

Accountability and publication

The Declaration of Helsinki at present requires that research not conducted according to its provisions should not be published. Research that does meet its provisions, however, is customarily published without comment. The intention here is commendable: to ensure that researchers do not gain any reward for conducting research that is unethical. However, this practice creates the impression (and is probably based on the assumption) that the issue is 'black-and-white': a research project is either ethical or not, and either way, there is no particular need for anyone to comment. But given the complexities of conducting research in developing countries, described at length here, this view is really somewhat inadequate.

The publication of research conducted in developing countries or on vulnerable populations should always be accompanied by a discussion of the relevant ethical issues. Questions of ethics will inevitably arise in such research, and it is appropriate to require evidence that researchers have given explicit and careful consideration to them, in just the same way that explicit description and justification of the scientific methodology of the research project is required. This can never be a matter of simply stating that the relevant guidelines have been followed. Whatever set of guidelines is ultimately adopted to govern medical research in this setting will necessarily be cast in general terms, and will require interpretation and application to the local setting. The sorts of ethical tensions described above will always need to be worked through, and evaluation of the reasoning behind the chosen resolution ought to part of the part of the process of peer review and publication.

Journal editors, then, should routinely require that every paper reporting the results of medical research in this context contain a section on ethical methodology. This would give the issue much more prominence than the occasional refusal to publish, and in addition would help to build up a body of expertise in dealing with ethically complex research settings that

is in the public domain and, thus, widely accessible. It would also avoid the problem, emphasized by the controversy over the vertical transmission trials, that post hoc justifications for ethically contentious research are often unconvincing and do little to allay concerns. Editors would naturally reserve the right to refuse to publish research that they believed to be egregiously unethical, but this would remain a rare event.

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Global health problems require global solutions, and public–private partnerships are increasingly called on to provide these solutions. But although such partnerships may be able to produce the desired outcome, they also bring their own problems. A first-of-its kind workshop in April, hosted by the Harvard School of Public Health and the Global Health Council, examined the organizational and ethical challenges of partnerships, and ways to address them.

Public–private partnerships for public health

Recently, many organizations in public health have declared partnerships with private-sector organizations. Academic institutions have created partnerships with private companies for specific research activities, such as the development of new treatment therapies. The World Bank has announced that it will encourage partnerships as part of its comprehensive development framework. The new director-general of the World Health Organization (WHO) has stated that she will promote partnerships with the private sector. Non-governmental organizations have established relationships with private for-profit firms. Private foundations are supporting and joining partnerships, exemplified by the surge of activities from the Bill and Melinda Gates Foundation. Similar trends are apparent for many international health issues, particularly in efforts to expand access to drugs and vaccines^{1–4}.

The trend is clear and widespread. But why has the issue of public–private partnerships become so prominent on the international

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policy agenda at this time? One reason is that new public health problems are being

pushed onto the international policy agenda by non-governmental organizations that have gained influence in the past two decades. These problems often involve issues of health equity between the rich and the poor of the world. Médecins sans Frontières, for example, has helped focus global attention on access to essential drugs in poor countries. Neither public nor private organizations are capable of resolving such problems on their own. Traditional public health groups are confronted by limited financial resources, complex social and behavioral problems, rapid disease transmission across national boundaries and reduced state responsibilities. At the same time, private for-profit organizations have come to recognize the importance of public health goals for their immediate and long-term objectives, and to accept a broader view of social responsibility as part of the corporate mandate. Pharmaceutical companies, for example, have become involved in a number of high-visibility drug

Table 1 Philanthropic drug donation programs

Drug Company	Drug and target disease(s)	Public health goal	Program manager	Major partners ^a
Merck	Mectizan:	Elimination of onchocerciasis (and lymphatic filariasis in Africa)	Mectizan Donation Program, in the Task Force for Child Survival & Development (Carter Center)	Merck
	Onchocerciasis Lymphatic filariasis ^b			Task Force for Child Survival & Development WHO African Programme for Onchocerciasis Control
Pfizer	Zithromax:	Elimination of blinding trachoma	International Trachoma Initiative	Pfizer
	Trachoma			Edna McConnell Clark Foundation WHO
SmithKline Beecham	Albendazole:	Elimination of lymphatic filariasis	WHO	SmithKline Beecham
	Lymphatic filariasis			WHO
GlaxoWellcome	Malarone:	Control of drug-resistant malaria	Task Force for Child Survival & Development (Carter Center)	GlaxoWellcome
	Malaria			Task Force for Child Survival & Development WHO—Roll Back Malaria

^aIn each case, many more partners are involved than are shown on these illustrative lists. ^bAn additional commitment by Merck. Source: ref. 5.

donation programs based on partnerships (Table 1). In short, both public and private participants are being driven towards each other, with some amount of uneasiness, to accomplish core objectives.

Yet we know little about the conditions when partnerships succeed. Partnerships can have positive and innovative consequences for well-defined public health goals, and they can create powerful mechanisms for addressing difficult problems by leveraging the ideas, resources and expertise of different partners. At the same time, the rules of the game for public-private partnerships are fluid and ambiguous, and constructing an effective partnership requires substantial effort and risk, as no single formula exists. How do organizations with different values, interests and worldviews come together to address and resolve essential public health issues? What are the criteria for evaluating the success of public-private partnerships? Who sets those criteria, and with what kinds of accountability and transparency?

In early April this year, a small workshop was organized to examine public-private partnerships in public health. The meeting was co-sponsored by the Harvard School of Public Health and the Global Health Council. This commentary summarizes the main issues examined and some of the lessons learned, as reflected in the discussion and the papers presented at the workshop. Papers from the workshop are available at the Harvard School of Public Health website (www.hsph.harvard.edu/partnerships/).

Description of partnerships

What is a public-private partnership? Although views differ, a good working definition includes three points. First, these partnerships involve at least one private for-profit organization with at least one not-for-profit organization. Second, the core partners provide a joint sharing of efforts and of benefits. Finally, partnerships in public health are committed to the creation of social value (improved health), especially for disadvantaged populations. But the work-

shop also identified ambiguities and conflicts in the definition of public-private partnerships, with important implications.

Some participants raised questions about the nature of public and private, and the nature of partners. What is public? What is private? Who is a partner, and who should decide? For example, are the recipients of a public-private drug donation program 'partners'? Should the recipients participate in the design, implementation and oversight of a public-private partnership? If so, in what ways? What kind of governance structure could allow the participation of recipients, to promote accountability but still assure effectiveness?

Partnerships thus involve both 'big p' Partners, who assume core responsibilities for the joint enterprise, and 'little p' partners, whose participation is necessary for successful implementation. Specific cases demonstrate the diversity of groups within a single partnership. For example, the International Trachoma Initiative (ITI) involves two core partners: Pfizer (a private for-profit pharmaceutical company) and the Edna McConnell Clark Foundation (a private foundation), plus additional partners, including national governments, other private foundations and non-governmental organizations (such as Helen Keller International), and the WHO represented on the Trachoma Expert Committee⁶.

Motives for initiating partnerships

Until recently, the public and for-profit private sectors often viewed each other with "antagonism, suspicion, and confrontation," as reported by Adetokunbo Lucas⁵. These tensions are now being supplanted by increasing rapprochement and positive encouragement for public-private partnerships in health. According to Lucas, a chief factor encouraging these partnerships is that neither side can achieve its specific goals alone; collaboration is unavoidable.

The paper by Lucas discusses partnerships initiated by the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) (where he served as director,

1976–1986). “TDR’s mandate was to discover and develop new and improved technologies for the control of tropical diseases affecting the poor in developing countries. Neither the public sector nor the private sector working alone was able to achieve this goal”⁵. The case of TDR shows that the public sector can work with the private sector in ways that advance public interest.

Lucas also presents four cases of philanthropic drug donation programs (Table 1). These efforts by pharmaceutical companies require clearly defined public health goals, involve several components (beyond the product) in a strategic plan for addressing the problem and depend on the collaborative efforts of several partners. These partnerships were pursued, according to Lucas, because there were no viable alternatives to solve the problems of drug development and distribution. Moreover, in cases in which partnerships have not developed, potential health gains have not been achieved in developing countries. One example is the drug praziquantel, which was developed for schistosomiasis⁷. Although public–private collaboration occurred during the development phase of praziquantel, an effective partnership for its distribution did not emerge, substantially limiting the number of people in developing countries who could benefit from this pharmaceutical product.

But considerable skepticism exists about the motives of private firms that engage in partnerships, even when the efforts have substantial public health benefits. Private firms are assumed to be seeking future profits and markets through partnerships; or to be seeking control over the agendas of international organizations; or to be seeking tax deductions for financial reasons; or to be seeking new products, subsidized by public funds, to be used for private sale and profits. These assumptions reflect the profound cultural gap between the private and public sectors, as well as real problems that require serious ethical consideration, as discussed below.

Processes for creating partnerships

“Cross-sector partnerships do not happen; they are built”⁶. Constructing an effective partnership among diverse organizations is hard work. The paper by Diana Barrett, James Austin and Sheila McCarthy⁶ introduces a general framework on the processes for creating partnerships, illustrated through an analysis of the ITI. Establishing the ITI involved the two core partners in “a highly integrative relationship of strategic importance to both organizations with high levels of engagement and managerial complexity”⁶. In this case, as in others, creating an effective partnership was more complicated than initially anticipated, because of the challenges in bringing together the core partners and in structuring relationships with other groups involved.

Partnerships confront seven organizational challenges—what Austin calls “the seven c’s of strategic collaboration” (see box)⁸. Navigating these “seven c’s” is not easy. Of particular importance is the challenge of creating value. To assure a sustainable collaboration, the value created must be useful to society, and value must flow to all core partners. In addition, creating a partnership is a continual learning process, with the potential for unexpected lessons. For example, for the ITI, the partnership on trachoma led the Clark Foundation to rethink its core work in philanthropy, to view its activities more in the form of long-term investments than short-term grants.

The Mectizan Donation Program is often considered one of the most successful partnerships so far—a partnership created by Merck and the Task Force for Child Survival and Development, a non-governmental organization. The paper by Laura Frost, Michael R. Reich and Tomoko Fujisaki⁹ reviews the history of Merck’s decision to develop and donate ivermectin for treatment of onchocerciasis and

The seven c’s of strategic collaboration

- Clarity of purpose
- Congruency of mission, strategy, and values
- Creation of value
- Connection with purpose and people
- Communication between partners
- Continual learning
- Commitment to the partnership

Source: ref. 8.

the processes for initiating this partnership. Although Merck and the WHO collaborated on the development of this drug, they did not create a formal partnership for the distribution. Instead, Merck worked with the task force to establish a new entity. Merck and the WHO were unable to agree on shared goals and were unable to create a relationship of trust—both of which are necessary conditions for a partnership—although the WHO has provided continuing technical advice to the partnership’s expert committee. The problems in this case reflect broader difficulties that the WHO has experienced in creating partnerships. These difficulties are attributed to the WHO’s organizational culture, resistance to information sharing and obstacles to network-building^{10,11}. WHO is now seeking to address these problems, and seems more open to partnerships with the private sector.

Merck and the task force managed to construct a successful partnership through their use of “boundary objects,” allowing them to span their diverse social worlds, decide on shared goals and create a relationship of trust. This partnership has been successful in terms of the benefits provided to recipients (a total of 132 million treatments approved between 1988 and 1999), the positive support provided to the partnership by the international community for onchocerciasis control, the enhanced public images of both partners (Merck and the task force), the reduced human suffering among persons affected by onchocerciasis and the persistence of the partnership for more than a decade. Whether the donation program will interrupt transmission of the disease remains to be seen, since Mectizan does not kill the adult worm in humans.

Unfortunately, the history of efforts to collaborate on new vaccine development shows how problems in the processes of creating partnerships can lead to organizational demise. The problems in this case involved high levels of distrust between the public and private sectors, and corrosive competition among international agencies. William Muraskin examines the history of the Children’s Vaccine Initiative (CVI) in his paper¹². He shows how individuals, international agencies and private firms interacted first to design the CVI and then to demolish it. He also demonstrates how technical analysis of the international vaccine market, undertaken for UNICEF by a private consulting firm, changed the terms of the debate and enhanced understanding across the public–private divide.

In reflecting on the birth and death of the CVI, Muraskin emphasizes the public sector’s need to gain a better understanding of the private sector. “For the private sector to successfully cooperate with the public sector it is necessary for the latter to understand and accept the basic legitimacy of private enterprise and the profit motive that drives it; that is very hard for many public health officials to do when children are sick and dying from the lack of money to buy vaccines.” He also emphasizes the need for industry to meet the public sector ‘halfway’ and recognize the public interests in vaccines. “If there are no industry leaders visionary enough to balance public and private concerns, then bridges cannot be built.”

These lessons will be important for the new partnership on

vaccines, known as the Global Alliance for Vaccines and Immunization, to consider and learn from; and for ongoing discussions about the idea of creating a purchase fund for an HIV vaccine. The fund would provide financial reward for the pharmaceutical industry's efforts and enable vaccine distribution to the world's poor.

Ethics of partnerships

Underlying the discussion of partnerships (and debates over definitions, motives, and processes) are basic questions of ethics. Which partnerships are good ones, and how do you know? Who has what kind of social responsibility, and why? How do you assure accountability of partnerships, and to whom? How should partnerships relate to international health agencies, such as the WHO?

There is growing agreement that partnerships can be pivotal in fulfilling our moral obligations to improve the health status of people in poor countries, as argued in the paper by Marc J. Roberts, A.G. Breitenstein and Clement S. Roberts¹³. They maintain that people in rich countries have a moral obligation to help people in poor countries. They further contend that private corporations have social responsibilities and that managers within firms have moral obligations. In their view, global health companies have a special obligation to help, because of their competence, resources, and expertise—their capacity to make a substantial contribution to the health of poor people. Finally, they believe that partnerships can have an important function precisely because they can bring the creative potential of multiple perspectives to bear on essential problems.

An ethical assessment of public–private partnerships depends partly on their consequences. This paper also provides a hopeful view, drawing on the idea of “social capital¹⁴,” which explains the capacity of some societies to solve collective problems by the greater accumulation of trust and connection among their members. Public–private partnerships thus may represent a form of international social capital, as new problem-solving institutions that can work creatively and flexibly outside the existing bureaucratic framework.

Others are less sanguine about the ethical basis of partnerships. Lucas suggests that the WHO should develop guidelines for philanthropic drug donation programs (in addition to the current guidelines for drug donations¹⁵). The new guidelines would seek to assure companies' long-term commitment, promote effective management of the program and collaboration with partners, and guard against real and apparent conflicts of interest⁵. The WHO is now addressing the ethical issues of partnerships through its *Guidelines on Interaction with Commercial Enterprises*¹⁶. This document, however, has generated criticism from some activist groups for not providing sufficient oversight to reduce conflicts of interest¹⁷.

Kent Buse and Gill Walt, in their provocative paper, express serious concerns about the effects and potential effects of partnerships on the United Nations (UN) system¹⁸. They state that partnerships “often circumvent the organizations of the UN” and “may even threaten ... unique characteristics of the UN.” In particular, they are worried about the accountability of partnerships, their effect on global standards and norms decided by UN agencies, and the potential negative effect on global inequities (by focusing on easily achievable goals rather than more difficult problems). To address these points, they recommend that a regulatory framework be established to “differentiate between acceptable and unacceptable” partnerships.

Buse and Walt view the UN system as accomplishing essential functions of global governance in health, and call for efforts to strengthen the coordination and protection of these functions. This

perspective seeks to include all partnerships within the UN system, through mechanisms of regulation, to assure UN control of the agenda in international health. A contrasting viewpoint considers the UN system inherently fragmented and competitive among its different agencies, and calls for public–private partnerships to fill in gaps not covered by the UN system. This perspective considers it counterproductive to seek a UN system that would try to do everything as being too centralized, controlling and ineffective.

This debate reflects fundamental questions about the kind of global health governance that is most desirable for international health: centralized versus decentralized control, international regulation versus other forms of intervention, mechanisms to assure the accountability of corporations and international agencies, and the compatibility of the core values of public and private sectors.

For now, it seems certain that the trend in public–private partnerships will continue, and that the kinds of partnerships will diversify. One example is the announcement in mid-May that five pharmaceutical companies will collaborate with five international agencies to find ways (including significant price discounts for anti-AIDS drugs) to accelerate access to HIV/AIDS-related care and treatment in poor countries. A fundamental dilemma of such partnerships is to assure their accountability without suppressing their creative influence, entrepreneurial spirit or potential effect on improving the health of poor people in developing countries. Resolving this dilemma will require the participation of all groups, including the intended beneficiaries, to expand mutual understanding and establish effective institutions that span the public–private divide.

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