Chapter 4

The ethical framework
Introduction

4.1 In Chapter 2 we noted the wide variations in the health of populations around the world. These variations exist in a context of considerable interdependence between countries, not least with regard to international trade. Scientific research and research related to healthcare are themselves international enterprises, the findings of which may transcend national and political borders. Commercial enterprises, including pharmaceutical companies, seek to take legitimate advantage of the economies of scale that global markets offer. The economies, social systems and politics of countries are thus bound together in complex ways.

4.2 As well as considerable variations in health of populations, there are also wide variations in the ability of different countries to cope with the problems which they confront. These differences of capacity stem largely from varying economic resources, but also relate to variations in administrative and political capacity and the differential development of expertise in scientific and technical disciplines in the world. Moreover, as discussed in Chapter 2, it is often the case that those countries with the greatest health needs are also those with the least capacity to deal with them. For example, some of the highest rates of HIV infection are in countries that are among the poorest of the world. In situations of poverty, with very limited scientific, administrative and political capacity, as well as economic inequalities, individuals and organisations face major difficulties in delivering the healthcare needed.

4.3 Many interpretations can be, and have been, offered for this pattern of global inequality. One view is that it is a legacy of colonialism and empire. Built upon a basis of economic exploitation, newly de-colonised nations in the middle of the twentieth century were left with inadequate political and social institutions with which to face the challenges of economic and social development. Another view is that the pattern of global inequality represents a series of structural barriers raised against the poor, making it extremely difficult, if not impossible, for them to develop an economic basis sufficient to sustain a reasonable standard of life for their citizens. A third view is that, despite the history of colonialism, the modern international order does offer opportunities for economic growth, provided that poorer countries have the appropriate policies and institutions in place to take advantage of their comparatively low costs to compete against established economic powers.

4.4 In this Report, we do not take a position on these competing interpretations. We simply acknowledge the difficulties confronting those seeking to improve the health of populations in developing societies, and we accept that the barriers to sustainable development are considerable. Yet within these constraints, individuals and corporate bodies still have choices. The moral burden of choice weighs especially heavily on those who enjoy a privileged position in the world order because, by definition, they have the greatest capacity to effect change, but it also applies more widely. In particular, the problem is raised of how to devise an approach to research related to healthcare that is consistent with the requirements of an ethical framework for research.

4.5 What do we mean when we speak about an ethical framework for research? We have in mind a set of principles that allow us to evaluate the actions and policies of individuals and bodies such as companies, non-governmental organisations (NGOs), international organisations or government agencies. These principles seek to identify the considerations that should apply to individuals and agencies when they make decisions or adopt policies. They constitute a framework for articulating the duties, obligations, claims and expectations of those involved in research related to healthcare.

4.6 We do not present these principles as part of a more general ethical theory. This does not mean that the principles are drawn from nowhere: they are widely discussed in works on ethics and...
political theory. We offer them as the basic considerations which anyone concerned to reflect upon and evaluate research related to healthcare in developing countries should take into account. We consider four principles in particular:

(i) the duty to alleviate suffering
(ii) the duty to show respect for persons
(iii) the duty to be sensitive to cultural differences and
(iv) the duty not to exploit the vulnerable.

The task of the Working Party was to consider how these principles should be understood in the context of research related to healthcare in developing countries and of the particular dilemmas that arise, while taking account of the practical, social, cultural and economic circumstances that are relevant to research.

The duty to alleviate suffering

4.7 Medical practice is fundamentally justified by the duty to alleviate suffering. This duty has long been acknowledged in moral codes and its application to medicine is enshrined in the Hippocratic Oath. It is commonly argued, and recognised in most political structures, that the needs of one’s own communities should have first claim on this duty and thus on the resources available. But this does not mean that we have no duty to contribute to the alleviation of suffering elsewhere, especially among the citizens of poor countries.

4.8 Since medical research, and research related to healthcare generally, make an essential contribution to the alleviation of suffering, the conduct of research which deals with the health problems in developing countries is not just legitimate, it is a moral duty. For most people, the duty to conduct research addressed to the needs of developing countries is discharged only indirectly, by government support for publicly-funded institutions such as the Medical Research Council (MRC) in the UK and the National Institutes for Health (NIH) in the US, the Framework Programmes of the European Union and the many national aid agencies in developed countries (see Box 2.2). Nonetheless, it matters morally to all of us that effective medical research and research related to healthcare is indeed carried out. There is an inescapable moral duty which must be the basis for public policy in this area.1

4.9 The duty to alleviate suffering enjoins us to do what we can to reduce the amount of suffering in the world. Thus we fail to act in accordance with this duty by doing nothing to help eliminate avoidable suffering; and the more suffering we help to eliminate, the better our action. But there are many other claims on our time and resources, and acknowledging the fundamental status of the duty to alleviate suffering does not mean that it always overrides all other claims. Instead, there is a difficult task for individuals and, especially, governments to strike an acceptable balance between competing demands. It is not part of this Report to propose a method for undertaking this task. But the fact that externally-sponsored research related to healthcare may be undertaken in a context in which resources are limited has important implications for its conduct. This is one aspect of the issues about standards of care discussed in Chapter 7.

1 Furthermore, this research is increasingly also a matter of enlightened self-interest, since immigrants from developing countries, and travellers to them, may bring some of the health problems of the developing world back to the developed world.
Respect for persons

4.10 The duty to alleviate suffering focuses on just one human quality, the capacity for suffering. But humans share many characteristics. As well as having common basic needs they also have the capacity to think, reason, use language and live in complex relationships with one another, thereby creating their own cultures and allowing individuals the opportunity to pursue their own projects within these cultures. This capacity for creating a life of our own is both an essential feature of common humanity and yet also something that marks out each of us as a unique source of value. It justifies the requirement that we regard each other as worthy of respect.

4.11 In holding every person worthy of respect, we commit ourselves to taking their interests into account when considering what to do. We may not use them as a mere means either to our own ends or to the welfare of others, and, on the presumption that they are the best guardians of their own interests, they should be involved in decisions which affect them. Hence, among other things we should not increase their risk of illness or death, misinform them, violate the integrity of their intimate relationships, or treat with indifference what they deeply value. Positively, we should support their sense of self-respect and self-worth, encourage them to develop and express their capacities, and help create conditions in which they can lead worthy and meaningful lives.

4.12 Understood in this way, the duty of respect for persons places important constraints on the implementation of the duty to alleviate suffering. That duty, by itself, may lead to the assumption that the less suffering there is, the better. However, the principle of respect enjoins us to consider carefully the ways in which we seek to alleviate suffering. For example, policies which violate other interests of those involved, even if they offer the most straightforward way of reducing suffering, are to be weighed carefully. Equally, issues related to balancing the interests of participants in research with the interests of the wider population who could benefit from the research results are addressed in Chapter 7.

Sensitivity to cultural differences

4.13 An important characteristic of externally-sponsored research carried out in developing countries is that there are often cultural differences between those organising or funding the research and the research workers and participants in the host country (see Chapter 3). The moral significance of these differences requires special attention.

4.14 Individuals live within particular societies, the cultural assumptions and practices of which shape their understanding of themselves and others. The ways in which different peoples define themselves in terms of gender, family, kinship, status and nation, and go on to organise relationships involving matters of authority and questions of sickness and health, are endlessly varied. Even when they are in revolt against their cultural upbringing, individuals often tend to think of themselves in the light of the concepts and understandings they have acquired in their society, including their understanding of sickness and health.

4.15 As a result, the general duty of respect implies a duty to be sensitive to other cultures. Thus one potential misuse of power is to be insensitive to the cultural perspectives that individuals bring to questions of health and healthcare. Indeed, the variety of beliefs and practices that exist may challenge the notions of overarching ethical principles. This in turn prompts an analysis of the relationship between the requirement of sensitivity to cultural differences and the concept of moral relativism, the view that different moral codes cannot be critically compared and evaluated.

4.16 In our view, recognition of the existence of diverse cultures and communities with different moral codes does not lead to moral relativism. The relativist position mistakenly suggests that because
4.17 What then are the demands placed on us by the requirement of sensitivity to cultural differences? Plainly, one demand is the willingness to explore such differences without prejudice and to seek as far as possible to understand them informed by knowledge of local traditions and material circumstances. Equally, once this understanding has been achieved, those organising research related to healthcare should as far as possible take account of the local culture, taking the trouble to find ways that respect local practices even where, on the face of it, they complicate the research. But, it does not require those involved to compromise fundamental values. In particular, since sensitivity to cultural differences is an implication of the fundamental principle of respect for persons, if local cultures transgress values inherent in this principle, researchers will need to follow different procedures from those prescribed in the local culture.

4.18 This analysis is particularly relevant when we consider the need for consent by participants in clinical trials. One of the distinguishing characteristics of cultures in developing societies is that they are often less individualistic than those in Western Europe and North America. In such cultures, consent may not be seen to be a purely individual matter. It may be associated with wider obligations to family, village or clan (see paragraph 3.18). Our approach in this chapter suggests that when we come to consider the requirements for consent in Chapter 6, we need to be sensitive both to local cultural traditions and to the general requirement of respect for persons implied by our common humanity.

**The duty not to exploit the vulnerable**

4.19 We have already stressed that the context of our Report is one in which there are considerable inequalities of power and advantage between developed and developing countries. We suggest that, as a matter of moral principle, the more powerful have a duty to refrain from exploiting to their own advantage the vulnerability of the weaker. Since those with power may always be tempted to misuse it, perhaps even for what they perceive as benevolent reasons, it is important to insist on this principle.² We have a number of points to make about the principle.

4.20 First, it can be regarded as a further implication of the principle of respect for persons, for in exploiting others we fail to give proper weight to their interests. Secondly, like the requirement of sensitivity to cultural differences, the duty not to exploit the vulnerable merits special attention in the context of developing countries, not least because outsiders and local citizens may well differ on just what counts as exploiting or taking advantage of the weakness of others. Thirdly, it is important that the duty not to exploit the vulnerable be observed uniformly by all individuals and organisations involved in research, to avoid unfairness and the danger of undermining the principle in practice. If only some sponsors act in accordance with the principle of non-exploitation, then such scrupulous sponsors would be disadvantaged in relation to unscrupulous sponsors. Fourthly, although the duty not to exploit the vulnerabilities of others falls on all, the

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nature of the obligation may change depending on who is involved. For example, those occupying positions as policy-makers in political and social organisations at national or international levels have an obligation not simply to provide for the avoidance of exploitation within the framework of existing practices and institutions, but also to pursue change in the functioning of those institutions and practices so as systematically to reduce the opportunities for exploitation.

4.21 Hence, the principle of not exploiting the vulnerable does not mean that we simply take the current context of research related to healthcare in the developing world as unchallengeable and unalterable. Just as it is unacceptable that local political and economic elites should seek to pursue their own goals at the expense of populations participating in research, it is unacceptable that researchers should select populations which are economically or politically weak, and therefore vulnerable to exploitation, in order to test therapies more cheaply in order to benefit other, wealthier communities. The wider roles and obligations of all those involved in research, pharmaceutical companies, international organisations, governments, and individuals in reducing global health inequities must always be borne in mind. In particular, in the context of research, researchers have a duty to enable the participant communities in developing countries to benefit, where possible, from the research conducted on them. This point, along with the broader question of developing expertise in research, is a matter to which we return in Chapter 9.

From principle to practice

4.22 We have discussed four interrelated ethical principles relevant to the conduct of research in developing countries. They should not be thought of as rules to be applied mechanistically. By their very nature, they call for interpretation and consequently for the exercise of judgement, especially in relation to the latter two principles concerning sensitivity to cultural differences and the avoidance of exploitation. The importance of some cultural difference may not be clear initially, nor may it be clear at what point the standard of care extended to participants in research becomes exploitative. Thus, when considering how research related to healthcare should be conducted, it is important to analyse how such judgements are to be made, appraised and implemented. Principles must be translated into practice, and for this a proper procedure must exist. The analysis of such procedures is an important part of our discussion. There need to be suitably informed and accountable bodies in both the country in which the research is sponsored and the country in which it is carried out to take responsibility for striking a proper balance between the various conflicting considerations which arise. In Chapter 8 we discuss the way in which research ethics committees can play this role.

4.23 We emphasise one point here: the establishment and maintenance of research ethics committees is just as much an essential ingredient in the proper conduct of research related to healthcare as the functioning of political institutions is essential to the proper conduct of government. An ethical analysis does not concern itself only with identifying and setting out appropriate general values and principles. It also has to concern itself with the institutions and procedures through which these principles are put into practice.