Responsibilities in international research: a new look revisited

Solomon R Benatar,1,2 Peter A Singer3

Following promulgation of the Nuremberg code in 1947, the ethics of research on human subjects has been a challenging and often contentious topic of debate. Escalation in the use of research participants in low-income countries over recent decades (stimulated by the HIV pandemic and the need to carry out clinical trials expeditiously on large numbers of patients), has intensified the debate on the ethics of international research and led to increasing attention both to exploitation of vulnerable subjects and to considerations of how the 10:90 gap in health and medical research (ie, 90% of resources being spent on 10% of the problems) could be narrowed.

In 2000, prompted by the discussions over several years that led to the US NIH launching a capacity-building programme on research ethics for members of research ethics committees in developing countries, we advanced a ‘new look’ for the ethics of international research.1 Since then progress has been made on several fronts.

First, our ideas—considered somewhat radical and impractical at the time—have been provocatively addressed by scholars who have either contested them or advanced similar conceptions of what obligations international researchers have to research participants and communities in low-income countries before, during and after clinical trials. Second, those researchers who have been sympathetic to our ideas have either endeavoured to put these into practice or have investigated the feasibility of doing so. Third, the intractability of the 10:90 gap and the escalation of interest in global health have sensitised many to the need to amplify the discussion.

Here, we briefly review the conceptual and practical developments in international research ethics. While much conceptual progress has been made (and the concepts are now appearing in practice), we advocate for intensification of endeavours to link research to improvements in healthcare and health and to build the capacity and independence of local researchers.

Intensification of controversies in international research ethics began with Marcia Angell’s vehement criticism in 1997 of exploitation and double standards in the placebo-controlled studies undertaken to develop rapidly an affordable and effective method of preventing mother to child transmission of HIV in developing countries.2 3

Since then debates on ethical aspects of international research ethics have progressed from assertions as to what is ethical in research to: (a) well-argued consideration of what the ‘standard of care’ (SOC) should be1 4 5 and how this could be ratcheted upwards through the development of strategic alliances and partnerships with other stakeholders;6 (b) the development of such concepts as fair benefits7 and ancillary care;7 8 9 10 (c) encouragement of community engagement11 and a broader understanding of what it means to do research on poor people from other cultures12 13; and (d) how, using such concepts, research could be linked to improved healthcare and greater social justice.14–17

Underpinning all these debates has been an intense controversy on what constitutes exploitation in international clinical research.18 Instead of attempting here to summarise the complex philosophical debate on exploitation we refer readers to a simple description that provides practical guidance.19 We also acknowledge that escalating demands on researchers for additional healthcare benefits in association with their research have been constrained by the need to set limits in order to avoid hampering research,19 and that research in developing countries may contribute to the brain drain.20

It was dissatisfaction with a SOC defined merely in relation to the drug used in the control arm of a clinical trial that led to our proposal almost a decade ago for a broader understanding of SOC through a new look at international research ethics linked more closely to health benefits and with enhanced community engagement.1 Our purpose was also to draw attention to the extent to which vulnerable populations benefited very little from much of the research in which they participated. In addition, we promoted the idea that if researchers understood that ongoing poverty and poor health in many countries were related to powerful system forces in which they were indirectly implicated,12 this could help reshape the ethics and practice of research by linking research to improved healthcare through strategic alliances with sponsors, and cooperative ventures with local Ministries of Health and philanthropists.1 21

Other significant simultaneous endeavours to avoid exploitation included development of the concepts of fair benefits5 and ancillary care.7–10 Within the framework developed for fair benefits and ancillary care the responsibility of researchers to provide such additional care is determined by the independently variable strength of four components of the underlying relationship with participants. Consideration of these components provides a range of possible pre-trial, in trial and post-trial benefits, the mix of which could be agreed on through negotiations between researchers and participants. While these approaches are of value, they have been criticised as being focused on micro-conceptions of exploitation and thus limited to a thin conception of justice (procedural in nature) to be applied on a case-by-case basis and without taking account of background conditions of injustice.22

A necessary, but not sufficient way to begin to rectify the latter shortcoming is through fuller engagement with communities. In seeking to be more understanding of local conditions, research groups undertaking long-term planning for HIV microbicide and vaccine trials have led the way in achieving more inclusiveness by establishing trusting working relationships with communities and negotiating standards of care or fair benefits that exceed those set in the past. An excellent example is the Vunindela clinical research centre, part of CAPRISA’s Women and AIDS Programme based at the University of KwaZulu Natal, where a longstanding relationship with the local community is the precondition of, and basis for all research conducted in true

1Bioethics Centre, University of Cape Town, Observatory, South Africa
2Dalla Lana School of Public Health, Joint Centre for Bioethics, University of Toronto, Toronto, Ontario, Canada
3McLaughlin-Rotman Centre for Global Health, University Health Network and University of Toronto, MaRS Centre, Toronto, Ontario, Canada

Correspondence to Professor Solomon R Benatar, Bioethics Centre, University of Cape Town, Anzio Road, Observatory, 7925, South Africa; solomon.benatar@uct.ac.za

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Despite the potential benefits of community-based research, there have been significant ethical concerns and dilemmas. While some community advisory boards have been established, their effectiveness is often limited by various factors. Community participation in research requires a careful balance between the benefits for the community and the potential risks to individual participants. 

One of the key ethical issues in community research is the participation of vulnerable populations. This can include individuals who are marginalized or have limited access to healthcare. The use of local research teams can help to address these issues by ensuring that the research is conducted in a culturally sensitive and appropriate manner. However, this also requires a commitment to improving the health and well-being of these communities, not just collecting data.

In the context of international research, there is a need to ensure that the benefits of research are shared fairly. This can be achieved through mechanisms such as benefit-sharing agreements, where financial benefits from the research are returned to the communities that contributed to it. Such agreements can help to address the ethical dilemma of the global health research system, where research is often conducted in poor countries with minimal benefits to the local communities.

Another important ethical issue in community research is the participation of vulnerable populations. This can include individuals who are marginalized or have limited access to healthcare. The use of local research teams can help to address these issues by ensuring that the research is conducted in a culturally sensitive and appropriate manner. However, this also requires a commitment to improving the health and well-being of these communities, not just collecting data.

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researchers to solve their own problems.59
While we do not endorse some of the claims made by the Indonesians, the argument that Indonesia will not share samples since they cannot be guaranteed access to any resulting vaccine, highlights the need to pay attention to issues of research self-sufficiency in the South.

Over and above attention to the much neglected social determinants of health, improvements in healthcare in developing countries can be achieved through advances in medical knowledge and in the ethics of how these advances are applied. Progress, albeit slow and inadequate, is indeed being made on both conceptual and practical fronts as illustrated with five examples40–47

These amplificatory approaches open up ambitious opportunities to replace a narrow research ethics framework, focused on protection of vulnerable participants, with a broader framework that could emancipate them and their communities, improve inadequate health-care systems, promote social justice, and foster development. In 2001 we expressed the view that strengthening ethics capacity would advance the cause of ethical research in the world far more than another revision of the Helsinki Declaration, and ultimately, by facilitating health research, help redress one of the greatest ethical challenges in the world—the unconscionable inequities in global health.45 Promoting a participatory framework that, through dialogue and cooperation uplifts people from dependence and facilitates self-sufficiency, could ensure that people are being helped from their own perspectives in addition to those of researchers.13 21 49

We suggest that the most important value driving this new paradigm, and underpinning these two principles, is ‘solidarity’, which can be defined as attitudes and determination to work for the common good across the globe in an era when interdependence is greater than ever and in which progress should be defined as enhancing capabilities and social justice rather than sustaining dependency. Strengthening solidarity requires an understanding of the range of social relations within different cultures and recognition of how much different people have in common, rather than how they differ.13 36

The two principles we promote here build on and augment our previous arguments for the need to expand the discourse on international research ethics beyond interpersonal ethics and civil and political rights, (based on the ideas of individual rights and freedom) to the ethics of how institutions operate and interact, the ethics of public health and social and economic rights (based on concern for equity) and the ethics of international relations (based on solidarity) that affect whole populations.36

Achieving the goals of these three principles in an interdependent world, where the poorest suffer most from systemic forces adversely affecting health, will need to be underpinned by promotion and achievement of solidarity with all as global citizens, and political efforts to move towards new paradigms of thinking and action that could begin to narrow widening economic disparities that threaten both our humanity and global security.36 38 50 It is important to note that our proposals, and the central value of solidarity underpinning them, are consistent with accountable private sector engagement in global health.

Since we wrote our original article a decade ago, significant conceptual progress has been made, but less translation into practice than we had hoped. We remain cautiously optimistic that our proposals for research to be linked to improvements in health and sustainable capacity building in research—based on an overarching value of solidarity—could contribute to an ongoing paradigm shift in thinking from research as merely a means of acquiring new knowledge, towards a much broader goal encompassing beneficial impacts on health, healthcare delivery and independence in poor countries.

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