

Chapter 3

Social and cultural issues

Introduction

- 3.1 Developing countries are not a homogeneous group. They differ in many ways: culture, history, size of population and rate of growth, gross national product (GNP) per capita and levels of education (especially of girls and women). As discussed in the previous chapter developing countries also vary in terms of the technological and other forms of infrastructure they have in place, in their spectrum of health problems and in the quality and availability of healthcare. There are differences in the degree of social and economic inequality within countries. The degree of freedom of expression, recognition of human rights and extent of social harmony or disharmony are also highly variable. Rapid social and cultural changes are occurring in some developing countries following increased interactions with external cultures and technologies. As a consequence of all of these factors, it is inappropriate to regard developing countries as a single entity and their diversity must to be taken into account when issues arising from research related to healthcare are under consideration. In addition, there are significant variations within developing countries, especially those countries with a number of ethnic groups and significant differences in socio-economic status.
- 3.2 This chapter discusses the social and cultural contexts in which research in developing countries is conducted, providing a background to the discussion in the following section of the Report. It also highlights issues to which external sponsors and researchers should pay particular attention when research in developing countries is proposed. The interpretation of universal ethical principles in the light of social and cultural contexts is discussed in Chapter 4, while the implications of such contexts for the consent process are discussed in more detail in Chapter 6. While traditional systems of medicine are discussed in this chapter, the purpose of the discussion is to illustrate the contexts within which prospective participants may make decisions, rather than evaluating the effectiveness and evidence base underlying such systems.

Prevalence of alternative medical systems

- 3.3 One factor that may influence prospective participants in research is their understanding and use of traditional methods of healthcare and medical treatment, as well as the nature and level of their familiarity with evidence-based modern healthcare and research related to healthcare. There are a mix of modern medical and indigenous healthcare facilities in developing countries. For example, in the Middle East, parts of Africa, and South and South-East Asia versions of the Yunani system exist (derived from classical Arabo-Greek Galenic medicine) alongside modern healthcare and folk healing, as do the Ayurvedic system in India and the various Chinese therapeutic systems. This co-existence of different systems is also a feature of developed countries, as people increasingly seek complementary and alternative therapies, in addition to modern healthcare.
- 3.4 While there is much variation between continents and between regions within continents, local populations sometimes identify modern healthcare as especially valuable for acute conditions (following the successful use of antibiotics for eliminating infections rapidly). In contrast, long-term recurring problems may be ascribed to social, emotional, cosmic or religious causes, for which practitioners of alternative therapies are sought. This sometimes entails patients making choices along established lines: the first visit being to alternative medical practitioners or healers and subsequent ones to modern healthcare practitioners, or vice versa. This is a form of decision-making that may be unwelcome to researchers in both host and sponsoring countries. It is, however, a reality that in the long term it is more efficient to address than ignore.

BOX 3.1 Combining medical research and traditional healthcare

Ghana

Although there are effective medicines to treat malaria, many children in rural Africa who develop severe malaria die before they can receive help. In some such regions, the severe form of the disease (cerebral malaria which causes convulsions) is thought to be caused by evil spirits. As a result, children who have severe malaria with convulsions are often sent to traditional healers. It is also sometimes believed that such children should not receive injections, although they cannot take medications orally. A new medicine (administered as a rectal suppository) that could treat such cases of malaria is being tested in a district in northern Ghana.¹ This is part of a multi-country study sponsored by WHO in Ghana, Nigeria, Tanzania and Bangladesh. The study team in Ghana is working very closely with over 400 traditional healers to identify cases of severe malaria, provide the new medicine, and refer these cases to the nearest health facility for treatment. In all these cases the traditional healers' role is recognised and the credit for the survival of the children jointly acknowledged.²

Burkina Faso

In Burkina Faso a current research programme combines modern healthcare and African traditional medicine in providing treatment for people living with AIDS. Practitioners of modern healthcare are working with traditional health practitioners to assess the effects of traditional healthcare practices on patients. In one example of effective integration of traditional medicine into a modern health system, a team composed of scientists, Health Ministry officials, members of the Burkinabe Association of Traditional Health Practitioners and others, developed a protocol for the management of patients.³

- 1 The research is designed to determine the benefit of early treatment with rectal artesunate capsules.
- 2 The double-blind randomized clinical trial of artesunate rectal capsules on child survival in the Kassena-Nankana district Ghana, is funded by the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Disease (TDR).
- 3 The Health Minister's meeting 'Integrating Traditional Medicine into Health Systems: the example of Burkina Faso' was held in Ouagadougou, Burkina Faso, from 28 August to 2 September 2000.

Combining modern healthcare and traditional medicine

3.5 Most healthcare-related research that has been externally sponsored in developing countries has not taken account of traditional medicine. In some circumstances, the belief systems of traditional healers and biomedical researchers may be so incompatible that the two groups will be unwilling or unable to collaborate in research. In other cases such collaboration is desirable, or even essential, for research to be successful. Two such examples involving malaria and HIV/AIDS are set out in Box 3.1.

Concepts of illness, disease, misfortune and death

3.6 In developing countries, sickness may become merged with general ideas of misfortune. For example, one villager may be physically sick, another emotionally distraught or suffering from a mental illness and yet another's herd of livestock may have died. All three may be regarded as suffering from the same generalised affliction, which may be diagnosed by a shaman as someone else's witchcraft or bad spirits.¹ The first two villagers' conditions may be treated by modern healthcare practitioners and indigenous herbalists as physical ailments.²

3.7 It is commonplace in Africa for certain ailments, especially those affecting children, to be ascribed to the effects of spirits or violations of prohibitions. Researchers may wish to avoid taking account of such explanations. Yet, these

- 1 A shaman is someone who is believed to mediate between the spirit world and humanity, and is able to enter into a trance or similar state and then diagnose and prescribe or effect cures for disease. The term was originally coined by scholars who were studying societies in Siberia and central Asia, and was later extended to similar religious complexes found elsewhere in the world.
- 2 Littlewood R (1988) From vice to madness: the semantics of naturalistic and personalistic understandings in Trinidad local medicine, *Social Science and Medicine*, 27(2) 129–48.

indigenous explanations have a kind of reality as an explanatory system of ill-health and need not be incompatible with the research. Thus, while malaria or diarrhoea are indeed often ascribed to affliction by spirits, they can also be treated as a biomedical condition.

- 3.8 Local people will usually accept both types of explanation as contributing to an understanding of malaria. Spirits may be invoked to explain recurrent illness (for which the traditional remedy is expulsion of the spirits causing the illness). Bad water or an infestation of mosquito larvae can be understood as explaining the immediate symptoms (with such remedies as the development and use of clean water, chemically protective mosquito nets and medicines, or clearing away undergrowth and stagnant pools around a homestead). Such conflict of ideas and explanations is structural and broadly unavoidable, and should be acknowledged and dealt with by researchers on a day-to-day basis.
- 3.9 Differences from Western beliefs are sufficiently widespread to affect the views of local participants in research and to influence the conduct and progress of research related to healthcare. Local researchers, even if trained in modern healthcare, are likely to be accustomed to the concepts and practices following from traditional health practices and may view them as useful. Although it is in practice difficult to assess the efficacy of such systems, biomedical researchers may wish, provisionally at least, to keep in mind a distinction between local practices which are beneficial and worth encouraging (such as passing a knife through a flame to sterilise it before cutting a newborn's umbilical cord), and those which are harmful (such as applying animal dung to the stump of the umbilical cord) and should be discouraged.³ The use of other kinds of treatment where there is no evidence base for the assessment of useful or ill-effects may be best left to the judgement of local individuals, families and practitioners, and in some cases may be worthy of research to establish effectiveness.
- 3.10 Participants' beliefs about common techniques used in research, such as taking blood and urine samples, or giving injections, will also have an impact on the conduct of research. For example, sensitivity to the taking of blood samples is widespread in many parts of Africa (see Box 3.2). Some potential participants in research believe that researchers sell blood. Such individuals may resent the exercise while others may agree to provide just a very small blood sample. This might encourage researchers and field assistants to use deceptive methods to obtain larger amounts of blood if this is required by the study protocol. Providing urine samples is less unpopular and where such samples are a possible alternative to blood samples, may be preferred by study participants. There is often greater reluctance to provide samples of faeces. In part this may be because of the messy procedures for sample collection, especially as water-based sanitary facilities are often not available and the only alternative is a pit latrine. There is, however, also the belief in some areas that faeces may be used for witchcraft. In contrast to reservations about giving samples, in many developing countries injections are very popular.⁴ If

BOX 3.2 Blood samples in Malawi

In Malawi there is a widespread belief that a person's blood contains his or her spirit. If blood is taken in any quantity it is feared that the spirit is also lost. Whoever takes blood is believed to control the spirit and body of the individual from whom the blood was taken. This belief does not prevent the taking of blood samples within health facilities when the individual is presumed to be sick. However, population-based studies which require blood samples are extremely difficult or impossible to conduct unless the participants are brought to a healthcare unit. As a result, taking blood samples is minimised in community-based research studies.

3 World Health Organization (1998) **Care of the umbilical cord: a review the evidence 1998 - WHO/RHTMSM/98.4**, World Health Organization, Geneva.

4 See Reeler AV (2000) Anthropological perspectives on injections: a review, **Bulletin of the World Health Organization**, 78(1) 135-43.

such belief systems are to be taken into account when research is designed, researchers will require knowledge of, or access to those with knowledge of, the languages and concepts used in discussions and practices of healthcare.

The doctor–patient relationship; the healer–client relationship

- 3.11 It cannot be assumed that there is only one model of doctor–patient or healer–client relationship. This applies not just across the spectrum of medical systems but also within healthcare systems. An early Western model of the doctor–patient relationship saw it as essentially harmonious and based on the patient’s unquestioning acceptance of the doctor’s superior status and skills.⁵ A later model proposed an inherent conflict between doctor and patient deriving from the difference in power between the two, a difference which in some cases has to be negotiated and which may therefore not be harmonious.⁶
- 3.12 A similar range of possible doctor–patient relationships is likely to be found in different cultures. One report from Pakistan refers to traditional Muslim healers (called *pir*) who are regarded as imbued with God’s power and so never need to make diagnoses: just seeing the patient will allow them to know the patient’s condition and prognosis.⁷ Reports from Africa suggest much more negotiability between doctor and patient, with the latter entitled to argue with the doctor or healer over the diagnosis and possible cure.⁸ In between are the more complicated variations, for example in which healers physically identify or empathise with patients, by co-ordinating their pulse rates with those of the patient and then using this common point of identification for diagnosis and cure.⁹
- 3.13 Researchers from developed countries may not be fully aware of prospective participants’ considerable trust in and respect for medical doctors and other healthcare practitioners, even those with modest qualifications. This may be especially true if the healthcare practitioners have been trained in Western countries. It is questionable whether researchers from developed countries are well prepared for the enormous responsibility that this attitude of respect and trust places upon them. The implications of this attitude for the consent process are discussed in paragraph 6.24.
- 3.14 In many instances researchers from developed and developing countries may have more in common with their counterparts from other countries than they do with the population under study in rural or less-educated areas. Discussion with interpreters, cultural assistants, indigenous healers and shamans will provide researchers with a means of understanding some of the religious and cultural issues that may have a bearing on research related to healthcare. Such cultural understandings are especially important if the researchers are principally male and the interpreters and cultural assistants are predominantly female. Similarly, gender differences among local practitioners may be significant: for instance, in some societies, traditional herbalists

5 Parsons T (1964) **Social structure and personality**, Free Press of Glencoe, New York; Collier-Macmillan, London.

6 Hahn RA and Gaines AD (eds) (1985) **Physicians of Western medicine: anthropological approaches to theory and practice**, Reidel, Dordrecht. Kleinman AK (ed) (1980) **Patients and healers in the context of culture. An exploration of the border-land between anthropology, medicine and psychiatry**, University of California Press, Berkeley.

7 Ewing KP (1984) The Sufi as saint, curer and exorcist in modern Pakistan. In Daniel EV and Puggy JF (eds) **Contributions to Asian Studies**, EJ Brill, Leiden, Netherlands.

8 Davis-Roberts C (1981) Kutambuwa ugonjuwa: concepts of illness and transformation among the Tabwa of Zaire, **Social Science and Medicine**, 15(3) 309–16.

9 Daniel EV (1991) The pulse as icon in Siddha medicine. In Howes D (ed). **The varieties of sensory experience, A Sourcebook in the Anthropology of the Senses**, University of Toronto Press, Toronto. Hsu E (2000) Towards a science of touch, Part I: Chinese pulse diagnostics in early modern Europe, **Anthropology and Medicine**, 7(2) 251–68. Hsu E (2000) Towards a science of touch, part II: representations of the tactile experience of the seven Chinese pulses indicating danger of death in early modern Europe, **Anthropology and Medicine**, 7(3) 319–33.

are male and shamans female. Differences in interpretation as a result of gender may need to be taken into account in planning local participation in research and understanding of research as carried out in developed countries.

- 3.15 In addition, there may be a tension between participants' respect for those with training in developed countries, education and knowledge and their respect for traditional figures of wisdom and authority, including leaders of the community. Elders in the community commonly occupy positions of trust and may be respected for their local knowledge: differing circumstances of particular situations may determine which kind of knowledge is preferred, and by whom. For example, differing views as to where pregnant woman should have their confinements were observed in rural coastal Kenya before the advent of AIDS. Some of the older men preferred pregnant women to have their confinements at home attended to by a traditional midwife.¹⁰ A number of them thought hospital confinements were an unnecessary expense, as they considered the traditional method to be successful. In contrast, almost all the pregnant women wanted to give birth at a local mission hospital, with family members in attendance.¹¹ However pregnant women also often turned to older members of the homestead for healing and dietary advice.

Informing prospective participants about research

- 3.16 In many developing countries, concepts of respect for the family and community are equally as important as, or more important than, concepts of individual autonomy and rights. The belief that there may be mutual effects on each other by members of a kinship or other group is found in many non-Western societies. For example, in parts of Africa, if one person commits an offence, such as the violation of a sexual prohibition, the whole village or family may have to undergo a cleansing ritual in order to rid themselves of the harmful effects of that person's act.¹² This is a quite different understanding of individual autonomy from that found in many developed countries. In such circumstances, to seek individual consent without first creating public or group acceptance is likely to cause conflict within a community.
- 3.17 Often public discussion, followed by consultation with family units including women members, appears the most feasible and productive course to inform prospective participants about research, although variations in the cultural context will shape the manner in which this can be done. Without doubt it is often a slow process, requiring knowledge not only of the local political structure, language and relevant idioms but also of the customs defining behavioural etiquette and local moral systems (see Box 3.3). Community discussion and acceptance are also perceived as valuable and integral parts of promoting respect for persons and the dignity of individuals in developed countries.

Decisions about research

- 3.18 In some districts of developing countries, decisions about an appropriate course of action are made within a hierarchy of customary roles in the family and community. Men are most often in

10 Parkin D (2001) Personal communication, University of Oxford.

11 This preference appeared to be based on two factors: young women's claims, based on observation, that hospital births were more successful than homestead ones; and a wish to avoid the traditional midwife's method of inducing slow birth by forcing the infant out through externally-applied pressure.

12 See, for example Turner VW (1968) **The Drums of Affliction: a study of religious processes among the Ndembu of Zambia**, Oxford University Press, Oxford.

BOX 3.3 Discussing research: China

Government policy in mainland China has imposed a degree of uniformity in the structure of rural villages, where public discussion is the most likely forum in which the objectives of research can be communicated to members of a village. Villages below the level of townships tend to be self-governing collective units, organised by elected village cadres, some of whom are government party members. It is, for instance, through these cadres that information and monitoring with regard to the one-child family policy is carried out. Although imperfect, there is thus in principle a well-established official medium for the public discussion of research related to healthcare, its objectives and the need for local participants. Provided that the cadres in China accept the value and feasibility of a research project, would-be participants can choose whether or not to consent to participate in research. Moreover, with the possible exception of some remote areas, it is unlikely in modern China that women are expected to obtain the permission of men or elders before agreeing to be involved in research. Nevertheless, before consent can be sought, a visiting research team's proposals will need to be discussed in an open manner through the offices of the village cadre committees.¹

1 Pieke F (1996) **The Ordinary and the Extraordinary: an anthropological study of Chinese reform and the 1989 People's Movement in Beijing**, Kegan Paul International, London and New York. Hsu E (1999) **The Transmission of Chinese Medicine**, Cambridge University Press, Cambridge.

charge of such decision-making about participation in research by virtue of their status as head of the household or community (see Box 3.4). In addition mothers-in-law commonly exert power over daughters-in-law in some South Asian regions. Women, particularly young women, may not therefore always be able to express personal opinions on even minor matters, let alone the issue of whether they would like to take part in research. The notion that individuals are free to make their own decisions will therefore be less familiar to such women. The role of researchers in such circumstances is discussed in Chapter 6. Given that mortality and morbidity in both children and women are unacceptably high in many developing countries, research relating to child and reproductive health remains a priority. In a social context where women and children are vulnerable, they may be excluded from participating in research that is likely to benefit them or, conversely, exploited for research purposes precisely because they are vulnerable.

3.19 Attitudes have changed dramatically in much of Africa, where many women, especially in non-Muslim societies, have now cultivated a more assertive position with regard to healthcare, often aided by mission hospitals, clinics and health-focused non-governmental organisations (NGOs) (see Box 3.5). The rapid and increasing emergence of households

BOX 3.4 Consent to research: Uganda

In some areas of Uganda that hold to traditional social and cultural values, the head of the immediate family is a man (husband/father) and it is widely recognised and expected that he takes the final decision on all matters, especially sensitive ones affecting family members. In these areas, family members who do not submit to such decisions may face serious consequences including domestic violence and/or divorce. Thus, in such circumstances women and children will tend not to participate in a study unless permission has been granted by the head of the household. However the Ugandan guidelines require investigators to obtain 'the legally effective informed consent of the individual research participant'. In addition they explicitly state that 'a community leader may not consent to the participation of community members'.¹

1 National Consensus Conference on Bioethics and Health Research in Uganda (National Consensus Conference) (1997) **Guidelines for the Conduct of Health Research involving Human Subjects in Uganda**, National Consensus Conference, Kampala, Uganda: 32.

headed by women in parts of Africa as a result of AIDS may have accelerated these changes in attitude. As cultures are not fixed, researchers may need to find means of fostering discussion about what is required by cultural norms in a particular context. For example, research in South Africa has shown that even within a culture with strong beliefs about the importance of the community, many women favour the approach of requiring individual consent to research.¹³ The issue of cultural sensitivity is discussed further in Chapters 4 and 6.

3.20 In contrast to the examples above, in Latin America, substitute consent, community consent or other types of group or corporate consent are usually not practised. Although collective information can be given to rural communities or ethnic minorities, such as indigenous populations, consent by individual participants has been the rule. In research into vaccines in Colombia involving the military population, consent was initially sought at the command level and then at the individual level, before participants were enrolled. Although the trial was fully supported by the military command, a large proportion of volunteers felt able to choose to withdraw from the vaccination scheme before the second and third doses due to a range of side-effects.¹⁴

3.21 As in developed countries, in developing countries there may be a variety of reasons why people are willing to participate in research projects. Participants may be motivated by self-interest, in particular by the belief that a research project may provide them with a new and effective treatment for their illness. Alternatively, participants may consent to take part in research because it provides their only opportunity to receive adequate healthcare. In the case of HIV-positive participants in research in Thailand, a primary motivation to participate was the provision of an effective treatment for their condition (see Box 6.5). Participants may also be motivated by altruistic beliefs about the power of the research to benefit their community, whether that community is defined in geographical terms, or in terms of the community of people with a particular disease. Research in Chile has shown that, for some women, participation in research was a valued opportunity to ‘contribute to all women’s health’, or ‘to a better future’.¹⁵

BOX 3.5 Consent to research: Ghana

In a study in northern Ghana to determine culturally appropriate models of health and family planning services for the population, a district-wide experiment was established to document the impact of health and family services on child mortality and fertility.¹ The community participated actively in the development of the experiment and approved its design. A key feature of the research was the provision of modern family planning services to men and women in this rural population, where they had previously not been available. The men insisted on being consulted before their wives were offered family planning services. However, the women, with the assistance of the research team, organised several community meetings to discuss the implications of consent in the male-dominated society. After several public meetings where the issue was openly debated between the men and women, the women succeeded in convincing the men to accept that the women could use the family planning services either with dual consent of the couple or with the consent of the woman alone. The research team also agreed that information on consent would be treated as confidential.

1 Binka FN, Nazzar A and Phillips JF (1995) The Navrongo community health and family planning project, **Studies in Family Planning**, 26(3) 121–39; Nazzar A, Adongo PB, Binka FN, Phillips JF and Debpuur C (1995) Developing a culturally appropriate family planning program for the Navrongo Experiment, **Studies in Family Planning**, 26(6) 307–324.

13 Lindegger G (2002) Culture and informed consent in clinical trials in South Africa, Third Global Forum on Bioethics in Research, Capetown, South Africa, 21–23 February 2002.
 14 Velez ID, del Pilar Agudelo S, Arbelaez MP, Gilchrist K, Robledo SM, Puerta JA *et al* (2000) Safety and immunogenicity of a killed *Leishmania (L.) amazonensis* vaccine against cutaneous leishmaniasis in Colombia: a randomized controlled trial, **Transcripts of the Royal Society of Tropical Medicine and Hygiene**, 94(6) 698–703.
 15 Sanchez S, Salazar G, Tijero M and Diaz S (2001) Informed consent procedures: responsibilities of researchers in developing countries, **Bioethics**, 15(S16) 398–412.

3.22 Prospective participants in developing countries place high value on healthcare. Consequently it is often assumed that they may be more likely to participate in research related to healthcare, although this is not easy to demonstrate. In addition, a lack of familiarity with the methods and rationale of research related to healthcare, may lead participants to believe that the primary purpose of research is to provide them with therapy, rather than to obtain information (commonly called ‘therapeutic misconception’). The US National Bioethics Advisory Committee (NBAC) recommended that investigators working overseas must indicate in their research protocols how they intend to minimise the possibility of therapeutic misconception.¹⁶ We conclude that investigators conducting studies in developing communities have a special responsibility to explain to those participating in research that the research may not benefit them as individuals so that they do not participate in the false expectation of gaining a direct benefit. In areas where physicians are thought of solely as healthcare providers, and where research is a novel concept, particular care must be taken. Issues relating to consent are discussed in more detail in Chapter 6.

16 National Bioethics Advisory Commission (NBAC) (2001) **Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries**: Recommendation 3.10.