Informed consent in psychiatric research

TEIFION DAVIES

Research is the life blood of a clinical discipline, and it is arguable that psychiatry's expanding empirical base has been an important factor in gaining equal status with the traditional medical disciplines. In common with research involving children and other vulnerable groups, psychiatry faces particular obstacles in establishing an ethical framework for informed consent that inspires confidence in patients who participate in research (Adshead, 1996; Doyal, 1997; Goodare & Lockwood, 1999). Despite existing guidelines (Medical Research Council, 1991; General Medical Council, 1999) there is a widespread perception among patients that research is not done for them but done to them for the benefit of the researchers (Mental Health Foundation, 2000; Smith, 2000). It is clear that for psychiatric research to continue to flourish we must create conditions under which patients wish to participate in research from which they might not benefit personally, and whose results are not predictable and might not be known for many years. What are these conditions and how should we promote them?

ETHICAL PRINCIPLES

Ethical conditions for psychiatric research derive from general moral principles of justice (Rawls, 1976) and respect for rights (Dworkin, 1992) and they are, therefore, qualitatively similar to those that apply to therapeutic treatment of patients (Davies, 1997; Doyal, 1997). It has been argued that because psychiatric patients might not benefit from research in which they participate, psychiatric research involves a separate set of ethical conditions from treatment (Adshead, 1996). This view cannot be sustained, since, taken to its limits, it implies a hazardous moral relativism in which circumstances rather than principles determine which ethical rules should be applied. The primary condition for ethical psychiatric research (as for treatment) is the duty to respect the patient's autonomy to exercise his or her rights as a moral agent (Dworkin, 1992). Specifically, a patient's right to grant or withhold consent to participate in research is infringed if he or she is denied the conditions necessary for its exercise: information (Osborn, 1999); trust (Davies, 1997); lack of coercion (Wing, 1999); and respect for previously stated wishes about future events ("advance directives"; British Medical Association, 1995).

For the individuals asked to participate in psychiatric research, information remains the keystone of informed consent (Osborn, 1999). A patient or participant has a right not to be denied such information as necessary to allow him or her to come to a reasoned decision, including information that does justice to the uncertainties inherent in medical and scientific knowledge (General Medical Council, 1999; Wing, 1999). A participant in a double-blind trial cannot be told precisely what treatment he or she will receive, but he or she ought to be told the chances of receiving each of the treatments, and their predicted benefits and adverse effects. Moreover, using appropriate 'decision aids' can assist the patient without increasing his or her anxieties (O'Connor *et al*, 1999). Where patients are invited to participate in non-therapeutic studies researchers have a duty to make clear the aims of the research and to ensure that participants are aware that they may not benefit personally (Medical Research Council, 1991; Doyal, 1997).

PARTNERSHIP IN RESEARCH

Information is a necessary, but not sufficient, condition for ethical research: the context of information-giving is also important (Charles *et al*, 2000). Patients cannot be expected to grant consent to researchers they cannot trust, and trust can only flourish where there is mutual respect (Davies, 1997): from a respect for the patient's autonomy arises a partnership between patient and researcher (Coulter, 1999). Increasingly, patients and their carers are asserting their desire for partnership in all stages of the research process, beginning with the choice of questions to be asked in research (Mental Health Foundation, 2000). Formulating research questions from the views of patients themselves (termed "experts by experience" by the Mental Health Foundation), involving patients in the design and monitoring of ongoing projects, and sharing results of research are important steps in regaining the trust of those invited to participate in research. National organisations such as the Medical Research Council are already formalising this process by setting up consumer liaison groups to advise on their activities, and it is likely that in future clinical researchers will be required to demonstrate that their research proposals have the backing of patients.

Partnership in research is a necessity if ethical research is not to wither away for lack of willing participants. The process of influencing hearts and minds should work in both directions: researchers, patients and carers must find ways of engaging with each other to share their ideas and facilitate the progress of the research they support. Researchers can facilitate the process by promoting discussions with patient groups, and by placing high-quality, unbiased information on mental disorders on the internet. Patients may agree to join monitoring committees, to be included in case registers, or to carry donor cards specifying the conditions under which they would or would not participate in research. The test of whether this partnership works will be that patients should want to participate in research, from self-interest or altruism, as an expression of their personal autonomy (cf. Titmuss, 1973; Rawls, 1976).

OVERCOMING DIFFICULTIES IN PSYCHIATRIC RESEARCH

Research with some groups of psychiatric patients poses additional problems that must be overcome if these patients are not to be disenfranchised therapeutic orphans (Adshead, 1996; Wing, 1999). For at least some of the time some patients will lack the capacity to grant informed consent (Osborn, 1999). Grounds have been proposed for

https://doi.org/10.1192/bjp.178.5.397 Published online by Cambridge University Press

waiving the requirements of informed consent in these circumstances (Doyal, 1997), including: minimising risks, ensuring no other participants are appropriate, and gaining the assent of carers. Since psychiatric diagnosis *per se* may not limit capacity to grant consent, where incapacity is a foreseen consequence of mental illness patients might be invited to consider giving an advance directive of consent to participate in research.

Other patients – for instance, those with personality disorders or relapsing psychotic disorders – might lack the sustained sense of cooperation to comply with a research protocol. However, these are exactly the problems that psychiatrists have to deal with on a day-to-day basis in their clinical practice. They should seize the challenge of using their interpersonal skills to engage these patients (and their advocates and carers) in the research process. For patients with severe personality disorders the strength of the treatment alliance with the therapist is an important variable in maintaining adherence (Bateman & Fonagy, 2000), whereas patients with psychotic disorders might respond to assertive outreach involving their keyworkers or other members of the multi-disciplinary team. Again, the groundwork involves fostering partnership with keyworkers, carers, advocates, patients' groups and, wherever possible, the patients themselves (Osborn, 1999).

MONITORING THE RESEARCH PROCESS

Who will monitor the process, and what will be the penalties for non-adherence? Research ethics committees and peer review (with all their faults; Smith, 2000) are likely to remain important components of the monitoring system, but they must be more proactive in fostering partnership. Patients should be involved not only in formulating the questions but also in setting standards, reviewing research proposals, and scrutinising papers submitted for publication. "It is unethical to carry out bad scientific experiments" (Altman, 1991), and professional and regulatory bodies have an important role in promoting trust by dealing transparently with the perpetrators of unethical research. Finally, and ominously, statute law is making inroads into the researchers' domain. In Britain, the Human Rights Act 1998 came into operation on 2 October 2000: this gives legal force to the articles of the European Convention on Human Rights first ratified in 1951 (Hewson, 2000). Article 3 prohibits "degrading and inhuman treatments" including those causing mental distress, and Article 8 sets out the "right to respect for private life". The courts are set to test compliance with the Act in many areas of mental health including research, and patients who feel that their rights have been infringed by researchers will have recourse to a powerful legal remedy.

Psychiatric patients ought not to be denied effective treatments either now or in the future, and this imposes a duty on society in general, and clinicians in particular, to perform medical research that is methodologically sound, participatory, and geared to the expected needs of patients. The challenge for researchers, patient groups and national bodies is to find the means of ensuring that research really is "good for everybody, including participants" (Smith, 2000). Psychiatrists should meet this challenge not because of political correctness nor even because of threat of legal sanctions, but because it is right to do so.

TEIFION DAVIES, MRCPsych, Division of Psychological Medicine, Guy's, King's & St Thomas' School of Medicine, Adamson Centre for Mental Health, St Thomas' Hospital, London SE1 7EH. Tel: 020 7928 9292 ext. 3771; Fax: 020 7633 0061; e-mail: teifion.davies@kcl.ac.uk

(First received 23 May 2000, final revision 6 October 2000, accepted 12 October 2000)

REFERENCES

Adshead, G. (1996) Ethics in psychiatric research and practice. *Current Opinion in Psychiatry*, **9**, 348–351.

Altman, D. (1991) Misuse of statistics is unethical. In *Statistics in Practice* (eds S. M. Gore & D. G. Altman), p. 1. London: British Medical Association.

Bateman, A. W. & Fonagy, P. (2000) Effectiveness of psychotherapeutic treatment of personality disorder. *British Journal of Psychiatry*, **177**, 138–143.

British Medical Association (1995) *Advance Statements About Medical Treatment*. London: BMJ Publishing.

Charles, C., Gafni, A. & Whelan, T. (2000) How to improve communication between doctors and patients. *British Medical Journal*, **320**, 1220–1221.

Coulter, A. (1999) Paternalism or partnership? *British Medical Journal*, **319**, 719–720.

Davies, T. (1997) Consent to treatment. Trust matters as much as information. *Psychiatric Bulletin*, **21**, 200–201.

Doyal, L. (1997) Journals should not publish research to which patients have not given fully informed consent – with three exceptions. *British Medical Journal*, **314**, 1107–1111.

Dworkin, R. (1992) Rights as trumps. In *Theories of Rights* (ed. J. Waldron), pp. 153–167. Oxford: Oxford University Press.

General Medical Council (1999) *Seeking Patients' Consent: The Ethical Considerations*. London: GMC.

Goodare, H. & Lockwood, S. (1999) Involving patients in clinical research. *British Medical Journal*, **319**, 724–725.

Hewson, B. (2000) Why the human rights act matters to doctors. *British Medical Journal*, **321**, 780–781.

Medical Research Council (1991) *The Ethical Conduct of Research on the Mentally Incapacitated*. Report of the Working Party on Research on the Mentally Incapacitated. MRC Ethics Series. London: MRC.

Mental Health Foundation (2000) *Strategies for Living*. London: MHF.

O'Connor, A. M., Rostom, A., Fiset, V., et *al* (1999) Decision aids for patients facing health treatment or screening decisions: systematic review. *British Medical Journal*, **319**, 731–734.

Osborn, D. P. J. (1999) Research and ethics: leaving exclusion behind. *Current Opinion in Psychiatry*, **12**, 601–604.

Rawls, J. (1976) *A Theory of Justice*. London: Oxford University Press.

Smith, R. (2000) Babies and consent: yet another NHS scandal. *British Medical Journal*, **320**, 1285–1286.

Titmuss, R. M. (1973) *The Gift Relationship. From Human Blood to Social Policy*, p. 272. Harmondsworth: Penguin.

Wing, J. (1999) Ethics and psychiatric research. In *Psychiatric Ethics*, 3rd edn (eds S. Bloch, P. Chodoff & S. A. Green), pp. 461–477. Oxford: Oxford University Press.

https://doi.org/10.1192/bjp.178.5.397 Published online by Cambridge University Press