

appropriate, although perhaps difficult to manage at times. This may be partly because we find it easier to 'blame' adults for their behaviour, whereas with children we find them less blameworthy, and tend to search for external causes and explanations for their behaviour.

4.5.6 - Conclusion: children and mental illness

Thus, it may be seen that there are a number of extra factors which contribute to compromised autonomy in children who are also mentally ill. It is important to recognise the existence of factors such as these, in order that understanding, proper research, and treatment can be optimised in these patients.

4.6 - The elderly and psychiatric research

The elderly also represent a special group on individuals when they suffer from mental illness. An awareness of the special factors affecting this group is important in dealing with them, particularly with a view to involving them in research.

4.6.1 - Multiple factors affecting elderly people with mental illness

The first main problem is that - as for children with mental illness - this group of research subjects have more potential factors which could affect their autonomy. Problems which are faced by elderly people generally are compounded by those factors which may affect the autonomy of psychiatric patients, thereby making this group particularly vulnerable.

4.6.2 - Underdiagnosis of mental illness in the elderly

Mental illness in the elderly can tend to be underdiagnosed. The elderly may: be less likely to seek medical treatment; have a greater suspicion and fear of mental illness than younger people; tend to present with less florid

symptoms than younger people; and attribute their symptoms to 'just getting old'. The patient may be viewed as being merely old and crabby and eccentric, or their symptoms may be attributed to the life changes which are common in this age group, such as retirement, increased medical problems, and deaths of spouses and friends.

It may also be argued that mental illness may be overlooked in the elderly because the may have had mental illness for much of their adult lives. Thus, those who remain undiagnosed by old age may have milder symptoms, or have learned techniques to help cope with their mental illness. They may also have had their symptoms for such a long period of time that others fail to recognise them; instead, such symptoms may mistakenly be thought to just be part of the person's normal, albeit somewhat dysfunctional, state.

4.6.3 - Treatment difficulties in the elderly with mental illness

Treatment of mental illness in the elderly may also be more difficult than in other age groups. As I mentioned above, mental illness may have been present in elderly people for many years, making a change of habits difficult. Some forms of mental illness in the elderly, such as depression, tend to be more refractory, and resistant to treatments such as electro-convulsive therapy. The elderly may be more prone to side effects, such as postural hypotension in response to tricyclic antidepressant medications.

4.6.4 - Problems related to psychiatric illness may be compounded by age-related factors

Some of the problems seen in psychiatric patients may be compounded in the elderly with mental illness. For example, understanding and communication which is already compromised through mental illness may be worsened by dementia, strokes, blindness and deafness. Poverty and

disempowerment may also be exacerbated, and the burden placed on families and the healthcare system is even greater.

4.6.5 - Conclusion: elderly and mental illness

Research is important to clarify problems such as these, and to optimise the treatment of the elderly with mental illness, but recognition of the way in which they impact on the autonomy of the individual, and, consequently, on the research process, is important.

4.7 - The doctor-patient relationship in psychiatric research

The doctor-patient relationship may be complicated by a number of factors when a clinician participates in research involving mentally ill patients. There are at least several such problems.

Firstly, there may be disruption of normal doctor-patient dynamics and roles. Secondly, there may be difficulties for the patient in recognising the distinction between the separate roles of doctor and researcher. Thirdly, there exists potential conflict of interest for the doctor at a number of levels, such as duty to safeguard the patient's best interests, pressure to perform research, and social conscience and need for preventative medicine. These will be discussed individually.

4.7.1 - Interaction between the doctor and the psychiatric patient

The doctor-patient relationship may be affected if the patient fails to act in the 'proper' way - that is, if they fail to act according to the 'rules' of the doctor-patient relationship. It is arguable that the doctor-patient relationship is very formalised, and this provides a security (for both parties) which can be threatened if the 'rules' are breached.

As a result, the quality of the relationship between doctor and psychiatric patient may be suboptimal, as many psychiatric patients fail to

behave in the 'normal' and essentially predictable way that most other patients behave.

This may have an adverse effect clinically - particularly for psychiatric patients, whose therapy is based primarily on the establishment of good rapport between patient and clinician.

However, other aspects of the doctor-patient relationship may be affected, an example being difficulties obtaining consent to participate in research, and ensuring retention of patients in a study.

4.7.2 - Difficulties in recognising dual interests for the doctor

Another problem with performing research on mentally ill individuals is that - as in the case of children[233] - they may have less perception of the vested interests of a doctor who has the dual role of clinician and researcher, if they are have very florid disease or are impaired through external factors, such as high doses of psychotropic medications.

4.7.3 - Conflict of interest for the doctor involved in research on mentally ill patients

4.7.3.1 - The duty to one's patient and the way in which this may be compromised when a clinician is involved with research on the mentally ill

One such way the doctor-patient relationship may also become complicated in a research context is because (as is the case with other groups of research subjects with whom a clinician has contact) the doctor has certain obligations to 'do his or her best' for a patient - that is to say, the well-being of the patient ought to be of paramount importance, and the actions of the doctor should be to maximise benefits to the patient.

---

[233]Weithorn, L.A. and Scherer, D.G., 'Children's Involvement in Research Participation Decisions: Psychological Considerations', in Grodin and Glantz, (eds) (1994), op. cit., p. 151.

However, the involvement of a clinician and his or her patients in research may lead to conflict in this respect, in that the patient may not be receiving the best intervention possible. Examples of this might be involvement in a randomised controlled trial, where different groups receive treatment of various kinds, or possibly placebo. The placebo is obviously ineffective, and denies some research subjects access to the treatment, which may be effective, ineffective, or less effective than the standard treatment for a particular condition. Thus, involvement of the doctor in a randomised controlled trial violates the Hippocratic tradition[234].

This conflict for the doctor is even more pronounced when the potential research subjects are people with compromised autonomy, such as children, the elderly, and those with mental illness, as they may be less able to understand the nature of research and potential complications and disadvantages.

It is arguable that this is most problematic for psychiatric patients, insofar as children (and the elderly to a slightly lesser extent) usually have a number of other people who can provide support and advice; their emotional needs and protection can be provided by a relatively broad support network. The social support network of psychiatric patients in general is less adequate, however, and sometimes the doctor and other health staff are the patient's only advocates. This, combined with the decreased autonomy of some psychiatric patients, makes to involvement of the doctor in research potentially complicated.

Another problem might be when a patient refuses to participate in a study when the doctor believes it would be in the patient's best interests to do so. The doctor may feel that he or she has a moral, social and professional duty to do what it 'in the best interests' of the patient. Many patients often end up thanking the doctor for a particular course of action, even if they initially

---

[234]Schüklenk, U. and Hogan, C., 'Patient Access to Experimental Drugs and AIDS Clinical Trial Designs: Ethical Issues', in Kuhse, H. and Singer, P. (eds) (2000), Bioethics - An Anthology, Blackwell, Oxford, p. 443.

resisted such a course of action. Society usually expects doctors to take ultimate responsibility for the well-being of patients. And some patients may want or expect the doctor to be coercive[235].

4.7.3.2 - Career pressure on doctors to become involved in research

The involvement of clinicians in research on the mentally ill also may be complicated by conflict of interest in a number of respects other than the duty to do the best for one's patients. One such problem is the increasing pressure on clinicians to participate in research.

Involvement in research is increasingly important for promotion for clinicians, and as a result, the doctor in question risks being over-zealous in recruiting patients for his or her study.

This is of particular relevance in psychiatric patients, insofar as they may be more prone to exploitation, often having fewer social supports and being more likely to be institutionalised, than other research groups.

4.7.3.3 - Social conscience and the way in which this may lead to conflict of interest for doctors

Another source of conflict for a doctor involved in research is social conscience. Social conscience may drive the doctor's participation in research, owing to the significant impact mental illness has on the lives of sufferers and their family and friends, and on society.

A doctor may also feel it is his or her duty to try to improve the quality of life for groups such as the mentally ill, by being involved in research to try to help them. Groups such as the mentally ill tend to be overlooked in terms of funding and research, compared with some other research groups, such as children with cancer; the latter seem to invoke greater sympathy and support.

---

[235]Breggin (1982), op. cit., p. 242.

A concern for factors such as these may lead the researcher to press for participation in a study, even when it is not directly of benefit to the patient, or in his or her best interests, which is where the conflict lies.

4.7.3.4 - Preventative medicine and the implications of this for doctors conducting research involving the mentally ill

Similarly, a doctor may similarly wish to recruit patients to participate in research in the hope that the study may provide means for prevention of various illnesses and problems.

This is particularly relevant for psychiatric illness, as it has such a broad and significant impact on the patient and his or her life. The financial cost to the community of mental illness is enormous, due to factors such as sick leave, long-term care as an in-patient/ long-term institutionalisation, and the decreased ability of the patient to work and contribute to society in the usual way.

Again, a focus on the social cost of mental illness, and a desire to minimise this through research may complicate the doctor-patient relationship as the patient's interests may not be consistent with this course of action.

4.7.3.5 - Potential areas of conflict of interest which may be less an issue when dealing with psychiatric patients

Some potential areas of conflict for a doctor involved in research tend to be *less* an issue when dealing with psychiatric research. These include: an increase in the amount of funding available, which is generally less marked in psychiatric research, compared with other ares such as HIV/AIDS and cancer; and the expansion of clinical research as a profession, which tends to be seen more often in areas such as clinical pharmacology[236], rather than in psychiatry.

---

[236]Beecher, H.K., 'Ethics and Clinical Research', in Kuhse and Singer (2000), op. cit., p. 422.

4.7.3.6 - Problems with the role of the doctor as a researcher

Finally, involvement of doctors in clinical research, particularly psychiatric research, may also be problematic in that they may exercise their 'therapeutic zeal' and be prone to offer advice or to make clinical interpretations of the data with which they are presented[237], rather than simply collecting information. This is particularly the case in psychiatric research, as the tool used to elicit data for the research study is the same as the therapeutic tool (i.e., discussion, interaction with the patient, questioning, and interpretation).

In addition, research of the sort performed in psychiatry differs from other kinds of medical research in that there are fewer objective markers that can be utilised; thus, findings may be less objective, and more dependent on the interpretation of the clinician. This can complicate the role of the clinician in research because the boundary between treatment and research can become blurred; and the objectivity of research findings is much less marked than in many other kinds of research, as it is clinician interpretation which is fundamental in gathering research findings.

4.8 - Ways in which ethical research involving psychiatric patients may be brought about

It may be seen from the preceding sections that there are a number of factors that adversely affect the research process when it involves mentally ill individuals. However, given the importance of at least some kinds of research, it may be more appropriate to consider how the autonomy of mentally ill individuals might be optimised, in order to allow appropriate research, in a safe, controlled environment that is acceptable both to researcher and patient.

---

[237]Attkinsson, C.C., Rodenblatt, A., and Hoagwood, K., 'Research Ethics and Human Subjects Protection in Child Mental Health Services Research and Community Studies', in Hoagwood, K., Jensen, P.S., and Fisher, C.B. (eds) (1996), Ethical Issues in Mental Health Research With Children and Adolescents, Lawrence Erlbaum Associates, New Jersey, p. 51.

4.8.1 - Emphasising the capacities the psychiatric patient does possess

Firstly, it is important to focus not on what the mentally ill person *cannot* do, but what he or she *can* do. That is, it is important to develop an awareness of the factors that are related to autonomy, the way in which these factors manifest themselves behaviourally, and how to assess whether they are present in a give individual.

These factors include the factors I described in the preceding sections, namely: the ability to reason and communicate; one's sense of self; the extent of a support network; exogenous adverse circumstances, such as poverty and lack of family and friends; the degree of institutionalisation present in a given patient; the severity of his or her mental illness and the autonomy factors likely to be most affected by the symptoms associated with the condition; and the effectiveness of therapy.

4.8.2 - The necessity of avoiding imposing unreasonably strict criteria when assessing psychiatric patients with a view to involving them in research

It is important also to avoid the temptation to be unreasonably strict in one's assessment of the capacities of a mentally ill individual in considering them for research.

As discussed earlier, an awareness of the poor treatment historically of research subjects and of different minority groups (such as children, the elderly, and psychiatric patients) has led to an enhanced awareness of the risk of exploitation of these groups. This may give rise to a tendency to lean to the other extreme - that is, to limit unnecessarily the involvement of some individuals in research.

It is worth noting that the Nuremberg Code - which represents a turning point in the way in which research subjects and their rights were viewed - was formulated in response to the treatment of prisoners by the Nazis. The majority

of these individuals were 'competent but confined'[238] - that is, the fundamental, internal factors that contribute to autonomy, such as reason, were intact, but their ability to exercise their autonomy was restrained by external factors.

However, many potential research subjects, particularly in the current scientific climate, are not externally confined or restrained, but may have some 'internal' restraints on their autonomy, such as memory or reasoning problems, difficulty communicating, limited comprehension, or an inability to appreciate the possible consequences of their actions. Application of codes such as the Nuremberg Code to individuals such as these may be inappropriate, given the type of research subject for whom it was originally formulated, and the fact that it was probably not envisaged that the Code would be used for non-competent people[239]. Despite this, such codes have become fundamental to the notion of research.

4.8.3 - Modification of the research methodology to increase the acceptability for psychiatric research subjects

The actual methodology of the research project may need modification, however, when dealing with patients or individuals with compromised autonomy. For example, the way in which information is conveyed to the patient in gaining consent may need to be modified, perhaps with alternative, more suitable language being used, and by communicating information at times that suits the patient (for example, when least sedated by psychotropic medications, or when symptoms best controlled).

Psychiatric patients may also be distressed by things that are less a problem for normal people, and such things may need to be modified to make the research process more acceptable to them.

---

[238]Grodin, M.A., 'Historical Origins of the Nuremberg Code', in Annas and Grodin (1992), op. cit., p. 138.
[239]ibid, p. 139.

They may be more fearful of confined spaces (either due to their underlying illness, such as anxiety or claustrophobia, or through negative associations they have developed through their treatment, such as being restrained or confined). This may mean that imaging techniques - such as PET scanning[240] and MRI, which are fairly commonly used in psychiatric research - may be unacceptable to these individuals.

Similarly, such patients may be more fearful of receiving injections or psychotropic medications, due to their treatment in the past. Or they may resist even the interview process involved in research, as for them, communication such as that is comparable to their treatment, which may have negative connotations for them.

It is also important to have sufficient flexibility in the research structure to accommodate patients who are comparatively well and autonomous, such as those who are currently asymptomatic, or who have well-controlled symptoms, or illnesses that have less impact on autonomy, such as some milder forms of the neuroses.

4.9 - Conclusion

To summarise, I have discussed ways in which poor treatment of psychiatric patients in the past has led to a reluctance to involve them in research.

The autonomy of psychiatric patients may also be affected by: an assumption that all psychiatric patients have similar capabilities; stigma; communication difficulties; involuntary hospitalisation and treatment; and psychotropic medications.

Children and the elderly with mental illness have the problems of being mentally ill compounded by other, age-related factors and represent an especially vulnerable group.

---

[240]For example, see Hoagwood, Jensen and Fisher (1996), op. cit., p. 148.

The doctor-patient relationship may also be disrupted by abnormal communication, and by conflict of interest.

However, research remains important in psychiatric patients to decrease suffering and to increase their quality of life. Research can be made more acceptable by: recognising the factors outlined above; emphasising the capabilities the patient does have; and modifying the methodology of the project to increase acceptability for the patient and for ethical considerations.

CONCLUSION

In chapter 1, I discussed ethical concerns which relate to research in general.

A focus on such concerns relate to increasing public awareness of research and its implications, an increased awareness of the rights of the individual, an increased capacity for funding and intervention, the increasing role of clinicians in research, and historical precedent of poor treatment of research subjects in the past.

A central premise of ethical research is informed consent. The notion of consent raises a number of issues. These include: difficulties in establishing what constitutes informed consent; 'patient' and 'professional' standards of information disclosure; problems with communication and misunderstanding; and risk assessment.

Experimentation and research both raise issues. Experimentation, although more *ad hoc*, allows the possibility of flexibility to accommodate the needs of individuals. Research, though more directed and less risky, does not allow the same degree of flexibility as experimentation.

Research may be clinical or non-therapeutic. Clinical research may lead to problems because it involves clinicians, who may experience conflict of interest, and because it also tends to involve ill people, who may be prone to exploitation.

Non-therapeutic research also raises issues. These include problems with risk-benefit analysis, whether patient consent is sufficient to compensate for the risk involved, the problems with involving ill people in non-therapeutic research, and motivation to participate in research.

An awareness of these issues helps permit more ethical research practices.

In chapter 2, I discussed the ethical problems of performing research on children. It may be seen that research involving children is necessary, at least to a certain extent, in order to optimise their wellbeing and safety.

The role of parental consent is often pivotal in such research, and can be seen to derive from a historical backdrop on which children were viewed more as property of their parents, than individuals in their own right. Increasingly, however, a more moderate role for parents is being advocated, with increasing weight and responsibility being given to children.

Difficulties with parental consent may arise when it is seen as a substitute for the child's own judgement, or to be in the best interests of the child. Other problems include lack of parental understanding, difficulties in assessing the amount of information to give to parents, and risks to the child secondary to parental consent.

Arguments in favour of parental consent include providing a means for the child to access certain benefits, the development of pro-social traits in the child, and preservation of family relationships. It may also be difficult to find a good reason to override parents' wishes, if there is no particular harm done to a child through such a decision.

The autonomy of the child raises certain issues. Firstly, it is partly dependent on age, so older children may be fully autonomous. Evidence suggests that the majority of children and adolescents have good powers of reasoning and often make similar judgements to adults. This suggests that a continuum of capabilities should be reflected by a continuum of consent.

Adolescents represent a special case, as although they reason in ways similar to adults, they have some special concerns and values which are age-specific and which need to be borne in mind when assessing a teenager's capacity to consent. There are a number of reasons why it may be appropriate to accept adolescent choices, but these may need to be overridden to ensure the safety of the adolescent at times.

Psychological and social research may pose particular problems. The abundance of comparatively well children available for this kind of research may lead to undue risk-taking when involving them in research. The subjective element of assessment may affect outcomes and cause problems within family relationships. Longer studies such as these may have difficulties recruiting and retaining subjects. Such studies are often also essentially non-therapeutic, and may raise problems because children are exposed to risks for comparatively little benefit.

The role of the doctor in research on children raises a number of issues. These include the conflict between research obligations and the duty to care for one's patient. The relationship of the doctor and the parents may be affected, with feelings of mutual obligation. Parents may also pressure the doctor to allow them access to high-risk or alternative trial therapies, especially if the condition is life-threatening. Limited understanding on the part of the parents may also complicate the research process and the involvement of the doctor.

Understanding the issues relating to research involving children may help minimise problems and maximise the involvement and well-being of this subgroup of the population.

In chapter 3, I discussed research on the elderly, and some of the problems which may be encountered when performing research on such a group.

I showed that the autonomy of elderly people could be compromised in a number of ways. The first such factor is ambiguity in the terminology applied to elderly people, which often leads to all elderly people being grouped together and thought to have similar capabilities, when in fact this is not the case. Secondly, stereotypic perceptions also work against those elderly people who are competent. Thirdly, a range of factors - both internal and external - may also affect autonomy, including physical and cognitive impairment,

poverty, reliance on family for support, institutionalisation, and relationships with relatives. It is important to note, however, that there is a significant range of capabilities in this age group.

Despite these problems with autonomy and consent-giving, research in the elderly is important to maximise the health and well-being of the people in this age group, as they can have special problems which do not exist in other age groups.

The acceptability of research on this age group may be increased by: the benefit to the research subject individually, and the group as a whole; alteration of the research methodology to increase involvement of and acceptability for elderly people; the satisfaction derived; previously-expressed acceptance of research; economic benefit to the community and older people generally, through improvements in health and lifestyle; and the existence of many elderly people who are autonomous.

In chapter 4, I discussed to problems encountered when involving patients with mental illness in research.

It may be seen that past exploitation of psychiatric patients has led to a reluctance to involve them in research.

This is compounded by the fact that the autonomy of the mentally ill may be compromised in a number of ways. These include: the continuum that exists between 'normal' and 'abnormal'; stigmatisation of the mentally ill; communication difficulties and abnormal interpersonal relationships; and the effects of hospitalisation, involuntary treatment, and psychotropic medications.

Children and the elderly with mental illness face added problems because they have all the problems associated with mental illness, as well as age-related constraints on autonomy (discussed in chapters two and three).

The doctor-patient relationship may also be affected because there is abnormal interaction between the doctor and the patient, the psychiatric patient

may have difficulty comprehending the dual roles of the doctor in this context, and there exists conflict of interest for the doctor on a number of levels.

Despite these factors, however, research involving the mentally ill is important to optimise their treatment, and to improve their quality of life. Research in the psychiatric population may be made more acceptable by being aware of the factors operating in this kind of context, by emphasising the capacities that such patients do have, and by modifying the methodology to optimise consent and acceptability for the patient.

So it is to be hoped that an awareness of the kinds of factors which serve to diminish the autonomy in groups who have compromised autonomy, may help to develop an awareness of the factors operating in such individuals, and to allow us to develop more ethical ways of conducting research, so that groups such as children, the elderly, and the mentally ill, may benefit from research and lead happier and healthier existences.

BIBLIOGRAPHY

Avorn, J., 'Including elderly people in clinical trials', BMJ, 1997; 315: 1033.

Avorn, J. and Gurwitz, J.H., 'Principles of pharmacology', in Cassel, C.K., Cohen, G., and Larsen, E. (eds) (1997), Geriatric Medicine, Springer, New York.

Annas, G.J. and Grodin, M.A. (eds) (1992), The Nazi Doctors and the Nuremberg Code - Human Rights in Human Experimentation, Oxford University Press, New York and Oxford.

Beauchamp, T.L. and Childress, J.F. (1994), Principles of Biomedical Ethics, Oxford University Press, Oxford.

Bell, J.A., May, F.E., and Stewart, R.B., 'Clinical research in the elderly: ethical and methodological considerations', Drug Intell.Clin.Pharm., 1987; 21: 1002-1007.

Bjørn, E., Rossel, P., and Holm, S., 'Can the written information to patients be improved? - an empirical study', J.Med.Eth., 1999; 25: 263-267.

Bloch, S. and Chodoff, P. (eds) (1991), Psychiatric Ethics, Oxford University Press, Oxford.

British Medical Association (1984), The Handbook of Medical Ethics, BMA, London.

Bradley, P., 'Should childhood immunisation be compulsory?', J.Med.Eth., 1999; 25: 330-334.

Bugeja, G., Kumar, A., and Banerjee, A.K., 'Exclusion of elderly people from clinical research: a descriptive study of published reports', BMJ, 1997; 315: 1059.

Department of Health, Scottish Office Home and Health Department, Welsh Office, Department of Health and Social Services (Northern Ireland) (1992), Folic Acid and the Prevention of Neural Tube Defects, Health Publications Unit, Heywood, Lancashire.

Downie, R.S. and Randall, F., 'Parenting and the best interests of minors', The Journal of Medicine and Philosophy, 1997; 22: 219-231.

Ekman Ladd, R. and Forman, E.N., 'Adolescent decision-making: giving weight to age-specific values', Theoretical Medicine, 1995; 16: 333-345.

Forman, E.N. and Ekman Ladd, R. (1991), Ethical Dilemmas in Paediatrics - A Case Study Approach, Springer-Verlag, New York.

Greengross, S. *et al*, 'Aging: a subject that must be at the top of world agendas', BMJ, 1997; 315: 1029-30.

Grodin, M.A. and Glantz, L.H. (eds) (1994), Children as Research Subjects, Oxford University Press, New York and Oxford.

Harling, R., 'Organophosphate pesticides are being tested on students', BMJ, 15 August 1998; 317: 430.

Hope, T., 'Aging, research and families', J.Med.Eth., 1997; 23: 267-268.

Jackson, J., 'Unproven treatment in childhood oncology - how far should paediatricians co-operate?: Commentary', J.Med.Eth., 1994; 20: 77-79.

Kuhse, H. and Singer, P. (eds) (2000), Bioethics - An Anthology, Blackwell, Oxford.

Little, M., 'Research, ethics and conflicts of interest', J.Med.Eth., 1999; 25: 259-262.

Macready, N., 'US to encourage more black people to join research trials', BMJ, 1997; 314: 696.

Mannesse, C.K. *et al*, 'Adverse drug reactions in elderly patients as contributing factor for hospital admission: cross sectional study', BMJ, 1997; 315: 1057-8.

Mason, J.K. and McCall Smith, R.A. (1994), Law and Medical Ethics, Butterworths, London and Edinburgh.

Melzer, D., Ely, M., and Brayne, C., 'Cognitive impairment in elderly people: population-based estimate of the future in England, Scotland, and Wales', BMJ, 1997; 315: 462.

Olde Rikkert, M.G.M., van den Bercken, J.H.L., ten Have, H.A.M.J., and Hoefnagels, W.H.L., 'Experienced consent in geriatrics research: a new method to optimise the capacity to consent in frail elderly subjects', J.Med.Eth., 1997; 23: 271-276.

Randall, F. and Downie, R.S. (1999), Palliative Care Ethics, Oxford University Press, Oxford.

Rutter, T., 'Drugs must be tested for use in children', BMJ, 1997; 315: 445.

Spece, R.G., Shimm, D.S., and Buchanan, A.E. (1996), Conflicts of Interest in Clinical Practice and Research, Oxford University Press, New York and Oxford.

The MRC Vitamin Study Group, 'Prevention of neural tube defects: Results of the Medical Research Council Vitamin Study', Lancet, 1991; 238: 131-137.

The Royal College of Physicians of London (1990), Guidelines on the practice of ethics committees in medical research involving human subjects, RCP, London.

The Royal College of Physicians of London (1990), Research Involving Patients, RCP, London.

The Scottish Office - Home and Health Department, Local Research Ethics Committees, Scotland, Dd 0011213 C10 8/92 Ed(203704).

U.S. Food and Drug Administration, Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, pages 66631-66672 [FR Doc. 98-31902] OC 98142, Docket No. 97N-0165.

Warden, J., 'Loophole exposed in testing of child medicines', BMJ, 1997; 314: 698.

Weir, R.F. and Horton, J.R., 'Genetics, adolescents, and consent', Theoretical Medicine, 1995; 16: 347-373.

Weithorn, L. and Campbell, S.B., 'The competency of children and adolescents to make informed treatment decisions', Child Dev., 1982; 53: 1589-1598.

Williams, S.J. and Calnan, M. (1996), Modern Medicine - Lay perspectives and experiences, UCL Press, London.

Wilson, P.S., Fleming, D.M., and Donaldson, I., 'Prevalence of hearing loss among people aged 65 years and over: screening and hearing aid provision', British Journal of General Practice, 1993; 43: 406-409.

Yeoh, C., Kiely, E., and Davies, H., 'Unproven treatment in childhood oncology - how far should paediatricians co-operate?', J.Med.Eth., 1994; 20: 75-76.

Zinner, S.E., 'The Elusive Goal of Informed Consent by Adolescents', Theoretical Medicine, 1995; 16: 323-331.