Toward Ethical Review of Health System Transformations

Efforts to transform health systems constitute social experiments on a population. Like clinical research, they deploy measures that are unproven in the context of the reform, and they often impose significant risks on some people in order to achieve a social goal: the improvement of health delivery.

The rationale for proactively evaluating clinical experimentation on human subjects also applies to these social experiments. We used the "benchmarks of fairness" methodology to illustrate the elements such an evidence-based review should encompass, leaving open the question of who should perform it. The review must include the ethical objectives of reform, namely, an integrated approach to equity, accountability, and efficiency; the fit between measures taken and these objectives; and the governance of the reform. (*Am J Public Health*. 2006;96:447–451. doi:10.2105/AJPH.2005.065706)

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EFFORTS TO TRANSFORM health systems are social experiments that require ethical and scientific review before they are implemented and ethical and scientific monitoring and evaluation afterwards. This thesis may at first seem perverse. Health system reforms are not intended as research aimed toward new knowledge; instead they aim to improve population health through better delivery of medical and public health services. Reform of some sort is often not discretionary, as is some clinical research, but obligatory because of serious failings in the system.

Nevertheless, reforms have important similarities to clinical research. They often deploy measures of unknown efficacy. They may impose health risks on subgroups in the population much greater than those involved in typical clinical research. Like clinical research, reforms trade on the credibility of science and the medical or public health establishment. Both raise issues about governance, including the control people can exercise over what happens to them in the pursuit of societal goals. Finally, both aim at desirable social goals—new knowledge or improved health delivery. Review should not make their pursuit too difficult, especially in light of the urgency of some reforms.

Domestic and international examples of social experiments conducted without review abound. Attempts to control costs in the US health care system aim at changing either physician or patient behavior in using health services. Two decades ago, diagnosis-related groups were introduced as a way of shortening hospital stays for Medicare patients without review of the risks imposed, although many physicians and hospitals protested that patients discharged too early could incur great risks.[1,2] During the 1980s and 1990s, capitation and other physician reimbursement schemes were introduced to change the amount and type of services physicians ordered for patients, again without review of the risks imposed on patients or empirical knowledge of the actual effects of these mechanisms, despite complaints about the risks of undertreatment.[3] Currently, insurers aiming to change patients' demand for services are introducing novel deductible structures. Despite warnings about risks to some patients and to insurance markets themselves,[4] there is no provision for ethical or scientific review.

Social experiments without ethical review are common in developing countries, where reforms are often initiated by external agents, such as the International Monetary Fund or World Bank, which offer loans only if certain measures are put into place. A classic example from the 1980s and 1990s is the requirement that systems in developing countries introduce user fees as a way of introducing new resources into underfunded public systems. Despite exemption mechanisms for the very poor, user fees in many places decreased access and created opportunities for corruption.[5] Similarly, many countries were induced to seek efficiency by expanding their private health sector. Unfortunately, weak powers of state regulation led to a health sector of questionable quality that pulled personnel from the public system and undermined equity in various ways.[6]

Decentralization was advocated as a way of improving local control over use of resources and making systems more responsive to local needs, but in many places, implementation has created serious problems for the delivery of public health services.[7] These social experiments now raise special ethical problems for international efforts to scale up antiretroviral treatments in countries with high prevalence of HIV/AIDS: user fees are barriers to access, personnel drawn to private clinics are not available for public delivery systems, and weakened public health structures make delivery of antiretroviral treatments more difficult.[8–10] Reforms may thus not only fail to accomplish their avowed goals, but their long-lasting effects can make it more difficult to implement better reforms.

The ethical and scientific review of experiments—whether clinical or social—should include assessment of their goals and expected outcomes, the appropriateness of their design to their goals, and their governance. A first step toward such review is development of an ethical framework for these substantive issues, although this leaves unexplored the exact institutional context for applying the framework.

JUSTIFYING ETHICAL REVIEW

Experiments on human subjects require proactive ethical and scientific review to ensure that they meet standards set by domestic[11] and international[12,13] commissions and accords. The review assesses the rationale for the research and the proposed experimental design as well as compliance with principles governing how subjects consent to the experiments and are treated while in them. Leave aside the mechanisms for such review (institutional review boards), since they are probably inappropriate for health system reforms, and focus instead on why some form of review is needed. Research generally imposes risks on relatively small groups of subjects in order to achieve a societal goal advancing knowledge and technology, without directly benefiting those subjects. It is generally ethically problematic when we deliberately benefit some at the expense of others.

Ethical review of clinical research is required from diverse ethical perspectives. People such as utilitarians who believe that the rightness of an action is determined solely by its consequences require a careful assessment of the effects of imposing risks on some in order to produce benefits for society. Are the risks minimized to the greatest extent possible? Is the experiment well enough designed to achieve its objective, or are there other designs more likely to produce the knowledge with less risk? Do we preserve the trust people have in scientists or science by making sure they do not perceive themselves as manipulated, deceived, or exploited? Ensuring informed voluntary consent is one way of minimizing those perceptions in the case of clinical research.

People who believe that the right thing to do is not simply determined by assessing the consequences of an action also have good reason to conduct proactive ethical review. Some people, agreeing with Kant,[14] believe there is a fundamental ethical rule that we should not use people merely as means to an end. The mere fact that knowledge is likely to follow from imposing risks on research subjects does not justify the research, even if the risks are minimized and the knowledge gains are significant. Unless those at risk make it their own goal or end to pursue that knowledge by giving informed consent to the risks, we would be using them merely as means to our societal goal of gaining knowledge.

Health system reforms often use unproven measures intended to improve the delivery of medical or public health services to a population. These measures impose risks on population subgroups. For example, decentralization of health systems risks undermining the delivery of immunizations or tuberculosis treatments by shifting personnel who are expert in centralized programs to positions where they cannot carry on the work or by substituting local priorities at the expense of important national programs. Successful reforms teach us that certain measures work. Unsuccessful reforms teach us that some measures do not work or were not properly implemented. Although knowledge may not be the main goal of reforms, it is a desired consequence that we acquire by imposing risks on our fellow citizens.

If we have good reason to carry out an ethical review of the scientific design of clinical experiments and to insist that people involved in them are not merely "guinea pigs" but appropriately govern their own actions, then we have comparable reason to review proactively efforts to transform health systems and to monitor and evaluate their effects so that we can minimize the harms they may impose. Labeling health system reforms as "operations" or "managerial prerogatives," not social experiments, ignores the fact that we often lack adequate knowledge about the safety and efficacy of reforms, which is the rationale for conducting clinical trials.

One objection to the analogy between clinical and social experiments is that mechanisms other than proactive ethical reviews already ensure public accountability for harmful decisions in health sector transformation. The public can hold domestic officials accountable for even internationally instigated reforms, through democratic processes or through tort law—where the law is developed and enforceable—or even through negative market effects, if private sector reforms prove harmful. Ethical review is an unnecessary extra layer of bureaucratic interference with necessary reforms that are already difficult to initiate.

Where democratic process and tort law are well developed, they work after the fact to hold authorities accountable for harms imposed. Where effective, they offer an incentive to avoid mistaken and dangerous reforms. Unfortunately, they are often not available or effective in the developing countries where externally imposed social experiments are most common. Even where these after-the-fact protections are in place, it is better to equip authorities with a tool, such as a framework for ethical and scientific review, that helps them to avoid problems before they are created.

ETHICAL EVALUATION OF GOALS AND OUTCOMES

In the ethical and scientific review of clinical research, a key question is whether there is a plausible scientific rationale, given the scientific literature, for pursuing this line of research in this way. Analogously, in the review of a social experiment, it is important to inquire whether the objectives of the reform have an appropriate ethical and scientific rationale.

What are the ethically acceptable objectives of health sector reform? One particular approach does not advocate a specific set of principles or values but calls for reformers to clarify their value commitments.[15] Arguably, all key aspects of health system transformation involve ethical commitments that reformers should make explicit. For example, equity considerations regarding access to services and financing of them have to be weighed against different views about what justice requires and about the importance of efficiency or other goals of reforms.

The "benchmarks of fairness" methodology developed over the last decade[16–19] illustrates a more explicit framework for assessing the goals and outcomes of reform than the simple demand for clarification of values. The international version of this framework, agreed on by collaborating teams from diverse

The 9 "Benchmarks of Fairness" and the Concerns They Address

Benchmark	Concern
1. Intersectoral public health	Equity
2. Financial barriers to equitable access	Equity
3. Nonfinancial barriers to access	Equity
4. Comprehensiveness of benefits and tiering[a]	Equity
5. Equitable financing	Equity
6. Efficacy, efficiency, and quality improvement	Efficiency
7. Administrative efficiency	Efficiency
8. Democratic accountability and empowerment	Accountability
9. Patient and provider autonomy	Accountability

Source. Daniels et al.[19]

[a]"Tiering" refers to the unequal benefits and financing available to different groups in the health care system—for example, the benefits available in the public sector vs those available through large employers, the military, or the civil service.

cultures, integrates 3 central goals of fairness: equity, efficiency, and accountability (see box this page). Five benchmarks address dimensions of equity: the exposure of people to public health risks and to inequalities in the distribution of the social determinants of health (i.e., "intersectoral public health"), financial and nonfinancial barriers to access to care, inequalities in the benefits for different groups, and the burden of health care costs among the sick or those less able to pay. Two benchmarks focus on clinical efficiency and quality and on administrative efficiency. Two benchmarks concern aspects of accountability and choice in the system.

Each benchmark includes criteria that emphasize key components of the goal addressed by the benchmark. For example, the benchmark on nonfinancial barriers to access includes criteria for the geographical distribution of resources, gender disparities, cultural barriers, and discrimination, and the benchmark on accountability contains criteria calling for public performance reports, transparency in resource allocation decisions, and grievance or appeals procedures in health care institutions.

Together, the benchmarks address the complaint that "it is unfair" when the system treats some patients differently from others with similar needs, when some needs are not met because of administrative or other inefficiency, or when people have no say in how the system treats them. Fairness involves various claims about what people are owed as a matter of justice.[3,20,21] This integrated ethical framework responds to efforts at health system reform imposed by external agencies on developing countries. Initially, many reform efforts focused only on enhancing efficiency, and critics complained that there was little attention to how equity was being sacrificed. Recently, there has been increased interest, especially in the World Bank, in issues about equity[22] and—more recently—about governance and accountability.[23] The benchmarks' framework integrates these various goals and assesses trade-offs among them. In addition, 1 benchmark points to the importance of intersectoral planning in determining population levels of health and its distribution.

The benchmarking approach shares 2 key points with the more modest call for clarification of values. First, there must be local weighing and balancing of values within a reform effort. Only then can various stakeholders be clear and explicit about the commitments of the effort, thus providing the public accountability for the reform's goals that enhances their legitimacy. The benchmarks eschew cross-country comparisons and embody local deliberation about how to improve fairness in reform.

Second, usually there is a range of fair ways to make reasonable trade-offs among the central goals of reforms. Most people engaged in health system reform have a central goal of improving population health. Many reformers also aim to distribute the benefits of reform equitably—for example, by reducing a society's unjustifiable health inequalities. Even so, reasonable people will disagree about what equitable distribution involves—perhaps debating how much priority to give to those who are worse off or how much weight to give to achieving "best outcomes" as opposed to giving people a fair chance at some benefits.[3,24–26] Fair procedures for resolving these disagreements may yield a range of legitimate proposals.

ETHICAL EVALUATION OF APPROPRIATENESS

An ethical and scientific review must assess the appropriateness of the design of the reform to the goals of the reform. Further, it must examine whether measures taken to achieve 1 goal interfere with achieving others. For example, user fees in developing countries were advocated by external agencies promoting reform in the hope that they would increase the resources available in underfunded systems. Where they created new barriers to access for the very poor, however, they frustrated the goal of fair access whether or not they somewhat improved sustainability.

In general, the review would ask: how good is the evidence that measures being advocated are likely to work if implemented? Are there adequate plans for implementing the mechanisms of reform? How sensitive is the estimate of benefits or harms to key features of the local situation? Have relevant stakeholders been marshaled to implement the reform?

The benchmarking methodology illustrates 1 way to organize this kind of ethical evaluation. An interdisciplinary team, including policymakers, academics, providers, and civil society groups, studies the proposed reform, adapting the generic benchmarking criteria to reflect local conditions. They agree on indicators to measure expected or actual changes from a baseline, taken to be the status quo prior to reform. To proactively evaluate a proposed reform, they must collect evidence about the projected effects of reform on the indicators. To conduct ongoing monitoring and evaluation of reform, they

must make periodic measurements of actual changes. Using the benchmarking methodology for evaluation both before and after implementation of reform provides appropriate ethical and scientific oversight.

This approach is illustrated by health reform in Guatemala, which involved subcontracting the delivery of basic maternal and child health services in districts with a high level of need for them. Because the capitation payment was low, the reform strategy called for subcontractors to rely on community workers to support the delivery of services. By developing an index to measure the availability of community workers in each district, a team using the benchmarking approach showed that the neediest districts were also least able to supply community workers.[19] The reform mechanisms were clearly inappropriate to the goals of reform.

A more comprehensive review of evidence, even in systems not well equipped to provide it, can offer some ethical oversight of a reform's design. Such a review must be sensitive to the fact that some improvements may take time to implement. Mechanisms may produce worse outcomes until they are fully in place or until responses to the change stabilize in the system. Ethical review must therefore be both proactive and ongoing, relying on monitoring and evaluation to make sure risks to a population are understood and can be minimized by the timely modifying of reforms.

If developing countries acquire the capacity to conduct such a review, they can better resist ill-conceived reforms imposed on them by external agencies. Moreover, their review imposes a form of accountability on such agencies. Independent ethical and scientific review of the reforms these agencies propose and fund also would provide accountability.

ETHICAL EVALUATION OF GOVERNANCE

In clinical research, ethical review and requirements of proper informed consent mean that the research's objectives can be met without manipulating, deceiving, or exploiting the subjects and without exposing them to undue risks. Ethical review also ensures that subjects will be given medical care that meets certain standards during and perhaps after trials. Subjects are assured that there is adequate surveillance of outcomes, including risks, so that harms can be minimized or benefits optimized. The ethical review of the governance of health system reforms should include analogous components.

In a political process, where reforms are implemented by democratically controlled agencies, the analogy to informed consent is democratic oversight of the reform process. Unfortunately, this analogy is problematic wherever democratic control of institutions is weak, whether in developed or developing countries, and wherever powerful external agencies offer large incentives and are not themselves held accountable for the reforms they impose. The remedy, however, is not to mimic clinical research by imposing requirements for some form of informed voluntary consent by the affected public. Rather, it lies in the development of improved mechanisms of accountability for external and domestic agencies and the democratic empowerment of civic society in countries undertaking reform. In addition, the capacity of these countries to monitor and evaluate efforts at reform must be developed if they are to have the evidence needed for ethical and scientific review.

The benchmarks of fairness illustrate 1 way a framework can combine ethics with an operations research approach that supports proper governance of social experiments. In the international adaptation process leading to the benchmarking method, participants claimed that the most important benchmark was the one that focused on democratic empowerment and accountability, since it addressed key gaps in the health systems of many developing countries. Unfortunately, there is little experience in measuring how systems establish transparency, accountability, and fair process in decisions involving resource allocation. This benchmark also encourages the development of civic society groups that can sustain pressure on ministries of health to implement appropriate reforms, but it is notoriously difficult to measure the effectiveness of such groups.

Despite these obstacles, organizers of the World Health Organization (WHO) 3 by 5 program, which aimed to deliver 3 million sustainable antiretroviral treatments for HIV/AIDS by 2005, judged improving accountability and fair process to be important. Many people familiar with the fragile health systems in the high-prevalence countries targeted by WHO expressed concern that introducing a well-funded vertical program for treatments without properly integrating that program into existing primary care institutions would weaken health systems and impose grave risks on populations. Others were concerned that important equity issues had not been addressed by the funding institutions—who should be treated when not everyone can be? By WHO's own criteria, 3 million was only half the number of people who could benefit from the program. Because every decision regarding the selection of patients and sites of health clinics is morally controversial, WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) encouraged health systems to develop a fair process for resolving these issues.[8,9,24]

The Malawi National Aids Commission demonstrated what form such good governance of key reform decisions might take.[25] The commission, which included a full range of stakeholders, held hearings and conducted public forums and radio and television phone-in discussions of the issues. They published a report that explained the grounds for their decisions, including an airing of minority views. The transparency of the process is a model for how reforms might be examined ethically. In Malawi, there remains a need for ongoing evaluation and monitoring of the implementation of these reforms to see if the publicly determined criteria for equity are met.

A key gap in developing countries is the lack of capacity to conduct research on the reform of health systems and to monitor and evaluate the effects of reforms. Without this capacity, and the evidence it produces, ethical and scientific review of reform is not locally feasible. Fortunately, international attention is being focused on this gap. The WHO Alliance for Health System and Policy and its Global Forum focus on the "90–10" gap in research capacity—10% of the world's research focuses on 90% of its

population.[26] The Ministerial Summit on Health Systems Research held in Mexico in November 2004 was aimed at encouraging ministries of health to develop the capacity to do research that can form an evidence base for policy and its evaluation. The benchmarks illustrate 1 approach that can be developed further in these efforts.

AN AGENDA FOR ACTION

To carry on ethical and scientific review of social experiments involving health system reforms, the following are necessary: first, a framework must be developed that plausibly captures and integrates the ethically desirable objectives of reform and that can, with thoughtful local adaptation, be accepted in various settings. Second, such ethical review requires an evidence base that can be used to assess the appropriateness of the measures or means used in system reforms. There must be not only a research capacity to provide that evidence prior to reforms but also a commitment to ongoing monitoring and evaluation of reforms so there is an ongoing evidence base to reevaluate what is being done. Third, the tools for evaluating reform efforts must include ways of assessing the key elements of governance that are involved in deciding on reforms, implementing them, and taking responsibility for modifying them if they do not go as planned or expected.

The benchmarks of fairness illustrate what 1 such ethical framework might look like. They also show how such a framework might be used to carry on prospective or retrospective assessment of the fit between reform measures and reform objectives and to evaluate governance and accountability in the design and implementation of reforms. Moreover, they provide a tool that can be used by policy developers or by external reviewers, leaving open the decision about who should conduct such a review. Still, the benchmarks are at best only a work in progress; they are time-consuming to adapt and implement. Much more work needs to be done with the benchmarks—for example, streamlining the process of adaptation and implementation through the sharing of techniques across sites or using other, better approaches for meeting the needs noted in this essay.

Ethics and social science must join in developing appropriate tools, and funding institutions must invest in relevant research capabilities. Health system transformation is a far more complex process than typical clinical trials, and it involves many more objectives. Its ethical review is a more complex task than the review of clinical research. Although we do not want to wait for social experiments in health system transformation to produce atrocities like those that made clear the need for review of clinical research, we also do not want to create insurmountable obstacles to needed reforms. ■

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