Issues concerning informed consent for medical research among non-westernized ethnic minority patients in the UK

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The ethics governing research are evolving rapidly, and we need to be sure that the principles of good practice are applied in all social groups. When research involves people from ethnic minorities, a major but neglected issue is the validity of consent. Informed consent, a legal concept developed over the years in Western Europe and North America, demands much more than a signed document. It is a process of communication in which the underlying ethical concepts, especially that of respect for autonomy, are not shared by all cultures. Here is what the Helsinki Declaration, in its 2000 version, says about informed consent:

‘In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflict of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the research and the potential discomforts it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw at any time without reprisal’.¹

Essentially informed consent consists of three steps. First, the research team provides full and transparent information about the nature of the project and the rights of the participant. Second, the participant must understand what is being asked and be competent to decide. Third, the person must decide freely whether or not to contribute. Because each element of this process may conflict with cultural values, research in certain UK minority groups has been problematic. In this paper we address the dilemmas of conducting research among individuals who, sometimes despite many years of living in the UK, adhere to their original religious and cultural values. Our own research experience has centred on elderly Bangladeshis in the UK, many of whom are illiterate.² We acknowledge, however, that a large proportion of individuals from ethnic minority

groups in the UK are well educated and in tune with the Western way of life.

OBSTACLES TO INFORMED CONSENT

Comprehension and capacity

Although language is an issue in securing informed consent,³ obstacles to comprehension go beyond the obvious linguistic barriers. The use of an interpreter may help, but different concepts of illness and issues of translation and cultural bias on the interpreter's part can compromise the extent to which information is understood.

In some cultural groups there may be little or no understanding of biomedicine, and researchers lacking knowledge of traditional belief systems may be wrong to conclude that the individual lacks capacity.

Literacy

Members of certain British ethnic minority groups—for example, elderly Bangladeshis from Sylhet—are unable to read or write even in their own language. Moreover, in societies where verbal communication is heavily relied upon, written contracts may be mistrusted or not upheld. To ask for a signature may thus cause offence. Illiteracy does not signify an inability to comprehend complex information; but it does mean the information must be presented in a special way. Consent in research can be seen not as a ‘one-off’ event but as a continuing process of negotiation between researcher and informant.⁴ This implies a long-term relationship of trust.

Autonomy

The notion of autonomy varies considerably between cultural groups. In contrast to the emphasis on personal choice seen in the USA and Europe, communal and hierarchical patterns of decision-making may take precedence. Family members will often take medical decisions on behalf of a relative; in India, patients place much trust in their family. The sense of wellbeing depends less on a feeling of personal control.⁵ Thus, the Western idea of respect for the individual may conflict with traditions that define persons by their relations to others.⁶ In the doctor–patient relationship elements such as loyalty, integrity,

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solidarity and compassion may be considered more important than autonomy.⁷

Disclosure

When a life-threatening condition such as cancer is diagnosed, the custom in many parts of the world is to tell the relatives rather than the patient. This is generally true of South Asian cultures. Among such groups, the disclosure of negative information is considered potentially harmful,⁸ and health professionals will sometimes collude with the family to prevent the patient discovering the diagnosis.⁹

Familiarity with research methodology

Groups living in isolation from mainstream culture may have little grasp of scientific method; and without such understanding a consent form will make little sense.

Although this may be partly a cultural issue, lack of education is an important determinant. Indeed, Hussain-Gambles *et al.*¹⁰ judged that South Asians (Indian, Pakistani, Bangladeshi) differed little from the general population in their attitudes to participation in clinical trials:

‘...poor understanding of science and increasing commercialisation of clinical trials means that the general population is just as likely as ethnic minority people to be mistrustful of medical research. Empirical evidence also illustrates more similarities than differences in attitude towards clinical trial participation between South Asian lay and the general population. There was little evidence of antipathy to the concept of clinical trials amongst South Asian lay people and awareness of trials appears to be a high correlate of social class, education and youth. ... The presence of diverse attitudes amongst South Asian respondents also suggests that the relevance of ethnicity and culture needs to be kept in perspective’.

Aspects of the process that researchers may find especially difficult to explain are randomization, risks, side-effects, and voluntary participation.¹¹

Power relationships

A difficulty with informed consent in any context, and especially when the researcher is ‘white’ and the potential subject is from an ethnic minority group, is the unequal power relationship and the patient’s feeling of obligation to the doctor. The researcher may be seen as an authority figure and the patient may worry that failure to comply will have serious consequences such as possible deportation. Such asymmetry in knowledge and authority, when extreme, must raise doubts about the validity of consent.¹²

CASE STUDY

Mr Abdul (a pseudonym) is a farmer from Bangladesh, age 55, who immigrated to the UK not long ago. Three months before arriving he was diagnosed as having Dukes grade C bowel cancer and he is a candidate for inclusion in a drug trial. The patient does not speak English, has little formal education and is illiterate. He now lives with his wife and two sons. In Bangladesh he was not told of his diagnosis or prognosis. Although he has now received a full explanation of the benefits and risks of the investigational drug (translated through his son) he does not appear to understand the details. During the consultation his son, who is fluent in English, says ‘Can I sign the consent form for him’? He points out, ‘at home it is the family who make decisions about health’.

Can Mr Abdul give informed consent, when the process is so alien to the way he and his family normally make healthcare decisions? One obvious response is to say no, and exclude him from the trial; another is to make strong efforts to increase his comprehension of the research project, to the point where he can propose a decision-making process that suits him. Exclusion of ethnic minority patients from clinical trials is highly undesirable because the findings will then be based on unrepresentative populations. Also it undermines efforts to reduce inequalities.¹³

Mr Abdul is not aware of his diagnosis and this in itself will make his consent uninformed. He lacks any sense of autonomy since, just as in Bangladesh, he expects his family to make decisions for him. An attempt to explain the issues would cover scientific research and how it works, but there would be difficulty in addressing a tradition of healthcare in which spiritual and religious values and a host of different healing methods are deployed alongside conventional medicine. His desire may be to defer to his relatives, but the doctors may not permit this to be the basis of consent; or he may defer to the doctors for fear of adverse repercussions, in which case the consent will have been obtained under a form of coercion, real or imagined.

WHAT CAN BE DONE?

So, can the Western notion of informed consent be properly applied in the UK to ethnic minority individuals who are not acculturated? In extreme cases such as that of Mr Abdul the difficulties may be too great, but in principle the ethical standards should be the same for everyone.

The answer, we argue, is to adapt the process, and on this matter there is useful experience from South Asia.^{14–16} One strategy is to concentrate on the information side. For literate individuals, information sheets can be written in the vernacular, and researchers can use a questionnaire or interview to make sure the information has been understood before consent is formally sought. For the illiterate,

videos or illustrations can enhance comprehension and retention¹⁷ and consent can be either witnessed or recorded by video or audio. A later interview is desirable, in accordance with the trend to replace one-off informed consent with a process model in which the patient is accepted as a member of the team, possessing knowledge of contextual facts that are unavailable to the healthcare providers.¹⁸ This may be a useful model for members of minority groups whose concepts of healing and sickness differ from the dominant biomedical model. The cultural sensitivity of informed consent procedures could be improved by inviting community members to liaise with researchers. The problem of undue influence over participants might be addressed by appointing an independent person such as a clinic nurse or patients' representative to monitor the process and ensure that consent is freely given.¹⁹ This is a commonly used procedure in non-Western cultures. Where the issues are complex and cultural issues loom large, the answer might be a panel including family and lay members who volunteer to safeguard the interests of the patient. The legal position of such a panel, however, might be questioned; the law does not allow one person to give informed consent on behalf of another. Moreover, in cases such as that of Mr Abdul, no progress could be made until the family had been persuaded to allow disclosure of the diagnosis and prognosis. So far, little has been published on how this might be facilitated.

CONCLUSION

Despite the difficulties of gaining informed consent from non-Westernized ethnic minority patients in the UK, the answer must not be to exclude such patients from clinical research. Some of the obstacles apply equally to UK-born patients with poor education. Cultural issues demand strategies that take account of traditional views of healthcare and the role of the family in decision-making.

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