Psychiatric ethics and research

Annie Bartlett

Formal teaching in ethics is neglected in psychiatric training. This paper takes a practical approach in outlining ethical issues relevant to different stages of a research project. It is suggested that whatever the scale of the research, it is important to examine the ethical issues which surround the development of a project, as well as those which are integral to the protocol.

Brecht argued that Galileo served science but in the end failed society (Brecht, 1977). Science and society need not to be odds; even so, Brecht's point may be extended to psychiatric research. To argue, as some authors do, that "All research is inherently ethical unless it can be shown to be flawed" (Gunn & Taylor, 1993) ignores an ethical duty to respect other ethical interests apart from the pursuit of scientific knowledge. This paper outlines some of the other ethical interests relevant to psychiatric research projects. There may be no easy solution to ethical dilemmas, but discussion may improve the quality of ethical reasoning and the solutions reached.

Why do people want to know what?

Research questions do not exist in a social vacuum. Different vested interests behind psychiatric research projects will inform the issues being researched, the design of the protocol and the publication of results. The motivation of researchers, funding bodies and potential readers influences the moral value of the research.

To illustrate why this is important, consider two common research issues: first, the introduction of new neuroleptic medication and second, the assessment of community care. Drug trials of new medication often have substantial financial backing from pharmaceutical firms whose primary motivation is commercial. In the absence of other readily available research funding, this can skew the research market (Bartlett & Drummond, 1992). Evaluation of community care is driven by a medico-political agenda, consequent on both deinstitutionalisation and the restructuring of the Welfare State (Clark *et al*, 1994).

What constitutes 'scientific' benefit in these instances is affected by the vested interests involved, and the theoretical 'mind-set' of the researchers. These are often open to argument and debate. 'Pure research', where it is asserted that the research questions are presented as apparently neutral lines of inquiry, may be a rhetorical strategy which evades ethical debate by reframing ethical issues as matters of 'science'.

Another vested interest is the possible benefit to the researcher personally. This may be related to career structures in medicine which emphasise publication of research, sometimes at the expense of clinical skill development. The quality of such research, on either ethical or scientific grounds may be suspect. Vested interests may provide justifications for the research process to funding bodies, to the researchers themselves or to the institutions in which research occurs, or both.

Such rationales constitute what might be described as conscious motivation and take no account of what might be termed the unpredictability of knowledge. To return to Brecht, out of atomic fission came atomic bombs; that which is known cannot then be unknown. Attention needs to be paid early in research to the possible use of research knowledge by others, which may be contrary to the wishes of the researchers. For example, a new drug can be 'hyped' by a pharmaceutical firm despite early signs that it has major adverse side effects. Such a drug might be belatedly withdrawn from sale but only after a number of adverse reactions.

What is the effect of the research on the subjects?

If a research protocol were to be subject to an ethical cost–benefit analysis, one component should be the likely effects on the subjects of research. It is helpful to think of this in terms of immediate and long-term effects, both positive and negative. Not all of these can be

Psychiatric Bulletin (1995), **19**, 670–672

anticipated. The most important question for the would-be researcher is whether there could be any immediate negative consequences for the research population from the application of the research process. For example, asking questions about child abuse may be so distressing to subjects as to render any plans to do so purely for the purposes of research ethically unacceptable. In this context, it may be helpful to consider the common distinction drawn between research which is therapeutic, and that which is non-therapeutic. Different kinds of negative effect need to be considered, both qualitative and quantitative, especially in relation to psychiatry where psychological harm may be harder to detect than physical.

If there are likely negative effects, these must be weighed against any therapeutic benefit to the patient, the population or some other group of patients. This applies to both short-term and long-term negative effects. A further question then arises as to whether and how the interests of future patients could outweigh the claims of current patients who are research subjects. In addition, it is not clear who should decide such questions: researchers, ethical committees or patient representatives.

This paper argues that when undertaking any piece of psychiatric research, the first ethical duty must be to attempt to avoid harm. This applies as much to a single case study as to large scale psychiatric epidemiology. This duty is independent of the status of the researcher. Furthermore, this duty would apply to all forms of research (including that under the guise of audit), even if free of the technical hurdle of the local ethics committee.

Issues of consent

For consent to research to be valid, it must be freely given and cover a number of terms. These terms of consent should include:

- an outline of the nature of the project
- its likely future use
- its possible effects on the subject
- discussion of the confidentiality of the research information derived from the subject.

These issues need to be addressed because, in most cases of research, the subject is doing the researcher a favour. Tobias & Souhami (1993) have recently drawn attention to the thorny question of whether or not the subjects of clinical research trials are given so much information about the possible disadvantages of participating that they are in fact deterred from taking part. This may, they argue, disadvantage both the subjects of the study and future generations of patients. The ethical principle of the right to know in this case is balanced against the possible harm to patients because of their incapacity to understand; and also the loss of potential benefits to future patients. Tobias & Souhami argue cogently that there is a sensible limit to the amount of information that the researcher is required to give, but they fail to discuss the need for ethical guidelines to protect the subject from unscrupulous researchers who may fail to provide relevant information if not required to do so.

Any consideration of consent needs to include an understanding of the circumstance or context in which consent is obtained. This is especially relevant to psychiatric populations, where the context in which consent is given is rather different from general medicine. In psychiatry, patients' autonomy and their competence to consent may be reduced not only by their illness, but by external institutional factors. Detained psychiatric patients, in particular, are potentially vulnerable to research abuse, by virtue of their *de facto* lack of autonomy. Critical to the discussion of informed consent in this case is an understanding of the social reality of the detained patient. A person's decision to participate in research may be affected if they believe it to be relevant to a clinician's decision about their detention. Therefore, the coincidence of responsible medical officer and researcher is to be avoided. The separation of research and clinical care needs to be explained – and believed.

Consent given may hinge on confidentiality offered. The general application of the principle of confidentiality between researcher and subject requires discussion before consent is given. Researchers need to address the different levels of identification and therefore the degree to which they promise confidentiality. Clearly, confidentiality in single case studies is very different from that in large scale epidemiological research (Wilkinson *et al*, 1995). Furthermore, certain aspects of an individual's history are undoubtedly more sensitive than others. Decisions about the limits of confidentiality need to be considered by the researchers and set against what can be usefully reported

https://doi.org/10.1192/pb.19.11.670 Published online by Cambridge University Press

with the general good in mind. Where confidentiality and the dissemination of clinically vital information confided in the researcher conflict, the research protocol must incorporate guidelines for the resolution of such situations, and for what is said to the patient. Examples common in psychiatric care relate to situations where research reveals the previously undetected risk of self-harm or risk to others.

Institutional consent has seldom been discussed. Researchers may need to consider at the start of the project the possibility that their research findings might embarrass the host institution (who may coincidentally be their employer). They may find themselves in a situation where the wish of the institution conflicts with the needs of the research population. The introduction of new style contracts of employment, such as those designed by hospital Trusts, with 'gagging' clauses may make the situation more likely in the future (Lennane, 1993).

Who will publish and to whom?

The results of many psychiatric studies are innocuous. However, some research findings may be less so. For example, in the early days of AIDS research, a number of interest groups asserted their right to know the results of research. Interested parties may include the research subject, patient populations, the general public, the profession and the institution (Smith & Goodare, 1995). It might not have been anticipated that the general public might need to know the outcome of a particular study but the prevention of future harm might render it necessary to publicise the results widely.

This raises the issue of validity of scientific findings, and the ethical requirement to carry out the best 'science' possible. For example, the claims of a patient group to know the results of a new drug trial may need to be weighed against the pilot status of the research. Decisions are sometimes rendered more complex where the funding body for the research project has a financial interest in a particular research outcome. Conflicts of interest about publication may use ethical argument but may well not be resolved on ethical grounds. Pragmatism, or the desire to live to research another day may prevail.

Conclusion

This paper has touched on only some of the ethical issues raised in psychiatric research. It is sometimes uncomfortable for researchers to consider that not all scientific questions or research methods are morally neutral or even desirable. The same intellectual rigour which is demanded of a scientific research protocol is required of the ethical justifications for that research. Reputable scientists could hardly claim otherwise.

References

BARTLETT, A. & DRUMMOND, L. (1992) The problem with registrar research. *Psychiatric Bulletin* **16**, 361–362.

BRECHT, B. (1977) *The Life of Galileo*. London: Eyre Methuen.

CLARKE, J., COCHRANE, A. & MCLAUGHLIN, E. (1994) *Managing Social Policy*. London: Sage.

GUNN, J. & TAYLOR, P. (1993) *Forensic Psychiatry: Clinical, Legal and Ethical Issues*. London: Butterworth Heinemann.

LENNANE, K. J. (1993) "Whistle Blowing": a health issue. *British Medical Journal*, **307**, 667–670.

SMITH, R. & GOODARE, H. (1995) The rights of patients in research. *British Medical Journal*, **310**, 1277–1278.

TOBIAS, J. & SOUHAMI, R. (1993) Fully informed consent can be needlessly cruel. *British Medical Journal*, **307**, 1199–1201.

WILKINSON, G., FAHY, T., RUSSELL, G., *et al* (1995) Case reports and confidentiality opinion is sought – medical and legal. *British Journal of Psychiatry*, **166**, 555–559.

A. Bartlett, *Senior Lecturer and Honorary Consultant in Forensic Psychiatry, St George's Hospital Medical School, Department of Mental Health Sciences, Jenner Wing, Cranmer Terrace, London SW17 0RE*

https://doi.org/10.1192/pb.19.11.670 Published online by Cambridge University Press