

Medical Research and Incompetent Adults

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Introduction

The spectre of Nazi medical experimentation during the Second World War undoubtedly hangs over any discussion of medical research and incompetent adults.¹ The concentration camp experiments² denied the rights of people who would have been able to give or withhold consent but were, of course, not asked.³ The fears raised by the nature of these experiments has given rise to a real, understandable and genuine concern that research participants, particularly those who are vulnerable, may be abused through their participation. For example, Professors Kennedy and Grubb take the view that non-therapeutic research on incompetent adults is prohibited and go on to say that “given the history of Europe in the 1930s and 1940s which culminated in the Nuremberg Trials ... it is entirely understandable that some European countries would hold the view that an absolute prohibition was the only defensible [position].”⁴ The question that arises is whether prohibition is always the correct approach, or whether some forms of research should be permissible, recognising that strict protections will be necessary.⁵ We reflect upon the rigidity of the distinction between therapeutic and non-therapeutic research in the context of a research project that we undertook.

Medical research: general ethical position

6 See, e.g., the Nuremberg Judgment (that is the opinions of the judges at the end of the post-Second World War war crimes trials) which contains a set of ten principles to control medical experimentation (available in Kennedy & Grubb, *op. cit.*, n. 1, at pp. 1022-1024; hereafter Nuremberg Judgment). The relevant principle is 2, which states, “The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.”

7 Subsequent to the Nuremberg Trials, the World Medical Association considered medical research and issued the Declaration of Helsinki in 1964 (subsequently amended). The relevant principles of the Declaration are (from the introduction): “The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of

disease... Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.”

8 “Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects:” Declaration of Helsinki, introduction.

9 See also the discussion in relation to distributive justice, below at p. 63.

10 See n. 40, below.

Medical research that is scientifically, ethically and legally sound enhances the welfare of society and its members.⁶ It produces advances in medical knowledge and takes that knowledge to general application.⁷ Medical research with human participants is, therefore, desirable.⁸ It is also essential, as the alternatives to the human participant (such as laboratory and animal-subject research) are often limited in their scientific and practical value. Sometimes medical research that has used human participants has general application. However, this is not always the case, as the nature of the condition of a group of human beings may be sufficiently particular that research, in at least some areas, can only be valid if carried out with humans having that condition being the research participants. There will be some research that must be undertaken with persons who cannot give or withhold consent by the nature of the condition that produces the incompetence.⁹

The ethical position, medical research and incompetent adults

International medical ethical instruments draw a distinction between therapeutic and non-therapeutic medical research. It does not necessarily follow from the distinction between the two that non-therapeutic research should be prohibited. This distinction between therapeutic and non-therapeutic research has a long tradition. It did not form part of the Nuremberg Judgment, but the distinction was drawn by the World Medical Association in the Declaration of Helsinki. Its introduction states:

“In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.”

This basic premiss was developed in the principles enunciated by the WMA. Section II of the Declaration is concerned with clinical research and section III with non-clinical biomedical research. The distinction is also fundamental to the latest international consideration. In the European Convention on Human Rights and Biomedicine,¹⁰ the distinction is relevant to research on people not able to consent to it.¹¹ Article 17.1 lays down the principles where the research has “the potential to produce real and direct benefit to his or health”. Article 17.2, “exceptionally and under the protective conditions prescribed by law,” allows for some non-therapeutic research.¹²

Examining the European Convention on Human Rights and Biomedicine in more detail, it can be seen that it lays down, in Article 16, the following criteria for research where the adult is competent:

“Research on a person may only be undertaken if all the following conditions are met:

- i there is no alternative of comparable effectiveness to research on humans,
- ii the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,
- iii the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability,
- iv the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

11 The distinction is not drawn where the research participant is capable of consenting to it: *ibid.*, Article 16.

12 See below, p. 71.

- v the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.”

In Article 17, the Convention proceeds to consider the situation where the adult is not competent. Here it draws the distinction between therapeutic research, in paragraph 1, and non-therapeutic research, in paragraph 2:

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:
 - i the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;
 - ii the results of the research have potential to produce real and direct benefit to his or her health;
 - iii research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
 - iv the necessary authorisation provided for under Article 6 has been given specifically and in writing, and
 - v the person concerned does not object.
2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:
 - i the research has the aim of contributing, through significant improvement in the scientific understanding of the individual’s condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.
 - ii the research entails only minimal risk and minimal burden for the individual concerned.

There are at least two ethical arguments in support non-therapeutic research. Whilst there may be an ethical imperative on scientists to undertake medical research,¹³ this is not sufficient to impose a moral obligation on any given individual to participate as a subject in it. Distributive justice requires a fair distribution of both the burdens and the benefits of research.¹⁴ Obviously, it is important that nobody, regardless of their level of ability to engage in the distributive process, is unfairly burdened with being participants in research. Therefore, people without capacity to make such a decision should not be

13 The argument is based on the ethical principles of beneficence and non-maleficence, as considered by Gillon: Gillon, R., *Philosophical Medical Ethics* (1986), at Chapters 12 & 13.

14 Levine, R.J., *Ethics and Regulation of Clinical Research* (2nd ed., 1988), at pp. 17-18.

15 Roberts, L.W., “The ethical basis of psychiatric research: conceptual issues and empirical findings” (1998) 39 *Comprehensive Psychiatry* 99.

16 Of course, such research has to be carefully regulated, as is required, e.g., by the European Convention on Human Rights and Biomedicine, as identified in this paper.

17 Harris, J., “The ethics of clinical research with cognitively impaired subjects” (1997) 5 *Italian Journal of Neurological Science* 9.

18 Tomossy, G.F. and Weisstub, D.N., “The reform of adult guardianship laws: the case of non-therapeutic experimentation” (1997) 20 *International Journal of Law and Psychiatry* 113.

involved in research just because they are vulnerable and available. However, a complete prohibition on research with incompetent adults as participants, for the sake of the protection of their welfare, may represent an injustice in itself.¹⁵ Owing to the close link between their condition/illness and the impairment in decision-making, advancement in knowledge about people falling in these groups cannot be obtained by studying other groups of people whose members are more intellectually able. Scientifically sound research needs to include appropriate test populations. Allowing research only on individuals with capacity to consent will limit the generalisability of any consequent research outcomes. Research with incompetent adults as participants is necessary to ensure that, as a group, adults with intellectually incapacitating conditions are not deprived of the benefits of scientifically sound research, and, therefore, are not doubly disadvantaged by their mental disability.¹⁶

Secondly, it is argued that, if one wishes to gain the benefit of medical research, one has an obligation to offer oneself for participation. Otherwise, the person gaining the benefit of the research is a mere parasite on society, taking only the advantages and undertaking no risks. Professor John Harris has taken this argument further. He argues that, with regard to incompetent adults, the same moral argument applies. He wishes that the preferred position be that people should consent or not object to research, but makes it clear that “free-riding is not an attractive principle; nor is it a moral principle. We should not ... assume that those incompetent to consent would wish to be free-riders, nor that they be excluded from discharging an obligation of good citizenship which we all share.”¹⁷ This argument, we would suggest, is consistent with principles of normalisation and social inclusion. It challenges stereotypes that incompetent adults are a drain on society. Of course, such an argument will not be received well by all interested parties. Tomossy and Weisstub have warned of reliance on what they term “imagined altruistic motivations of mentally incompetent subjects.” They argue that the presumption of desire for altruistic action cannot be attributed to individuals who can neither conform or deny such a presumption.¹⁸ Of course, Harris’ argument is not that simple, and communitarian values inherent in being a human being are worthy of recognition.

19 See, e.g., Royal College of Psychiatrists, “Guidelines for research ethics committees on psychiatric research involving human subjects” (1990) 14 *Psychiatric Bulletin* 48.

20 Law Commission, *Mental Incapacity* (1995, Law Com 231), at para. 6.28.

21 *Ibid.*, para. 6.29.

22 See also, Kennedy & Grubb, *op. cit.*, n. 1, at p. 1054.

23 *Ibid.*

An ethical argument that we believe does not have a role to play is that identified as a moral fiction by Tomossy and Weisstub. It is the argument that research on incompetent adults is justified by their 'right' to participate in research.¹⁹ Potential participants do have rights, but they do not extend to this purported position. If there were to be a right to participate, this could imply a duty on researchers to engage a particular person in a research project. It is clear that such a duty does not exist. No one can demand to be a participant. He or she may be invited by a researcher, if the latter either identifies the other as a potential participant or the other responds to an invitation to participate. The potential participant has a freedom or liberty to participate, but not a right strictly so called.

The legal position, medical research and incompetent adults

In its impressive investigation of decision-making by adults, the Law Commission relied upon this distinction between therapeutic and non-therapeutic research procedures. "The former covers procedures which, whether or not there is also a research objective, are intended to benefit the individual participant."²⁰ "Non-therapeutic' research, on the other hand, does not claim to offer any direct or immediate benefit to the participant."²¹ Whilst such procedures may be ethically and scientifically sound, they are contrary to the law unless either the participant is competent and consents or the participant is not competent and the research procedure falls within the best interests criteria. So, it is possible for therapeutic medical research to be carried out on an incompetent adult, provided it falls within the best interests test in *Re F*.²² However, non-therapeutic research, it would appear, cannot be in the best interests of an incompetent adult. This conclusion is reached by the Law Commission, which points out that the "simple fact is that the researcher is making no claim to be acting in the best interests of that individual person and does not therefore come within the rules set out in *Re F*."²³ The same conclusion is also reached by the leading medical lawyers, Professors Kennedy and Grubb. In their book, *Medical Law: Text with Materials*, they state

"The first criterion that must be satisfied is that there is a real and justified need for research on *incompetent* adults, ie that the knowledge sought may not be discovered from research on competent consenting adults. This is only a particular illustration of the general legal principle that the law seeks to protect the vulnerable. Satisfying this criterion by no means implies that it is lawful thereafter to carry out non-therapeutic research. Indeed, it would appear that such research cannot lawfully be carried out. There is no one who, in law, can authorise it as a proxy. Even the court if it were to have a *parens patriae* power could not authorise such research since the power exists specifically for cases where 'some care should be thrown around [the ward]' (*Wellesley v Duke of Beaufort* (1827) 38 ER 236 at 243). Also, of course, the approach of the House of Lords in *Re F* would not assist since non-therapeutic research could not be said to be in the '*best interests*' of the incompetent adult. If, however, the law does permit any non-therapeutic research on an incompetent adult, the curious situation would arise that such research may be permissible in the case of children but not in the case of adults. This apparent anomaly could be explained by noticing that in the case of children the parent can act as the protector of the child's interests whereas no such person exists in the case of the adult. Whatever the legal position, it is undoubtedly the case that there has been a shift in thinking about the ethics of non-therapeutic research on the incompetent adult."

24 See below, at p. 66-67.

25 Kennedy & Grubb, *op. cit.*, n. 1, at p. 1067.

26 As for the European Community's Guidelines, see CPMP, *Guidelines on Good Clinical Practice for Trials on Medicinal Products in the European Community* (1991).

27 445 S.W. 2d 145 (1969) (*Kentucky Court of Appeals*), and see Gunn, M.J., "Treatment and Mental Handicap" (1987) 16 *Anglo-Am. L.R.* 242.

28 (1990) 4 *A.L.R. 5th* 1163.

29 *Ibid.*, at p. 1185.

30 *Ibid.*, at p. 1204.

There are proposals for reform of the law from the Law Commission,²⁴ but these do not alter the current legal position. Professors Kennedy & Grubb note the Law Commission's proposals and then state²⁵

"Notwithstanding the Law Commission's proposals it is important to notice the position adopted in the [European Community's Guidelines on Good Clinical Practice]. While paragraph 1.13 permits in limited circumstances *therapeutic* research on the incompetent if certain safeguards are observed, paragraph 1.14 provides:

1.14 Consent must always be given by the signature of the subject in a non-therapeutic study, ie where there is no direct clinical benefit to the subject.

It could not be clearer from this paragraph that the European Guidelines prohibit non-therapeutic research on incompetent adults. ... Many might regret the absolute nature of the prohibition. Given the history of Europe in the 1930s and 1940s which culminated in the Nuremberg Trials which we referred to at the outset, however, it is entirely understandable that some European countries would hold the view that an absolute prohibition was the only defensible one."²⁶

Of course, the ethical position is not, at a European level, the same as that from which Professors Kennedy and Grubb were operating, but their view is likely to be one held by others. In the short term, at least, the legal question is whether non-therapeutic research on an incompetent adult could be in that person's best interests. It is easy to see the argument why it is not, since the person gets no direct or personal benefit from the research. However, there is, implicit at least, in the European Convention on Human Rights and Biomedicine an argument that non-therapeutic treatment might be in the best interests of an incompetent adult. This presumes the possibility that a person's interests may include, e.g., providing assistance to others now or in the future.

The courts have not had to address the question of whether medical research with incompetent adults is lawful, but some guidance may be found in the following American cases. In *Strunk v Strunk*²⁷ it was held, by the Court of Appeals of Kentucky, that a court could authorise a kidney donation from an incompetent adult to his brother. Whilst the court endeavoured to apply a substituted judgement test, the reality is that, in the light of the lack of information about the value system or preferences of the proposed donor, a best interests test was used. It is an extension of what might normally be regarded as being in an incompetent adult's best interests to include his quality of life taking into account the essential support that his brother provided. In *Curran v Bosze*²⁸ the Supreme Court of Illinois explicitly recognised that, in a case where there is no knowledge or information as to "the incompetent person's intent," the substituted judgement test is impractical. Following *Strunk* (amongst other State court decisions), the Court held that "a parent or guardian may give consent on behalf of a minor daughter or son for the child to donate bone marrow to a sibling, only when to do would be in the minor's best interest."²⁹ It was then for the court to determine the circumstances in which such a donation might be authorised. It held that there are "three critical factors which are necessary to a determination that it will be in the best interests of a child to donate bone marrow to a sibling. First, the parent who consents on behalf of the child must be informed of the risks and benefits inherent in the bone marrow harvesting procedure to the child. Second, there must be emotional support available to the child from the person or persons who take care of the child.... Third, there must be an existing, close relationship between the donor and recipient."³⁰ The court considered what benefits might accrue to the donor child.

“The evidence clearly shows that there is no physical benefit to a donor child. If there is any benefit to a child who donates bone marrow to a sibling it will be a psychological benefit. According to the evidence, the psychological benefit is not simply one of personal, individual altruism in an abstract theoretical sense, although that may be a factor. The psychological benefit is grounded firmly in the fact that the donor and recipient are known to each other as family. Only where there is an existing relationship between a healthy child and his or her ill sister or brother may psychological benefits to the child from donating bone marrow to a sibling realistically be found to exist. The evidence establishes that it is the existing sibling relationship, as well as the potential for a continuing sibling relationship, which forms the context in which it may be determined that it will be in the best interests of the child to undergo a bone marrow harvesting procedure for a sibling.”³¹

On the evidence of this particular case, it was not in the best interests of either of the three and a half year old twins to donate bone marrow to their half-brother whom they hardly knew and with whom they did not have an existing family relationship. This contrasts with the factual outcome in *Strunk*, which arose because of the significant life-enriching benefit that the donor brother would gain from the continued contact with his ill brother.

Of course, it is a significant step further to say that involvement in a research project that is unlikely to provide personal benefit may also be in that incompetent adult’s best interests. However, it should not be regarded as impossible to contemplate cases where such a benefit might be identified, though we recognise that such an argument is not likely to gain much favour with many commentators. The importance of medical research for incompetent adults as well as competent adults and a realisation that not all relevant and important non-therapeutic research can be carried out on competent adults is the basis for arguing that some, restricted, non-therapeutic research can be permissible and therefore ought to be regarded as being in the best interests of the incompetent adult. For these reasons it may be likely to be the case that non-therapeutic research would normally not be regarded as in the best interests of the incompetent person, and so, we would argue in favour of the changes proposed by the Law Commission to allow such research in carefully circumscribed circumstances as they propose.

Kennedy has proposed an approach that may allow limited forms of non-therapeutic research to be undertaken with incompetent participants, namely that research would be legally permissible where it was “not against the [participant’s] interests.”³² Whilst this was argued strongly with regard to children, Kennedy recognised that it could only be put forward much more tentatively with regard to incompetent adults. Nevertheless, we support the argument.

The legal/ethical position: the future

Not all commentators will approve of the ethical permission thereby given for some forms of non-therapeutic research on incompetent adults. But, e.g., the Law Commission has made proposals which

33 *Mental Incapacity Bill*, clause 4(1) in *Law Commission*, *op. cit.*, n. 20 at p. 224.

34 *Ibid.*, at para. 6.31. *We would wish to see element (1) extended beyond the “incapacitating condition” for the reasons that we give below at p. 71.*

35 *Mental Incapacity Bill*, clause 11(3) in *Law Commission*, *op. cit.*, n. 20, at p. 228.

36 *Ibid.*

37 *Lord Chancellor’s Department*, *Making Decisions: The Government’s proposals for making decisions on behalf of mentally incapacitated adults* (1999, Cm 4465).

would make some non-therapeutic research legally permissible. The Law Commission's review was undertaken in a particularly principled fashion, which has resulted, largely, in a consensus about its general thrust and the majority of its proposals.

What the Law Commission proposed is that therapeutic procedures (including research) should fall within the general authority to provide care. Anything that falls within the general authority is something that it is lawful for another to do, "if it is in all the circumstances reasonable for it to be done by the person who does it."³³ This, it is submitted, introduces little change to the existing position. Significantly, the Law Commission recommends that "research which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent if (1) the research is into an incapacitating condition with which the participant is or may be affected and (2) certain statutory procedures are complied with."³⁴ The statutory procedures would include approval of the research by a Mental Incapacity Research Committee. The Committee would be able to approve any proposed non-therapeutic research if it was satisfied

"(a) that it is desirable in order to provided knowledge of the causes or treatment of, or of the care of persons affected by, mental disability;

(b) that its object cannot be effectively achieved without the participation of persons who are or may be without capacity to consent; and

(c) that it will not expose such a person participating in the research to more than negligible risk and that what is done in relation to such a person for the purposes of the research will not be unduly invasive or restrictive and will not unduly interfere with his freedom of action or privacy."³⁵

Further statutory procedures would be that the research would be lawful if one of the following requirements were to be satisfied:

"(a) the approval of the court;

(b) the consent given within the scope of his authority by the donee of a continuing power of attorney granted by the person concerned or by a manager appointed for him by the court;

(c) a certificate in writing by a registered medical practitioner not involved in the research that the person concerned is without capacity to consent and that his participation in the research is appropriate;

(d) the designation by the committee of the research as not involving direct contact with the person

38 This is a very simple procedure with negligible risks. Indeed it is one of those treatments recognised by the Medical Research Council as an example of a procedure involving negligible risk: Medical Research Council, *The Ethical Conduct of Research on the Mentally Incapacitated* (1991), at para. 6.3.3.

39 The team has published an overview paper of issues in relation to capacity and decision-making: Wong, J.G., Clare, I.C.H., Gunn, M.J. and Holland, A.J., "Capacity to make health care decisions: its importance in clinical practice" (1999) 29 *Psychological Medicine* 437; and a paper assessing the outcomes of our research from a legal perspective: Gunn, M.J., Wong, J.G., Clare, I.C.H. & Holland, A.J., "Decision-making capacity" (1999) 7 *Med. L. Rev.* 269. A detailed data paper is in press with *Psychological Medicine*.

40 This is required, e.g., by the European Convention on Human Rights and Biomedicine, Article 16.iii: Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine Convention on Human Rights and Biomedicine* (1997, ETS 164), available at www.coe.fr/eng/legaltxt/164e.htm

41 This satisfied, e.g., the European Convention on Human Rights and Biomedicine, Article 16.iii and the Declaration of Helsinki, Principle 1.2.

42 Whilst there are other protections (including assessment of risk, etc), the consent of the participant is the most important ethical principle, see, *European Convention on Human Rights and Biomedicine*, Articles 16.v & 5, and also *Nuremberg Judgment*, Principle 1; *Declaration of Helsinki*, Principle 9.

concerned.”³⁶

It seems to us that these proposals achieve a reasonable balance by providing significant protections for the vulnerable person without prohibiting what would be important medical research. Thus we welcome them. However, the Government has decided not to progress such proposals. In its recent White Paper, *Making Decisions*,³⁷ it is noticeable that there is no commitment to deal with research, although introducing most of the recommendations made by the Law Commission are adopted. We have presumed that this is for the perceived practical difficulty of getting new provisions with regard to research through Parliament rather than any view that they are unacceptable. Whilst understanding the view, and recognising that some Parliamentarians may struggle to understand the importance what the Law Commission proposes, we regret this decision.

43 Assuming that the law would require consent, which is discussed below in the text.

44 European Convention on Human Rights and Bioethics, Articles 16.v and 5.

45 E.g., if they were clearly becoming disturbed or distressed by involvement in the assessment procedure, it was terminated.

46 Whilst not legally valid, it is both common sense to involve carers interested in the welfare and interests of the potential research and it has an ethical value: European Convention on Human Rights and Biomedicine, Articles 17.iv and 6.3. The Law Commission, in its review of the law in relation to adults and decision-making, discovered that “some funding bodies and Ethics Committees stipulate for consent by a relative where the research participants cannot consent.

As a matter of law, such ‘consent’ is meaningless.” Law Commission, *op. cit.*, n.20, at para. 6.29.

47 Whilst one cannot always make presumptions from the ability to make one decision to the ability to make another decision, it would seem to follow that were someone unable to consent to venepuncture that they would also not be able to consent to participate in the research, though the matter would need to be assessed separately.

48 E.g., it would be good ethical practice to ensure that each patient consents to the oral taking of drugs. This may be signalled by the fact that the patient does take them. Legally there is unlikely to be an assault or battery or false imprisonment, so no interference demanding the consent of the patient. Ethically, it would be right to wish to ensure that the patient understands sufficiently what he or she is taking and why.

Our research project

We have undertaken a research project that has caused us to reflect on medical research and incompetent adults. We are interested in how a person's capacity to make health care decisions can be assessed and maximised. To that end, we sought, and received, funding support from the Nuffield Foundation. We had four groups of participants. Three of the groups consisted of people with particular mental health conditions that have often given rise to a concern about their decision-making capacity. These three groups consisted of people with a learning disability, people with dementia and people with chronic schizophrenia. The fourth group, the control group, would consist of people with no mental health problems. This could have been undertaken by way of an hypothetical or an actual treatment. There are research projects that work on the basis of hypothetical treatments or health care procedures, but our practical and research experience led us to believe that that research would have less validity than if an actual treatment or procedure were part of the research project for the participating individuals. We felt that the treatment or procedure would have to be a relatively minor one, and selected venepuncture, that is the taking of a blood test.³⁸ We were able to recruit sufficient research participants who were identified, on independent clinical grounds, as being in need of venepuncture. The procedure, therefore, was one that each of the research participants would be having (or not having) regardless of any impact that our research project might have. In other words each of the research participants was facing the real prospect of a blood test and had to make an actual decision. The outcomes of our research are not, for present purposes, relevant.³⁹ What is relevant is that we were clearly faced with the need to ensure that participation of the research participants was lawful and ethical. Ethical approval of our research programme was provided by the funding body itself and by the local research ethics committee.⁴⁰ Further, a multi-disciplinary and multi-agency body was appointed to act as an Advisory Board⁴¹ and this approved the approaches that we proposed to take.

Research participant involvement

Some of our intended research participants were capable of deciding whether to participate.⁴² It was gratifying to discover, at the end of the research, that we identified all the participants in the comparison group as being capable of deciding to have the blood test. The members of this group were also

49 [1990] 2 A.C. 1.

50 We did respect both the dignity and privacy of the research participants, as the Law Commission notes is relevant to research where an assault, battery or false imprisonment may be involved, but also where alternative methods of research are involved, as in the case of our research: Law Commission, *op. cit.*, n. 20, at para. 6.30.

51 See Kennedy, *op. cit.* n. 5, at para. 13.01..

52 If anyone was not interested in the procedures we adopted or was showing signs of distress, etc, the research was terminated.

53 The House of Lords would not regard it as false imprisonment to decide to prevent someone from leaving, even though currently no procedure has been used to detain a person at all: *R v Bournewood Community and Mental Health NHS Trust, ex parte L* [1998] 3 All E.R. 289 at p. 298. We believe this not to be the correct view of the law, and would rather take the view of Lord Steyn in the House (at 306) that this is false

imprisonment, which accords with that of the Court of Appeal as expressed by Lord Woolf M.R. [1998] 1 All E.R. 000; see Gunn, M.J., "De Facto Detention" (1996) 2 *Tizard Learning Disability Review* 11 and Smith, J.C., Smith and Hogan: *Criminal Law* (9th ed., 1999), at p. 436, n. 3.

54 The Law Commission accepts that "questions of dignity and privacy arise [where the non-invasive research is based on observations, photography or videoing of participants (sometimes covertly)] where the project is not designed to benefit the research participant:" Law Commission, *op. cit.*, n. 10, at para. 6.30. The manner in which our research was conducted respected the dignity and privacy of the participants. See also Kennedy, *op. cit.*, n. 5, at paras. 13.57-13.64.

55 Mental Incapacity Bill, clause 11(4)(d), and see above at p. 67.

56 As for ethical compliance, see below at p. 71.

57 See Gunn *et al*, *op. cit.*, n. 39, at pp. 286-8.

identified as being capable of deciding to participate in the research project, after having been given appropriate information.

58 *The European Convention on Human Rights and Biomedicine, Articles 16.iv & v and 5. Article 16 is reproduced above. Article 5 establishes the general rule in relation to consent: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as in its consequences and risks. The person concerned may freely withdraw consent at any time."*

59 *Thereby, Article 16. i-iv were also satisfied.*

60 *Article 16, i - iv, compliance with which is required by Article 17.1.i, have already been considered above.*

61 *Article 17.1.iii. Whilst each demand independent consideration, the likelihood is that participation in research would demand more of the participants, if only because of its more abstract nature.*

62 *Article 17.1.iv.*

63 *Article 17.1.v.*

64 *Article 17.2.ii.*

Of course, it was not the case that all our other intended research participants were capable of deciding to participate. We wished to have participants from the groups who might be capable or might not. If all participants had clearly sat one side of the line, the research would have had little value, as it is only in assessing decision-making criteria in the borderline cases that we can begin to assess the validity of an approach and procedure that the law mandates.

We endeavoured to obtain the consent of our intended participants, after giving them appropriate information about the research project in appropriate, simple language. If they were competent and did not give consent, they were not involved in the research. If they did consent initially, but subsequently withdrew their consent, that withdrawal was immediately respected. This satisfies both the legal requirements⁴³ and the ethical requirements.⁴⁴ Where the potential participant was not competent to decide upon participation, we respected whatever expressions of opinion he or she might make,⁴⁵ through verbal or non-verbal communication. We also took into account the views of the carer(s) (even though, legally, the consent of a proxy when the research participants are adults has no validity⁴⁶).

The dilemma for our research

It is here that we begin to see the dilemma that has caused us to share our thoughts in this paper. Not only were some of our research participants not capable of deciding to have a blood test (in some cases even after the implementation of intervention techniques intended to maximise decision-making capacity), but also they were not capable of agreeing to be research participants.⁴⁷ Should we have undertaken our research in the light of the preceding ethico-legal discussion?

Research of the type in which we were engaged is, we believe, critical in enabling service providers to offer appropriate care and treatment to people who are not capable of making their own decisions. Capacity to make decisions is the basis upon which the individual either determines what will happen to him or her. Otherwise that decision is made by someone else. Having an effective and appropriate means of determining someone's capacity to make decisions is, therefore, critical to respect for the principle of autonomy. Only if someone cannot make a decision is it possible for a decision to be made for them. This question of capacity determination arises prior to any health care intervention being initiated. The law requires the consent of the patient when an intervention involves contact or apprehended contact with the person of the patient (whereby it would be a battery or an assault) or to involve the detention of the person (whereby it would be false imprisonment). On ethical grounds, consent would be required even if no such contact or detention were to form part of the intervention.⁴⁸ The patient's competence to decide must be determined so that the health care provider knows whether he or she is dependent upon the consent of the person for the legality of the intervention. If not dependent on the consent of the person, the health provider must turn to the best interests test developed by the House of Lords in *Re F*.⁴⁹

Therefore, in so far as the lawfulness of our research might be concerned, first, we hold the view that it was not covered by the law under consideration.⁵⁰ Our research involved talking to the patient and performing neuropsychological tests. Strictly speaking, there was no direct physical contact as part of our research and, therefore, we were not engaged in an intervention that could have been regarded as an assault or a battery.⁵¹ Moreover, it did not expose the participants to more than negligible risk. The research team was not involved in identifying the need for anyone to have a blood test. Nor was it

involved in the carrying out of that blood test. It was a procedure which each of the research participants faced regardless of the research programme. Nor were we detaining people⁵² and so there was no false imprisonment. Indeed we would not have prevented anyone from leaving the presence of the researcher. Such an act, or intimation of it, would have indicated dissent, and that was sufficient for us to terminate the participant's involvement.⁵³ There was, therefore, no activity for which a defence of consent or acting in the best interests of an incompetent adult was needed.⁵⁴ One particular advantage of the Law Commission's proposals is that research, such as ours, would still fall within the remit of the new procedure, but the lack of direct contact would be a good reason, providing the other requirements were satisfied, for approval of the research by the Mental Incapacity Research Committee.⁵⁵

Secondly, and if we are wrong in law,⁵⁶ we argue that our research was therapeutic. The research either identified a participant as capable to make the decision or we used strategies that we anticipated would improve the individual's chances of becoming capable of making the decision.⁵⁷

Finally, if our research were thought to be sufficiently invasive to fall within the area of the law requiring consent and our research was not categorised as being therapeutic, we would argue, on principle, that some non-therapeutic research should be permissible within the existing law. Our argument centres on the point that the nature of this research is critical to a proper respect for the principle of autonomy.

We have taken the stance that our research is clearly lawful for a variety of reasons. We also take the view that it is ethically sustainable. First, some of the participants were competent and did consent to the research, having been provided with the depth of information demanded by the European Convention on Human Rights and Biomedicine.⁵⁸ Further, our research complied with the other imperatives established by Article 16 for the protection of persons undergoing biomedical research. Research on humans is essential in determining the reliability of approaches taken by clinicians to assessing research participant's competence. The risks associated with our research were definitely negligible as we were not engaged in any health care intervention. Our investigations of the abilities of the research participants were terminated where someone no longer wished to participate. The research project was approved by the local research ethics committee and we were advised by an independent, multidisciplinary and multi-agency body during the course of our research. The research participants were informed of their rights and were clearly informed that they could say no and could withdraw from the research at any time, and that declining or withdrawing participation would have no clinical impact.⁵⁹

We also had research participants who were not competent. Article 17 of the European Convention was satisfied.⁶⁰ Research of comparable effectiveness could not have been carried out only on individuals capable of giving consent. The whole point of the research was to determine how to assess capacity. Therefore, it was reasonable to presume, at the outset, that, if we had, as we expected, participants not capable of consenting to a blood test that they would not be capable of consenting to the research.⁶¹ We had authorisation from carers for participation.⁶² The participants did not object, and, if they did, the research was terminated.⁶³ The one problematic principle is the requirement in Article 17.1.ii that "the results of the research [must] have potential to produce real and direct benefit to his or her health." Our research was not likely to have any impact on the health of any of the research participants, unless a broad approach were to be taken to the concept to include the individual's capacity to consent. We

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1 See, for example: Lunacy Amendment Act 1889, section 12(2); Lunacy Act 1890, section 330(2); Mental Deficiency Act 1913, section 62; Mental Treatment Act 1930, section 16; *Pountney v Griffiths* [1975] 3 WLR 140, per Lord Edmund-Davies at pp 143-147

2 7 & 8 Eliz. 2, c. 72

believe that it would, putting at its lowest, be unfortunate if research of the type in which we were engaged, were to be regarded as unethical. We do not believe that such ethical instruments are intended to rule out our type of research. We suggest that non-invasive research, like ours, which is designed to address a key ethical and legal principle, competency, that lies at the heart of respect for autonomy, should be ethically valid.

Though we believe it not to be the case, if our research were regarded as non-therapeutic, it would be ethically valid under the European Convention on Human Rights and Biomedicine. The risks and burdens for the participants were minimal.⁶⁴ The Convention, in Article 17.2.i, requires that “the research has the aim of contributing, through significant improvement in the scientific understanding of the individual’s condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.” The problem is, again, that our research would have no effect on the participant’s disease or disorder. It might, however, be regarded as having an effect on his or her “condition”, provided a similarly broad approach is taken as to “health” in Article 16. Having greater understanding of the capacity assessment process and of maximisation of consent would certainly confer benefit upon any individual concerned or to other persons with similar difficulties.

Conclusion

There are understandable concerns about research and people with mental disabilities, especially people who may lack capacity to make decisions. However, to ensure that people with mental disabilities which impair capacity benefit from scientifically sound research, research with such people is sometimes required and may be ethically justified, provided certain strict safeguards are in place. At present, this is recognised both at law and in ethics, provided that it is therapeutic research which is undertaken. Where the research is non-therapeutic, there is a discrepancy between ethical codes, such as the European Convention, and the law. We believe that this discrepancy should be addressed by introduction of the relevant recommendations made by the Law Commission. We, therefore, regret (as stated above) their omission in the Government’s commitment to introduce proposals in relation to people incapable of making decisions.

In relation to our own research, we believe that research on decision-making capacity is important in examining how to assess capacity for decision-making and how to maximise that capacity. In so far as the research participants were competent to decide whether to participate, we complied with the law and the ethical requirements of the European Convention on Human Rights and Biomedicine. In so far as the research participants were not competent to decide whether to participate, we have argued that our research was both lawful and ethical, though there are issues that we have identified that might demand further consideration. In particular, we venture to suggest that the normal interpretation of the European Convention might be too limited since the only research that can be undertaken must address the health of the participant, which our research did not do. A more holistic approach ought to be adopted so as to enable improvement in the well-being and enhancement of life opportunities for people not able to make decisions for themselves.

3 *Pountney v Griffiths* [1975] 3 W.L.R. 140, at p 141

4 [1975] 2 W.L.R. 291

5 *Op cit.*, at p 144

6 *Ibid.*, at p 145

7 *Ibid.*