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Evolving values in ethics and global health research

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Over the past 25 years, the ethics of international health research have shifted from addressing narrow issues such as cultural differences in informed consent practices towards a greater emphasis on development and social justice. We anticipate that the next 'era' in international research ethics will involve an intensification of this focus on the role of research in achieving global justice. Three values, in particular, will shape how ethics considerations should evolve: solidarity; respect for Southern innovation; and commitment to action. We expect continuing debate on whether researchers and research sponsors should recognise more than a minimal set of obligations for the care and benefit of research participants and their communities. As the debate about the role of research in development intensifies, we expect to see new and more elaborate mechanisms for financing on-going access to beneficial interventions, ancillary care and other research-related benefits, as well as a greater involvement in research funding by developing country governments and private foundations. Ethics review and oversight need to reflect on these new values and on ways of operationalising them, or risk becoming marginalised in the research process.

Keywords: ethics review; international health research; changing values; social justice; developing countries

Introduction

The ethics of international health research captured public attention in the late 1990s when placebo-controlled trials to reduce the maternal–infant transmission of HIV in Africa used lower doses and more simplified administration procedures than the 'best proven treatment' in use at the time in the North. The simplified regimen was more logistically feasible for resource-limited settings, but was also potentially less effective. As a result, the same research protocols would not have been acceptable in the researchers' home countries. The ensuing debate put the ethics of international health research firmly on the radar screen of researchers, bioethicists, funders, editors and journalists (Lurie and Wolfe 1997, Varmus and Satcher 1997). This

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collective interest in the ethics of international research – especially in research conducted in low and middle-income countries – has fuelled an expansion of scholarship. Attention has been directed towards not only the ethical aspects of individual research projects, but progressively also on the adequacy of the governing policies in the field, and increasingly on the context in which such research is conducted, raising profound questions about the relationship between health research and global justice.

An expanding range of concerns regarding justice

The core controversy introduced by the HIV perinatal trials was whether interventions that were known, or widely expected, to be inferior to the best available worldwide options should be used in trials in developing countries. Proponents argued that doing so was permissible when the potentially inferior treatment might be logistically or economically more feasible to distribute locally, thus eventually leading to broader-based public health improvements in resource-poor environments than would be possible by allowing only the ‘gold standard’ intervention. That is, such a design might allow more hope for benefit than if no research had been conducted at all (Wendler *et al.* 2004). Opponents argued that what counts as the ‘best’ intervention should not vary by region or background resources, and that global health research that does not fundamentally alter the ‘normative baseline’ of disadvantaged communities cannot ethically be endorsed (London 2005).

Beyond individual benefits during and after trials (Lavery 2008), there has been increasing attention to the need for population benefit sharing through, for example, intellectual property rights (Nishtar 2004), as a way to operationalise the principle of justice. While many commentators in global health research have examined the fairness of circumstances, transactions and benefits at the level of individual research studies, others have begun to ask whether the agenda for global health research as a whole is just. The landmark 1990 report by The Commission on Health Research for Development illustrated that the way in which global health resources are distributed has little to do with global health needs (Commission on Health Research for Development 1990). The report described that only 5% of global health research expenditure is used for research on conditions that cause 93% of global premature mortality, now known as the ‘10/90 gap’. The consequences of this gap are stunning in terms of health outcomes and pose new challenges to ethical scholarship. For example, ‘diseases affecting large proportions of humanity are given comparatively little attention [while] simple and low cost technologies ... are undervalued and hence inadequately researched’ (Lee and Mills 2000). Labonte and Siegel (2003) suggest several criteria to help set global research priorities, including conducting research where questions are defined by developing countries – a step rarely undertaken by funding agencies – and conducting research that increases equity in health outcomes within nations.

Ethical values for the next decade

The ethics of international health and health research have shifted over the past 25 years. Early scholarship on research ethics focused largely on cultural differences in the conceptualisation of health (Kleinman 1991) and personhood (Tangwa 2000),

and on communitarian norms in developing countries that called into question the relevance and value of individual informed consent (IJsselmuiden and Faden 1992). More recent analyses have focused on broader challenges, such as exploitation in international research (Hawkins and Emanuel 2008), responsiveness to the health needs of host communities (London and Kimmelman 2008), and the implications of key research events, such as the HIV perinatal trials, for international relations and international law (Fidler 2001).

Greater attention to international issues in research ethics has made them less exotic and other-worldly to researchers and funders in the North, while closer and more careful analysis of key issues (Hawkins) has revealed the inescapably broad nature of international justice that underlies international research ethics. This normalisation of international research ethics has meant that the implications of difficult ethical questions related to the funding, organisation and conduct of international research are and must increasingly be addressed.

One touchstone issue may be how Northern research funding agencies respond to the rich debate about the scope of researchers' and sponsors' obligations. Although far from settled, the debate is anchored at one end by what some have called a 'minimalist' position (London 2005), which posits that researchers and sponsors' sole obligations are to conduct high-quality and useful research with voluntary participants that is, in the aggregate, more beneficial than harmful. Others have argued in opposition, that research is unethical to the extent that its actors are complicit with systemic international and institutional injustices, and that these give rise to reparative obligations for past injustices (London 2005). That funding agencies may be showing increased attention to even discussing these issues through their own policy development, as well as funding relevant empirical research, training and capacity-building, reflects an elevation of the status of research ethics and suggest a growing acceptance that these broad concerns of justice cannot simply be swept aside in favour of narrower ethical issues.

Controversy has also encouraged research funders to engage in other creative developments, such as public-private partnerships in research and trial-specific insurance programmes to help guarantee on-going access to beneficial interventions. As the debate about the role of research in development intensifies, we expect to see new and more elaborate mechanisms for financing on-going access to beneficial interventions, ancillary care and other research-related benefits, and also a greater involvement in research funding by developing country governments and private foundations.

There are many good examples of how values have helped to shape policy and practice in global health (Frenk and Gomez-Dantes 2009). In the remainder of this paper, we address the question of changing values in global health: What values should we embrace to guide the next phase in the evolution of international research ethics? We settle on three main values that we believe should be given prominent status in guiding the next phase of the evolution of international research ethics: global solidarity; respect for Southern innovation; and commitment to action.

Value 1: global solidarity

Global health is now seen as an achievable, if still daunting, objective (Koplan *et al.* 2009). Spurred on by massive increases in donor spending and mass media coverage,

global health and health research has become serious business. Working on the tight schedules of grants based increasingly on a product development model, Northern institutions and researchers are clamouring for Southern partners. Yet, research grant mechanisms, with only a few notable exceptions, do not include local research capacity development within the operational criteria for global health research quality, suggesting that such capacity development is not highly or ultimately valued. Therefore, these activities continue to fall outside the current funding envelope or are funded through other, sporadic mechanisms, suggesting that the responsibility for capacity development is separate from the responsibility to fund high quality and ethical research. Evidence from countries like Tanzania and Uganda, as well as from institutions in developing countries, such as the International Centre for Diarrheal Disease Research in Bangladesh, illustrates the problem: the grants provided by Northern granting agencies rarely provide for adequate overhead costs to build local research institutions and systems (Sack *et al.* 2009). Furthermore, because of the competitive nature of grants, Northern institutions continue to get the lion's share of those aimed at global health, strengthening already strong institutions. The expression that has arisen is that most global health research is done 'for them [low and middle-income countries], sometimes with them, but rarely by them' (IJssemluiden and Kennedy *et al.* 2007).

Further attention must be devoted to ways in which research and study interventions can be used as a means to *strengthen and be integrated into* local health systems. Indeed, even some locally relevant research studies have raised concern by draining scarce local personnel from existing health systems where they are desperately needed. An ethical dilemma arises when one clinical trial in Malawi can recruit as many nurses to be trial staff as are produced annually by the national university, while Malawi already has a significant nursing shortage (Muula *et al.* 2003). As is frequently the case in just about all low and middle-income countries, national health or health research priorities do not match global health and health research priorities, a lack of concordance resulting in ethical problems. One example is the near-monopolisation of health research and researchers in low and middle-income countries by internationally funded HIV/AIDS, TB and malaria research programmes, and by the still-dominant private sector drug trials, which in many cases are conducted in hospitals sponsored by the drug companies themselves. Who will decide what counts as sufficient benefits to a resource-poor country, and who determines the correct balance of the contribution to scarce researcher capacity to serve global priorities and to address local and national health priorities?

We believe solidarity can serve as a useful guiding value for improving the ethics of international health research, in two main ways. First, through the continued evolution of a sense of the 'global' in global health research among wealthy country research funders, and with it a greater willingness to devote research funds to a broader range of issues and needs, including increased attention to enhancing local capacity, building strong institutions and supporting more robust and equitable collaborations between Northern and Southern institutions. This reconsideration of the 'global' is essentially a social and political challenge, urging governments, powerful private sector interests and the general public of high-income countries to increase accountable access to funding for research and development. These diverse actors are further urged to work more directly with recipient countries to enable them

to formulate their health and health research priorities, beyond the huge international funds for major killers, such as HIV/AIDS, TB and malaria, which have attracted unprecedented funding over the past 10 years, but whose governance is largely rooted in the North. Solidarity, in our view, requires more attention to developing relationships of understanding and cooperation with the institutions and countries where or with whom research is being conducted, than with the governors and executives of these large funds.

The second way in which solidarity might improve the ethics of international health research is through an aggressive expansion of investment in health research by developing countries themselves. This heightened investment has occurred in the ‘innovative developing countries’, including India, Brazil, South Africa, China and Thailand, and as called for by a variety of ‘high level’ meetings in Africa (African Union, NEPAD, Accra), and even by some low-income countries, like Rwanda, which has adopted an aggressive domestic policy of innovation in science, with an emphasis on biotechnology (Kagame 2008). Traditionally, solidarity has been viewed as a duty for wealthier, Northern countries to act in support of Southern countries. However, this one-sided view of solidarity, which inaccurately and unfairly regards all Southern countries as dependent on the good graces of Northern countries for their progress, must give way to greater cooperation and strategic alliances among Southern countries to develop and share policies and approaches that can help to ensure that international research serves their interests.

Value 2: respect for Southern innovation

The understanding by nations that investments in science and technology are a crucial pre-requisite for development has led to a group of ‘innovative developing countries’ making substantial investments in health research – often focusing on pharmaceutical or medical technology rather than immediate health problems (Thorsteninsdottir *et al.* 2004, Masum *et al.* 2007). Developing country researchers, having long been assistants to Northern research programmes, are increasingly demanding leadership roles in all phases of research and are becoming increasingly successful in achieving principal investigator status, even if they are not always studying the most pressing health problems in their immediate environment. This dilemma poses a serious ethical challenge, as it is contrary to the usual interpretation of paragraph 19 of the Declaration of Helsinki, which can be broadly interpreted to mean that research should be ‘responsive to health needs in the population’. Many will question the ethics of research conducted in low-income countries for the sole purpose of individual researchers or countries becoming globally competitive, although this clearly happens in the North with breathtaking frequency (consider the global market for cosmetics or enhancement drugs, for example). Perhaps this ethical dilemma can be resolved if research is also viewed for its potential to promote economic growth rather than as only a component of the local health and research infrastructure.

Health research with *social value* (Commission on Health Research for Development 1990, London 2005), by contrast, may be defined in part by its ability to fit within the national health priorities of host countries. Research review, whether by existing boards or by an alternative, more central mechanism, may need to

scrutinise the fit for questions of local relevance. New approaches to social review or social audit could be developed to help ensure that funding schemes developed in the North fit appropriately with the problems they aim to address in the South, e.g., research capacity building (Editorial 2009) as is happening in general development support. A national system may be required that examines the broader ethical questions of fit between proposed research and local priorities and to resolve other justice-policy issues like the type or level of care that needs to be provided during or after studies.

Research ethics guidelines from around the world have consistently included some considerations related to the social value of the proposed research. However, the review of research proposals by local institutional review committees, the dominant paradigm of research ethics review, has all but eliminated judgements about the social value of research as an effective mechanism for shaping research activities. Local committees have no jurisdiction over research funding, and the institutions they represent are too dependent on research overhead to reject lucrative research proposals on the grounds that they are not sufficiently valuable to developing countries. There needs to be greater attention to determining the social value of global health research proposals, through mechanisms that more explicitly recognise Southern innovation as a key avenue to reducing global health disparities. This value should help define the next phase in research ethics, and might give rise to more collaborative forms of research ethics review and perhaps even to increased collaboration among Northern and Southern funding agencies to ensure greater responsiveness to local priorities.

Value 3: commitment to action

There are many expressions in use to emphasise that the ultimate goal of research should be meaningful health improvement of individuals and populations. ‘Commitment to action’ is our proposal for a third guiding value that expresses the obligation to act on knowledge obtained through research and use it in a manner that promotes health and health equity. One advantage in the current ‘product development’ approach to development and to health research may well be the insistence on demonstrable benefits – on ‘saving lives’. A further innovation would be to encourage collaborations with policy makers, donor agencies and citizen or private sector groups in a position to facilitate local implementation of research with promise. The question of who should carry the responsibility for effective action following research – researcher, research sponsors, ‘global advocates’ or host country – is an increasingly discussed issue in ethics analyses of international research.

Typically, ethical review of health research has not dealt with questions of future implementation and impact. Yet across the globe, in low as well as in high-income countries, explicit attempts have been made to more directly incorporate such discussions: from creative prior agreements to implement research findings as one of the criteria for allocation of research funding in the Netherlands (ZonMW 2009), to increasing emphasis on multi-disciplinary ‘implementation science’ at the US National Institutes of Health (NIH), to modelling the potential gains for global health that could arise from greater emphasis on research on how to deliver existing technologies more effectively versus developing new technologies (Leroy *et al.* 2007).

These are indications that ‘research for research’s sake’ is increasingly recognised as problematic. Although this is not an argument against discovery, or ‘blue sky research’, more research should be designed to be consistent with local priorities and endorsed by local authorities to increase the likelihood that the research results will inform future action. This is less of a strategy to constrain the thinking and curiosity of scientists and more of an attempt to draw those with authority and resources to implement research results closer to the scientific process.

Most global health research funding continues to be allocated through Northern competitive mechanisms, which generally do not allow budget allocations for the implementation of research findings. Research ethics guidelines and research ethics committees should continue to emphasise the importance of responsiveness to host country priorities as well as attention to foresight and planning for implementation and action. The principle of ‘complementarity’ may help make the link between research and implementation in resource-poor environments more direct and could become a recommendation or requirement from those providing national ethics oversight. Research funding agencies, which are usually restricted in their ability to fund implementation activities, could seek complementary support from foundations, bilateral aid agencies or the private sector operating in the same countries to provide material support to maximise the impact and therefore the ‘social value’ of research. Indeed, a radical reform would require research funders and programme funders (e.g., the NIH and US Agency for International Development) to work collaboratively on some projects, to participate in projects implementing specific research findings, and to study whether such implementations of research translate into public health change on the ground.

A critique of our own view: the argument for alternative sets of values

We quickly acknowledge that many scholars, practitioners and funders of global health research will not agree with our selection of values, nor will they agree with our view that these should be or will be prominent as the field moves forward. It is not, of course, that professionals in this field believe that solidarity or complementarity are unimportant – let us assume that they do – but they may disagree about the place that such analyses should have in ethical decisions on whether or not research should be allowed to proceed into the field. Such views may be motivated by values such as quality or efficiency. There may be some in the North who worry that relinquishing control of the study protocol, methods or implementation will compromise study quality, who worry that training is well and good, but ultimate authority for study procedures must remain in the North. Probably the strongest value that may be seen to conflict with what we have put forward is that of efficiency. Such a view states that requiring funders to ensure future access to successful interventions would greatly limit the number of projects that can be conducted, or that requiring additional review steps will cause ethics review to take even longer than is already the case. Our goal, obviously, is not in any way to decrease research portfolios or increase the burden of conducting research projects. However, it is arguable whether efficiency, in the long run, is maximised through current approaches. Surely, more projects are conducted when deep examination of future availability is not required. At the same time, research is conducted in order to

improve public health locally. If only a fraction of current projects have the fruits of their work actually reach their intended audience, adopting an approach of solidarity, respect for Southern innovation and action/complementarity from the beginning may, paradoxically, begin to emerge as the *efficient* approach. Imagine what a well-functioning national research environment with an efficient local ethics review process could do for enhancing the ability to conduct studies and translate them into action!

Increased linkages between assistance in health and foreign policy, the trade and political objectives of donor countries (Kickbush *et al.* 2007), and a growing reliance on partnerships with private sector organisations may compound the ethical challenges posed by global health research. These will almost certainly require new skills and knowledge on the part of researchers and research ethics committees that review research proposals to understand and navigate the complex ethical stakes involved. The urgent need to translate research into meaningful health action, especially for the disadvantaged, will demand a reinvigorated ethical scholarship and consequent ethical review practices of global health research (Lavery 2002). As research governance in low and middle-income countries becomes more explicit and institutionalised, negotiations with researchers from the ‘North’ are likely to be more assertive and may include benefit negotiations that go well beyond those traditionally defined by benefits to individual study participants.

Three values – solidarity, respect for Southern innovation, and commitment to action following research – are likely to and should inform how ethics considerations within international collaborative health research will grow and develop over the coming years. We argue that formal ethics review should expand to consider wider health and socio-economic benefits, including intellectual property rights, technology transfer, institutional capacity strengthening and other ways of sharing the benefits of research. Perhaps ethics review committees are not able to achieve these ends on their own and an alternative body with an ethics-policy mission may need to be created to take on this agenda at the national level. Partnership characteristics, fair research contracting practices and complementary funding proposals to enhance implementation may become core issues in the checklist of such committees. Increased attention to ethics review capacity development that specifically addresses these values and encourages scholarship to understand their implications and applications in not only low and middle-income countries, but also in high-income countries and research sponsoring agencies, will help to enhance the ability of future research partners to operationalise these values and engage in dialogues. Without attention to these new values and the development of appropriate guidelines, training and mandates of research ethics review and/or policy committees, ethics review may well become marginalised in the research process in the future.

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