Research involving detained patients / Mental Health Act Commission.

MENTAL HEALTH ACT COMMISSION

Position Paper 1

RESEARCH INVOLVING DETAINED PATIENTS

issued January 1997

1. INTRODUCTION

1.1 The purpose of this paper is not to give legal advice, but to clarify and update the Commission's position and policy on research involving detained patients[1] and the capacity of such patients to give informed consent to participation in medical research. While this paper concentrates on the position of detained patients, it is recognised that research involving such patients may have commenced before they were detained, raising separate issues which are not addressed here. The Commission's policy seeks to incorporate and commend good practice. However, the Commission does not seek to endorse any particular procedure or to offer any formal advice on how to conduct clinical trials on detained patients.

1.2 The issue of involvement in research by detained patients is approached on the basis and understanding that each and every patient detained under the Mental Health Act 1983 (the 1983 Act) should receive the best and most appropriate medical treatment.

1.3 There is a fundamental difference between the position of the detained patient and of other members of the community. Patients who are not detained have the right not to receive treatment - they have a common law right not to be assaulted, or otherwise subjected to coercive and intrusive measures. On the other hand, the detained patient, on admission to hospital, loses the right not to receive treatment. Part IV of the 1983 Act creates a regime both for establishing the existence of consent to treatment and for allowing the requirement for consent to be overridden, so that treatment can be given without consent and contrary to the express wishes of the patient and his/her family.

2. DEFINITION OF RESEARCH

2.1 We take as our definition of "research" the following from the Shorter Oxford English Dictionary:

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1 The reference here to "detained patients" is to patients detained under any section of the Mental Health Act 1983, and includes patients "liable to be detained".

'An investigation directed to the discovery of some fact by careful study of the subject; a course of critical or scientific inquiry'".

2.2 We are here principally concerned with research related to the patient's mental condition, (including associated subject-matter), rather than research into treatment in relation to physical problems. Further, "research" can be broken down into 2 broad categories, based on the intention of the researcher:

i. research which is an integral part of, or consequent upon, medical treatment - so, in the case of a detained patient, this means treatment which has been prescribed and/or approved by the patient's RMO and falling within Part IV of the 1983 Act: (we propose to adopt the traditional distinction and terminology and refer to such research as "therapeutic research"); and

ii. research where the principal intention or motive is for information gathering purposes, whereby the patient is treated as no more than a source of that information (referred to as "non-therapeutic research").

2.3 Although these are generally accepted definitions (see, for example, Assessment of Mental Capacity - Guidance for Doctors and Lawyers, Chapter 11[2]), it is to be noted that strict categorisation can raise its own problems of inclusion and exclusion. We have included drug trials in our consideration of therapeutic research; however, double blind or placebo controlled trials may fall into either category depending on various factors such as:

- the stage of development of the use of the drug;
- the intention and motive of those using the drug;
- whether or not a placebo is being used.

2.4 It is not, of course, to be assumed that research on, or involving, a detained patient is harmful, non-beneficial, or even unethical.

3. *GENERAL CONSIDERATIONS*

3.1 The law relating to research (both therapeutic and non-therapeutic) concerning persons who are not detained patients is reasonably well settled. Research is monitored and regulated (although without the force of law) by local ethics committees. The lawfulness of research will depend on (1) consent by or on behalf of the patient and (2) whether or not research is consistent with the duty of care arising from the relationship of doctor and patient. There may well be other factors. Where the patient is not detained under the 1983 Act, but is

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2 Published in 1995 by the Law Society and the B.M.A..

incompetent to give informed or real consent, then the difficult questions of authorisation and approval for the proposed treatment or involvement in research arise[3]. It is neither necessary nor appropriate to consider in this document the position of non-detained patients (whether or not mentally incapacitated) in detail[4]. It has already been considered by the Law Commission[5], which recognising the distinction between "therapeutic" and "non-therapeutic" research, has said in relation to non-therapeutic research:

> "If, however, the participant lacks capacity to consent to his or her participation, and the procedure cannot be justified under the doctrine of necessity, then any person who touches or restrains that participant is committing an unlawful battery. 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 rule so set out in *Re F* [1990]. In some cases relatives are asked to "consent" to what is proposed, and do so. It appears that some funding bodies and ethics committees stipulate for consent by a relative where the research participant cannot consent. As a matter of law, such "consent" is meaningless. It appears that the question of the legality of non-therapeutic research procedures is regularly misunderstood or ignored by those who design, fund and approve the projects."

3.2 It is to be noted that, in relation to research involving pharmaceutical products, the European Commission Guidelines on Good Clinical Practice for Trials of Medicinal Products effectively restrict research on subjects incapable of giving personal consent to that which "promotes the welfare and interests of the subject"

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3 Such as considered by the House of Lords in In re F. (a mental patient - sterilisation) [1990] 2 AC 1.

4 Apart from Kennedy & Grubb, *Medical Law* (2nd Ed.), Chapter 14; see also, by way of examples only, Powers & Harris, *Medical Negligence* (2nd Ed.), paragraphs 12.66 to 12.68, and McHale "*Guidelines for Medical Research - Some Ethical and Legal Problems*" ((1993) Med.L.Rev. 160.

5 See Law Commission Report No. 231 on *Mental Incapacity* at paragraphs 6.28 and 6.29. See also *Assessment of Mental Capacity - Guidance for Doctors and Lawyers*, a report of the Law Society and the British Medical Association (December 1995) - paragraphs 11:3.2.2 and 11:4.2.

(i.e. therapeutic research).[6]

3.3 A detained patient occupies a different position and is admitted to hospital so that he/she can be treated; an important criterion for the compulsory admission of a patient to hospital is that such admission is necessary for his/her health - see, e.g. s.3(2)(c). Part IV of the 1983 Act makes no provision for consent to, or involvement in, research on a detained patient. The starting point for the interpretation of the 1983 Act must be that, as with all statutory restrictions on liberty, the presumption prevails that all freedoms or rights not taken away (either expressly, or by necessary implication) are preserved[7]. Therefore, although the 1983 Act does not deal with research, it is to be assumed that a detained patient is not prevented from taking part in research if:

- he/she has the capacity to consent and does consent,
- such involvement does not conflict with any provision of the 1983 Act, or any prohibition or restriction imposed by law, and
- such involvement is not otherwise inconsistent with the patient's status as a detained patient.

4. *THERAPEUTIC RESEARCH*

4.1 In relation to therapeutic research (but not involving ECT or the administration of medicine), the position under the 1983 Act for a detained patient (or more correctly, a patient "liable to be detained"), is that consent by the patient to such research is not necessary if:

- the research falls within the definition of "medical treatment given to him for the mental disorder from which he is suffering", and
- the treatment is "given by or under the direction of the responsible medical officer"

(see s.63 of the 1983 Act).

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6 It is acknowledged that this reference to an international obligation is selective and incomplete. A complete study of the subject of research, whether or not involving detained patients, would require reference to international and national obligations imposed or suggested by, for example, the Helsinki Declaration.

7 See, for example, Raymond v. Honey [1983]1 AC 1, and R. v. Halstrom, ex parte W. [1986] 2 All ER 306.

4.2 We have excluded ECT and the administration of medicine from the previous paragraph because of the effect of s.58 of the 1983 Act. S.58(1)(a), with regulation 16 of the Mental Health (Hospital, Guardianship and Consent to Treatment) Regulations 1983, and s.58(3) ensures that a patient will not receive ECT unless the patient has consented or the SOAD has approved the treatment, in the absence of consent, on the basis that the treatment will alleviate or prevent a deterioration of the patient's condition. S.58(1)(b) makes it clear that non-consensual involvement in research, which involves the administration of medicine, cannot extend beyond 3 months - after that period of time, the certified consent of the patient is required, or if consent is refused (or is not possible because of deficiencies of understanding), the approval of the SOAD.[8] (Further, the subject matter of s.57, namely any surgical operations for destroying brain tissue, and surgical implantation of hormones for the purposes of reducing male sex drive, requires actual consent, together with SOAD approval - save where s.62 emergency treatment applies.)

4.3 The possible problems in relation to research involving detained patients were raised by the Commission in its 6th Biennial Report, at paragraph 5.17 as follows:

> "The Commission has, as yet, made no formal statement on this matter. However, it does seem clear that even if, for example, a detained patient consents to take part in a randomised drug trial, the consent to treatment provisions still apply, which may cause some difficulty. For example, during the initial three months period of treatment whilst detained, the Code of Practice states (Para. 16.11) 'The patient's RMO must ensure that the patient's valid consent is sought prior to the administration of any medication, and (para. 16.13), Although the patient can be treated in the absence of consent in this period no such treatment should be given in the absence of an attempt to gain valid consent.' "

4.4 The problems arising from involvement in randomised drug trials can be illustrated by considering the position of two detained patients in the same hospital, who have been detained <u>for treatment</u> (for these purposes it is assumed that they would receive the <u>same</u> treatment) - one is given medication, the other

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[8] The above is of course subject to the exception of emergency treatment under s.62 - not relevant when considering research.

is given a placebo. If both patients are capable of giving real, informed consent and do so, perhaps the only concern is that the patient receiving the placebo, although in hospital for treatment, is not receiving treatment, thereby undermining the reason for his or her detention. Where, however, there is no consent (or no 'real', 'informed' consent) then there can be no justification for the use of the placebo. Further, it is difficult to see any justification for the use, in a trial or study involving detained patients, of a drug which is known to be ineffective. The involvement of a detained patient in a drug trial may also raise particular ethical considerations and questions. Is the trial really necessary? Will the patient benefit from involvement in the trial? Is the patient's involvement in the drug trial approved, in writing, by the patient's Responsible Medical Officer? Should an independent advocate be present when the consent of the patient is requested and obtained? Is the possibility of benefit to others of any significance - and if so, how is such possible benefit to be weighed in the context of a trial involving a detained patient? Could the trial be conducted without the involvement of detained patients? Has the trial been approved by the local research ethics committee? If these or similar questions are not considered, there is a real danger that the duties owed by the medical profession to the detained patient will be in conflict with the advancement of medical research. Of course, the research project should not be one in which the RMO or any other member of the clinical team has a direct pecuniary interest.

4.5 The Code of Practice does not impose any legal duty to comply with its provisions (see paragraph 1.1 of the Code), but it seeks to incorporate and apply best practice and should be followed. For legal responsibility, however, it is necessary to look to the 1983 Act and to Court decisions. As set out above, unless the research falls within s.63 (and s.58(3)(b)), a patient cannot be involved without his or her consent.

5. *NON-THERAPEUTIC RESEARCH*

5.1 In relation to non-therapeutic research, which does not involve any element of treatment, the position in law for the detained patient is the same as for other citizens; we have nothing to add to the views of the Law Commission set out above. Whether or not the involvement of detained patients, who lack capacity, in non-therapeutic research could be considered as ethical, the lawfulness of such involvement must be the paramount consideration.

6. *OTHER VIEWS*

6.1 The overall position in relation to treatment and detained patients has recently

been considered by the Ethical Committee (Research) of the Bethlem and Maudsley NHS Trust and Institute of Psychiatry, which has issued a statement[9] beginning as follows:

> "It is a fundamental principle that patients who are detained under the Mental Health Act 1983 have the same right as informal patients to enter research studies as long as they are capable of giving valid consent...."

6.2 If this proposition goes no further than to state that, as a general rule, detained patients should not be prejudiced when compared with informal patients or other members of the community we do not disagree; however, the elevation of involvement in research to a <u>right</u> goes too far.

6.3 The Statement includes the following suggested principle:

"A detained patient who (being capable) gives proper consent may take part in a research project/drug trial involving therapeutic research, subject to the safeguards given below;

1. No detained patient should take part in non-therapeutic research involving invasive procedures, whether or not they can give consent;

2. No detained patient should, by reason of participation in a research project, be deprived of appropriate and immediate treatment. "

7. CONCLUSION

7.1 It is difficult, and not always helpful, to state principles which are said to apply to all situations. Further, the Commission recognises that research techniques and standards will develop and change over time. However, we have sought to draw together various propositions of law and of good practice, which may assist in the consideration of the issues which could arise when research involving detained patients is suggested.

i. Research involving detained patients must be clearly identified and described as research, separate from routine or established forms of treatment.

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9 Dated December 1995, but subject to annual review.

ii. Such research should be clearly identified and described to show whether or not it is considered to be therapeutic or non-therapeutic.

iii. If a patient has capacity to consent to participation in research, and does in fact give actual and informed consent, then participation should not be prevented unless:

- involvement conflicts with any provision of the 1983 Act;
- involvement is inconsistent with treatment being received as a detained patient.

iv. If a detained patient does not have capacity to consent to participation in research, his or her involvement can only be justified if the research forms a part of that patient's treatment under the Mental Health Act.

v. Local research ethics committees should establish agreed protocols designed specifically for research which may involve detained patients.

7.2 We also recommend that the following topics should be addressed when protocols are drawn up:

i. the need for the involvement of detained patients in research at all, or in the particular study;

ii. the need for the approval, in writing, of the patient's RMO to the research;

iii. whether or not written consent from the patient should be obtained;

iv. the desirability of consultation with the patient's nearest relative - subject, always, to the consent of the patient;

v. the desirability of consultation with the patient's ASW and other members of the multi-disciplinary team;

vi. the need for a clear explanation (both oral and written) to the detained patient of the nature of the research, possible risks and potential benefits, details of the duration of the research and whether or not any information, personal to the patient, will be used (and if so how, and for what purpose);

vii. the need for the protection of patient's confidentiality.

7.3 Detained patients and user groups should be made aware of the protocols established by local research ethics committees and of any amendments or alterations.

7.4 Medical research is constantly changing - as such the Commission will keep its own position on research involving detained patients under close and regular review. The Commission would welcome comments on this paper, which will be subject to review within two years.

MENTAL HEALTH ACT COMMISSION POSITION PA

GENERAL INFORMATION

The Commission will from time to time publish Position Papers containing its views c issues drawn to its attention. The Commission also publishes Guidance Notes (formerly cal Notes) which give advice on matters not included in the Mental Health Act Code of P below for current list).

Any authoritative interpretation of the law can be given only by the courts. In the abse judicial decision, the Commission's view of any interpretation can at best only be informed o must not be treated as, or substituted for professional legal advice.

The Commission welcomes any comments on the contents of the Position Papers. They shou to:

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Please feel free to make your own copies of the Position Papers.

In order to maintain relevancy, Position Papers will be reviewed no later than two years follow date of issue.

COMMISSION PRACTICE AND GUIDANCE NOTES CURRENTLY AVAILABLE

PRACTICE NOTE 1	:	"Guidance on the administration of Clozapine and other treat requiring blood tests under the provision of Part IV of the M Health Act 1983"
PRACTICE NOTE 2	:	"Nurses; the administration of medicines for mental disorder an Mental Health Act"
PRACTICE NOTE 3	:	"Section 5(2) of the 1983 Mental Health Act and transfers"
PRACTICE NOTE 4	:	"Section 17 of the Mental Health Act"
PRACTICE NOTE 5	:	"Guidance on issues relating to the administration of the Me Health Act in nursing homes registered to receive detained patier
GUIDANCE NOTE 1	:	"Guidance to Health Authorities : The Mental Health Act 1983"
GUIDANCE NOTE 2	:	"GPs and the Mental Health Act"

OTHER RELEVANT PUBLICATIONS AVAILABLE

The Memorandum on the Mental Health Act is available from all HMSO stockists, priced £4.95.

The Revised Edition of the Mental Health Act 1983 Code of Practice was published on 27 Augu 1993. It is available from all HMSO stockists, priced £4.50.

The Mental Health Act Commission Sixth Biennial Report was published on 30 November 1995. is available from all HMSO stockists, priced £10.