MEETING REPORT

Ethical review, remit and responsibility in biomedical research in South Asia

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In recent decades, research in the biomedical sciences has been increasingly located in settings outside of the global north (1). Much of this research arises out of transnational collaborations made up of sponsors in richer countries (pharmaceutical industries, aid agencies, charitable trusts) and researchers and research subjects in poorer ones. A recent workshop on the ethics of international collaboration, held in Sri Lanka,* confirmed that in addition to the usual concerns about the protection of human subjects in biomedical research, these engagements raise a host of new ones.

Research may well be carried out in populations rendered vulnerable because of their low levels of education and literacy, poverty and limited access to health care. The protections that medical and research ethics offer in these contexts tend to be modelled on a western tradition in which individual, informed consent is paramount and, furthermore, is couched in legal and technical requirements. When science travels, so does its ethics. Yet, when cast against a wider backdrop of global health, economic inequalities and cultural diversity, such models often prove limited in effect and inadequate in their scope (2, 3). Attempts to address both of these concerns have generated a wide range of "capacity-building" initiatives in bioethics in developing and transitional countries. Organisations such as the Global Forum for Bioethics in Research, the Forum for Ethical Review Committees in the Asia Pacific Region and the World Health Organization have sought to improve oversight of research projects, refine regulation and guidance, address cultural variation, educate the public about research and strengthen ethical review committee structures according to internationally acknowledged "benchmarks" (4, 5). They are also an essential prerequisite when it comes to attracting and hosting future collaborations, whether these are commercially sponsored, humanitarian or complex hybrids of the two.

Bioethical capacity building

As part of a larger study of the ethics of international collaborations in biomedical research, the work of BS, RDJ and SS has focused on the ways in which a heightened preoccupation with the ethics of research is playing out in contemporary Sri Lanka. The aim is to map and to understand both the spread of international collaborative research as well as the intellectual, bureaucratic and political activity that is stimulated in the name of bioethics capacity building. However, in studying collaboration, we ourselves are also drawn into collaborations of various kinds. In this article we report on an event which was held to facilitate dialogue between ourselves and other regional stakeholders **. The event focused on the ethics of international collaboration and provided an important context for reflection on the current state of play and an opportunity to air some of the issues that are faced when it comes to national and regional engagement with global science and experimentation.

At one level, the workshop provided an opportunity for participants to show the considerable progress made in responding to the ethical challenges posed by the growing traffic in international collaboration and particularly where these concern the outsourcing of phase II and III clinical trials. Significantly, many of the discussions gravitated towards ethical review committees: their constitution, operation, remit and effectiveness. In conformity with the Declaration of Helsinki, such advisory groups are seen as crucial when it comes to anticipating the costs and benefits to those who are to be enrolled into biomedical research projects. Here, continuities with ethical review as a global bureaucratic form were clearly in evidence: reference to international protocols, membership of trans-national fora and operation within standard guidelines. However, what became apparent in discussions throughout the day was the difficulty that participants had in stabilising this form in practice. The field of international biomedical research is changing extremely quickly, as are the mechanisms that are put in place to regulate and ensure protection of subjects. The effect of this would seem to leave the work of ethical review in a state of perpetual insufficiency: an ever-widening remit, not enough committees, not enough scrutiny, not enough trained people and not enough public participation. Anxieties were expressed that shortcomings in ethical review could bring charges of being "unethical" due to "incompetence". Such anxieties are greatly exacerbated when operating in settings where inequalities of risk are high, for example, because of poor education and literacy on the part of subjects and where negligence, corruption and exploitation are made possible by paternalistic and poorly regulated medical systems.

Where external audiences are concerned, there is anxiety that such charges might be indexed to estimations of national development and scientific credibility. Apart from feeding unwelcome national stereotypes, appearing inadequate when it comes to the conduct of ethical review could have real consequences when it comes to the ability to attract

research to the region, be this researcher-led research (funded by universities, charities, non-governmental organisations or governments) or sponsor-led research (funded by pharmaceutical companies). Where internal audiences are looking on, a different set of anxieties present themselves. Discussion of contentious cases suggested that the committees find themselves walking a fine line. On the one hand, they may be perceived as too restrictive, that is, unreasonably protective of human subjects and their interests and therefore impeding scientific and economic development. On the other hand, the expectation that ethics committees will operate as a kind of bulwark against moral and scientific imperialism might bring charges of excessive permissiveness, that is, they are not nearly protective enough of subjects and therefore are complicit in abuse, injustice or exploitation in research. Members can easily find themselves vilified from all sides. In this regard, an important question that emerged from the discussions is what happens when things go wrong following positive approval by an ethics committee and how to manage the professional and, possibly, legal ruptures that this brings.

Ethical vanishing points?

The way to prevent "unethical" process and outcome in the ethical review of research that was proffered by many of the participants was further resort to "capacity building". Yet, it was hard to see that this strategy would not result in a remorseless game of catch-up into which all are drawn in the quest for some kind of ethical vanishing point. Indeed, as the discussions progressed, the load that ethical review was taking on seemed to get heavier and heavier, and, as a consequence, focus fell more on operating procedures and the way that these might be tightened up to ensure effective regulation of research. The momentum appeared to be moving firmly in the direction of greater procedural elaboration, more formulaic approaches to evaluation and a consequent consolidation of power in the process of ethical review, as national ethics cultures expand to fill the ambiguous moral spaces that international research increasingly opens up.

On the evidence of the collaborative workshop, the list of competences and responsibilities that ethics committees active in the field of international collaboration might be expected to have is a long one. They must cover relevance of the trial design, its scientific validity, the balance of risks and benefits, the suitability of investigators and the appropriateness of informed consent procedures. Furthermore, the list is expanding as ethics committees strive to discharge their duties responsibly and embrace new dimensions of what it is to be "ethical". Here committees must, perforce, move into complex cultural territories for which there is little in the way of guidance. Examples alluded to included information sheets, the technicalities of translating informed consent documentation, insurance and compensation arrangements and the complex entanglement of voluntarism and commerce that runs through questions of payment to research participants. The waters were further muddied as participants grappled with "social benefit" or assessing the extent that certain kinds of research might result in "ethnic disharmony". There was little evidence that the participants were in anyway shying away from the challenges that engaging with this agenda carries despite the considerable investment needed in terms of knowledge, time and resources. However, it was clear from the discussions on this particular occasion that those who are most centrally involved in conducting ethical review see themselves as carrying enormous and, on occasion, impossible responsibilities and expectations. The task of making appear stable and authoritative that which is constantly evolving is a significant one. For these reasons, the emergence and consolidation of ethical review in developing world contexts is an increasingly important site in which to study the transactions in knowledge, resources and finance that currently constitute international collaboration in biomedical research.

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Notes

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* The workshop took place in March 2009 in Colombo and was co-organised by three researchers from Durham University along with staff of the Faculty of Medicine of the University of Colombo (specifically the Human Genetics Unit and the faculty's ethics review committee). The theme for the day was the ethics of international collaboration. Case studies of international collaboration were presented by Harun Ar-Rashid (director, Bangladesh Medical Research Council), Vasantha Muthuswamy (former deputy director general, Indian Council for Medical Research), Shri Krishna Giri (secretary, Nepal Health Research Council), Hemantha Senanayake (chairperson of the ethics review committee, Faculty of Medicine, University of Colombo, Sri Lanka). Cristina Torres (co-ordinator, Forum for Ethical Review Committees in the Asia Pacific Region) gave an overview of the challenges faced in developing ethical review capacity in the region. The audience consisted mostly of local academics, doctors and clinical researchers.

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