

Occasional essay

Humanitarian aid and medical research: an illusion of dichotomy in international health

Daniel E. Roth

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If you're a physician and you say that you're heading to the tropics for a few weeks to offer your medical expertise to the members of a remote tribe, people are likely to smile and wish you the best in your altruistic pursuit. If, instead, you say that those same tribespeople are going to be participants in medical research you're conducting, the reaction may not be one of smiles but of raised eyebrows. International work in health care is generally looked upon favourably, but fitting biomedical research into the picture is another matter.

Let's say a group of Canadian family physicians takes several box-loads of donated antibiotics and anti-inflammatory drugs to an isolated community in a developing country. Over the 3 weeks they are there, they go home to home, carrying out medical check-ups and handing out drugs when indicated. Access to treatment is normally limited in this community by the cost of medications and the distances that people have to travel to obtain care. The doctors leave with their boxes successfully emptied. There are few opportunities for follow-up exams, and no means of assuring compliance with medication. However, pill bottles in hand, the villagers express their gratitude for the foreign doctors' visit and cling to the hope (conveyed by a local health promoter who understands some English) that the doctors will perhaps return the same time next year.

Let's also imagine that some Canadian researchers conduct an epidemiologic study that undertakes passive and active surveillance of malaria in a lowland region of a tropical country. Diagnosis and treatment are free in this particular country, but many people in remote areas use these services infrequently because of barriers such as distance and a lack of awareness of the national malaria program. The treatment that the investigators provide is already available, although the study doctors (local physicians hired by the foreign researchers) provide, in addition, regular physical exams. Their effort to detect every case of *Plasmodium vivax* or *P. falciparum* infection using regular home-to-home visits over the course of a year results in access to a diagnostic service that many people would not seek out on their own. Foreign medical students or residents paired with lo-

cal health care workers act as the study's fieldworkers; they facilitate treatment access for participants in need and monitor treatment compliance. The only extra risk or discomfort associated with participation pertains to the extra sample of blood that the fieldworkers request periodically. Also, the villagers are sometimes frustrated when the doctors inform them of possible health problems, only to indicate that they cannot give them medications apart from the malaria drugs or other medicines provided free by the government. Still, they know that they are being cared for better than usual (often, the doctors or fieldworkers ultimately do find a way to provide free medications or hospital access). As well, many people feel some satisfaction that their participation will help doctors learn about malaria so that the disease can be better prevented in the future.

Both projects provide some benefit to the participants and their communities, but health care workers involved in either type of project need to be honest about their motives and their capacity to bring about change. In the absence of peace, shelter, clean water, food, effective waste disposal and, perhaps, immunizations and basic maternity care, medical doctors can't make an ounce of impact on the actual health of a population. The fact is that no more than a barely sustainable improvement is likely to be achieved by either of the 2 efforts. Both may, however, be beneficial in increasing contact with health care professionals and raising awareness of certain health issues in the community.

The research study would have had to pass through at least 2 institutional review boards (IRBs), one at the North American university to which the investigators are affiliated, the other in the local nongovernmental organization sponsoring the research. Did the charitable project require the same type of approval? Did it also require formal expressions of informed consent, as was sought from the participants in the research study? Probably not. It was charity, to be sure. But the assumption that such work is inherently more ethical than a research study is questionable. Doing a research study and handing out free drugs are far more alike in a developing country than they might be in an affluent one. Both put people in contact with interventions

and their associated risks that they would not normally encounter. Ethical principles may be universal, but standards of medical care certainly are not.¹

Sustainability and equality in health care access are generally not high on the list of research ethics problems in countries like Canada, where most clinical studies offer treatments or procedures for which there is a universally accessible alternative. In developing countries, alternatives may be nonexistent, and the experimental intervention may not be sustainable. But it is also true that when the charity doctors leave their adopted community, or when their drugs have run out, the community's access to medications drops to the preintervention level. In the short time they were there, the doctors will have made only superficial contact with local health care providers, leaving many villagers with the impression that good Western medicine equals the dispensing of drugs. On the other hand, after the researchers in our example have completed their study, community members may no longer have the advantage of physician home visits, yet actual access to malaria diagnosis and treatment remains relatively unchanged. Perhaps the study will also have raised awareness of the free malaria care that *is* available. Local health care workers may have benefitted from their interactions with doctors and medical students from other countries. And, not least, the researchers may have gained valuable information about incidence and transmission patterns that may aid in the development of more effective control measures.

Of course, not all research studies have such clearly definable benefits to participants or are as easily compared to charitable missions. Some studies have spurred furious debate, as in the case of recent placebo-controlled antiretroviral studies for perinatal HIV transmission in Africa.² Studies in developing countries commonly raise questions about the motives for conducting such research outside the West³ or the justification for using an experimental method that might not be acceptable at home.⁴ Many humanitarian medical aid efforts are, likewise, not represented by our first example and provide much more comprehensive and sustainable health care than the group of well-intentioned family physicians in our example.

Nevertheless, we might question the assumption of an ethical dichotomy between research studies and charitable medical interventions in developing countries. It is wrong to assume that research studies in developing regions are ethically precarious simply because they involve data collection. It is easy to accuse medical missions of not always being beneficial. It should also be understood that medical research is not necessarily exploitative.

Not all research projects in the developing world are like the controversial studies that give placebos to HIV-infected pregnant women when effective means of reducing viral transmission to newborns have already been established. Most original research projects involving human subjects in developing countries are surveys, observational studies, epidemiologic explorations or community-based longitudinal

analyses of baseline health parameters. Such research projects are aimed primarily at acquiring a clearer understanding of population health in developing regions. These types of studies are never free of ethical complexity. However, they can benefit participants in ways that are well-defined, clearly explained and even sustainable, without raising false hopes of greatly improved medical care in the immediate future.

The examples we have considered also point to the powerful role of IRBs in the conduct of collaborative projects overseas. Increasingly stringent requirements for research protocol development and informed consent, not to mention steep fines for transgressions, are being established.⁵ A protocol review process replete with overwhelming administration obstacles (or at least the perception of such barriers) creates a risk that investigators will disproportionately abandon their research in disadvantaged regions, where logistics and feasibility issues are already at a maximum. We should not be fooled into believing that bureaucratic zealousness implies a system that more vigilantly protects human rights. The complexities of the process might even distract us from the real reasons why we concern ourselves with research ethics in the first place.

IRBs should focus on developing specialized review processes for international collaborative projects to address the specific implications of their stipulations on health research in developing countries. They should train selected personnel to look at the issues that matter most in international health and to work as consultants to support investigators who study non-Western health problems. Although such a suggestion may invoke the fear of double standards in international bioethics,⁶ these changes would actually strengthen the crosscultural application of universal ethical standards. For example, written informed consent forms required by IRBs increasingly involve sophisticated and legalistic phrasing that is likely to be a barrier to the informed decision-making of technically inexperienced or illiterate participants. Greater emphasis could be placed on exploring alternatives to standard informed consent procedures for studies in developing countries. Of course, any such modifications need to coincide with a move toward greater collaboration with local ethics committees of the countries in which the studies are carried out.⁷

A priority in international health should be to encourage investigators from affluent countries to continue biomedical research into the problems that afflict developing countries. Just as free medications are not always equivalent to good health care, Western investigators in developing countries are not necessarily cultural imperialists. Rejecting such assumptions will permit us to demonstrate that both charitable interventions and clinical research have their place in international development strategies. We are capable of conducting both in a manner that will aid our neighbours and, ultimately, help to reduce global inequities.

Mr. Roth is a third-year medical student at the University of British Columbia, Faculty of Medicine, Vancouver, BC.

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Correspondence to: Mr. Daniel Roth, 4274 11th Ave. W, Vancouver BC V6R 2L7; daniel_e_roth@hotmail.com

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