Apology and Unintended Harm in Global Health

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Abstract

Over the past few decades, investments in global health programs have contributed to massive advances in health for human populations. As with clinical medicine, however, global health interventions sometimes result in unintended harm, economic adversity, or social disruption. In clinical medicine, when medical error occurs, it is increasingly common for health care workers to offer apology, which involves acknowledging the error, taking responsibility for it, and expressing genuine remorse. In addition, hospitals are beginning to offer affected patients and their families reparation or compensation in an attempt to restore patients' health and repair relationships, as well as take steps to prevent similar harm in the future. By contrast, little is known about apology and reparation for unintentional harm in global health practice. Several factors, including the scale of global health programs, diffusion of responsibility across international networks of state and non-state actors, and concern that acknowledging harm could threaten otherwise successful health programs, render apology and reparation in global health more difficult than in clinical medicine. This article examines how and when individuals and global health organizations address inadvertent harm, illustrated by four case studies. It also describes ethical, legal, and human rights principles that could inform a more systematic approach. Addressing unintended harm in global health requires further attention at the individual, organizational, and global levels.

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Introduction

Public health programs—conducted by local and national governments and global organizations—have contributed to massive advances in health for human populations, doubling the average life expectancy over the last century and reducing child mortality by nearly 90%.[1] Interventions such as large-scale vaccination campaigns, mass drug administration to treat and prevent neglected tropical diseases, vector control, improvements in water and sanitation, nutrition and fortification programs, and oral rehydration therapy have benefited millions of people in both high- and low-income settings.

Like clinical medicine, however, global health programs sometimes result in unintended harm. For example, stigma or serious adverse events can be associated with health promotion interventions or with programs administering vaccines or drugs to reduce the transmission of infectious diseases.[2] The history of global health provides several examples of well-intentioned interventions that, for a variety of reasons, resulted in unintentional injury, economic adversity, environmental harm, or social disruption.[3] The principle of *primum non nocere* (first, do no harm) remains an aspirational but often elusive goal in actual practice.[4]

A key ethical question for individuals and global health organizations is whether we acknowledge inadvertent harm when it occurs, and if so, how we respond to it. The field of global health ethics currently lacks a cohesive framework for navigating these and other ethical dilemmas. It draws on the values and principles of medical ethics and biomedical research ethics, which have developed robust (if not always adequate) approaches to reducing and addressing harm. However, the complexity and scope of global health render these frameworks insufficient. This article examines how and when individuals and global health organizations address inadvertent harm, illustrated by four case studies. It also describes ethical, legal, and human rights principles that could inform a more systematic approach.

Responding to harm in clinical medicine and research

A landmark report in 2000 by the US Institute of Medicine, *To Err Is Human*, highlighted the unacceptable incidence and enormous cost of human error in medical settings.[5] Increasingly since then, medical professionals have been trained to offer apology, which involves acknowledging medical error, taking responsibility for it, and expressing genuine remorse to affected patients and their families.

But as ethicist Nancy Berlinger notes, to be effective, apology must be accompanied by "actions that materially restore the injured person to health, that repair the relational breach, and that safeguard against future injuries."[6] With medical error, restitution—the restoration of what has been lost (in this case, health)—is often not possible. In its place, hospitals are increasingly offering some form of compensation or reparation, which, as Berlinger points out, is "always symbolic on some level, a repair of damage rather than a literal return of goods."[7] Even in the absence of a verbal apology, reparation represents an acknowledgment of harm and an effort to take responsibility for it. Still, in many medical settings, apology and reparation are not offered effectively or well.[8]

Medical errors are rarely caused by the isolated actions of a single health care provider; systemic factors embedded within medical institutions also contribute. Power differentials between patients and health care providers and institutions contribute both to medical error and to reluctance to disclose it. For health care institutions, as for individual providers, disclosing and offering apology for medical error can be difficult. Barriers include fear of litigation, reputational risk, and concern for financial well-being.[9] However, where medical institutions have committed themselves to disclosing medical error and offering apology, they generally experience *fewer* lawsuits and *lower* costs of legal settlements.[10]

In biomedical research, egregious ethical lapses that result in harm to research subjects are often widely publicized. As in clinical medicine, these lapses are, to a large extent, the inevitable result of structural and functional differences in power

between investigators and research subjects. They also reflect a focus on ends over means, and the resulting acceptance of what Adriana Petryna calls "ethical variability" in conducting clinical trials. Ethical variability refers not to cultural relativism or legitimate differences in medical practice but to the exploitation of local factors such as poverty, lack of access to medical care, and substandard ethical review to efficiently recruit human subjects, resulting in "cost-effective variability in ethical standards in human research."[11]

Two examples of ethical lapses in biomedical research involve studies of syphilis by the US Public Health Service. The infamous Tuskegee study, started in 1932, was intended to be a six-month long observational study of syphilis in black men. It ended only in 1972 after an Associated Press story led to widespread outcry.[12] The second study, also on syphilis, was conducted with sex workers, prisoners, and soldiers in Guatemala between 1946 and 1948.[13] Vulnerable persons in Guatemala were deliberately exposed to sexually transmitted infections without their consent. In both the Tuskegee and Guatemala studies, participants remained untreated long after effective treatment was available.

Revelations of ethical abuses in these and other trials provided an impetus for strengthened oversight of ethical review committees and international standards for conducting medical research. Increased funding was also provided to develop ethical review committees in low- and middle-income countries. Because of the high profile and seriousness of the abuses in Tuskegee and Guatemala, US political figures also offered apologies. President Clinton offered a public apology to the few remaining survivors of the Tuskegee study in 1997.[14] The apology was criticized by some as too little, too late.[15] A US$10 million out-of-court settlement was reached with former study participants, and the US government promised to give lifetime medical benefits and burial services to all living participants (wives, widows, and offspring were subsequently added to the program).

In response to the Guatemala case, President Obama and Secretary of State Clinton apologized to Guatemalan officials in 2010.[16] The United States increased financial support for the Guatemalan government's sexually transmitted disease surveillance and control efforts and allocated funds for research ethics training in the country. While a lawsuit against the US government was dismissed, a suit against Johns Hopkins University, the Rockefeller Foundation, and Bristol Myers Squibb is ongoing.[17] The Office of Human Rights of the Archbishop of Guatemala filed a petition on behalf of victims with the Inter-American Commission on Human Rights in 2015.[18]

In response to the issues raised by these and other cases, new initiatives have been launched to bring attention to issues of fairness, ethics, and power dynamics in global health research.[19] However, proactive plans for compensation or apology in the case of harm during research studies are rarely discussed by researchers or ethical review boards. In addition, in some low- and middle-income countries, ethics committees have limited capacity or conflicting priorities, which can compromise their mission to protect individual research participants.[20]

Responding to unintended harm in public health practice

Whereas ethical abuses in research settings present clear violations of research participants' rights and call for accountability and reparations, unintended harm in public health *practice* presents a murkier case for understanding responsibility and appropriate responses. A recent review identified 26 articles published between 1992 and 2013 that described unintended harm in public health interventions.[21] The authors classified five specific types of harm: physical, psychosocial, economic, cultural, and environmental. Theo Lorenc and Kathryn Oliver, in a conceptual essay, provide a similar categorization.[22]

Even less examined than the documentation of unintended harm in the public health literature is the issue of when or how such harm is disclosed or addressed in practice, whether by individual health workers, organizations, or government leaders. In the highest-profile cases, public or political apologies for misguided or failed practices or omissions may occur. For example, the prime minister

of Japan apologized for discrimination against and poor treatment of persons with Hansen's disease, and the president of Liberia apologized for the government's failure to protect health workers from Ebola.[23] But how often do private apologies occur? What other steps are taken by global health practitioners or their institutions to apologize or implement approaches to restore relationships, such as some form of reparation, when breaches of trust occur between themselves and the intended "beneficiaries" of their programs? We examine these questions through four case scenarios from the field of neglected tropical diseases.

Scenario 1: Potential harm through inaction

On a hot August morning along a dusty road near Leogane, Haiti, a farmer approached me (DGA), holding his sick infant daughter in his arms. His eyes met mine as he pleaded for help. The little girl was suffering from severe diarrhea. As a physician, I could see that she needed urgent hospital care. But my role in Haiti was to help implement a lymphatic filariasis control program, not to work as a clinician. I felt ashamed as a physician: I knew what the girl needed but I was paralyzed by my own insecurities, my ignorance of the local health system, my lack of formal credentials to provide clinical care within that system, our pressing research schedule, and the social, structural, and economic inequities that separated us. Caught up with the research, which we hoped would someday benefit the entire population, we gave the man enough money to take his daughter to the hospital and went on our way. I never saw them again. I never returned to ask the man about his daughter.

Scenario 2: Adverse event following mass drug administration

Chris King, a physician and medical researcher from Case Western Reserve University, was working in a remote area of Papua New Guinea. He and his team were trying to stop the spread of lymphatic filariasis, a disabling and stigmatizing tropical disease that affects 120 million people worldwide. Their approach was to offer a single dose of medicine to the entire community, a strategy known as mass drug administration. The project was going well until the team encountered strong resistance in one particular village. The reason, they learned, was that a woman in a neighboring village had suffered a miscarriage shortly after taking the medication. Word spread quickly and people were upset; they blamed the miscarriage on the medicine.

Scenario 3: Serious adverse events causally associated with mass drug administration

Soon after the discovery that ivermectin was safe and effective for onchocerciasis, also known as river blindness, Merck Inc. donated the drug free of charge to control this parasitic disease, which affected 25 million people, primarily in sub-Saharan Africa. Once-per-year treatment of all eligible members of at-risk communities provided massive relief from suffering; was associated with only mild, transient adverse reactions related to the death of the parasite; and had collateral benefits against other parasitic infections, such as intestinal worms and scabies.[24] It also advanced social justice.[25] The African Program for Onchocerciasis Control pioneered community-directed treatment in which communities made autonomous decisions regarding whether and when to participate, who would administer the tablets, and how community drug distributors would be compensated.[26]

This highly favorable benefit-risk balance shifted radically when a cluster of treatment-associated serious adverse events with neurologic complications was first reported, some of which were fatal. Initially, the cause was unclear, but investigations soon determined that these cases occurred in persons with high levels of infection with another, co-endemic parasite, *Loa loa* (also known as African eye worm).[27]

Scenario 4: Iatrogenic transmission of hepatitis C

Beginning in the 1950s and extending into the 1980s, the Egyptian Ministry of Health embarked on a community-wide treatment campaign for schistosomiasis, a debilitating parasitic disease endemic to the Nile Delta. At the time, intravenous injection of tartar emetic was the standard treatment. More than two million injections were given to approxi-

mately 250,000 persons annually.[28] Glass syringes were used—and reused—during this campaign, and sterilization was inadequate to inactivate the hepatitis C virus (HCV), which was not known to medical science at the time. Epidemiologic evidence suggests that this resulted in large-scale iatrogenic transmission of HCV, although other sources of transmission likely occurred as well.[29] The prevalence of HCV infection in Egypt is now among the highest in the world.[30]

These four examples illustrate specific types of unintended harm that can occur in global health practice. In the first scenario, harm may have resulted from a physician not providing medical care that was unrelated to the specific health project on which he was working. That the health outcome remains unknown is indicative of the extent to which the physician, for a variety of reasons, turned away from a direct, personal appeal for help. This is an example of potential harm by omission during the course of fieldwork. It also illustrates the problem of dual loyalties, which arises frequently in global health practice.[31] In this case, the moral claim on the physician to attend to the "patient" in front of him was in conflict with his responsibilities as a public health worker on a specific project.

In the second scenario, although the relationship between mass treatment for lymphatic filariasis and the miscarriage was uncertain, the team discussed—at length—what to do. They decided to return to the village where the woman lived and to apologize. Dr. King explained, "We sat down with the family. We explained why we were doing this research, that it was a mistake on our part if we gave her the drug without asking about her last period. We asked if they would accept our apology. Sitting down with them provided an opportunity for us to accept some responsibility for the mistake and to let them know that we would do our best to ensure that we wouldn't give the drug to pregnant women in the future."[32] The apology was accepted, the relationship between researchers and the community was restored, and the project continued.

In the third scenario, a surveillance system for serious adverse events during mass drug administration identified an unusual cluster of cases that was unexpected. An international investigation was launched to identify the etiology, further define risk, understand pathogenesis, and develop alternate treatment strategies.[33] Several measures were taken to prevent and reduce the severity of further cases, including enhanced adverse event surveillance and reporting, improved clinical care for persons with neurological complications, and halting the onchocerciasis control program in areas known to be endemic for *Loa loa* until safeguards could be put in place.

In the fourth scenario, the first publications linking HCV with the schistosomiasis campaign did not appear until 1994, more than 10 years after parenteral antischistosomal therapy was replaced by an effective oral medicine.[34] The initial response to the HCV epidemic was slow, compounded by the lack of effective treatment for HCV infection. In the past few years, the Egyptian government has prioritized HCV treatment and, with the development of new drugs that can effectively cure infection, has expanded its program and launched a large-scale treatment and prevention plan that would set Egypt on a path toward eliminating HCV as a public health problem.[35] Although government officials have not provided a formal apology to persons infected through the schistosomiasis campaign, the plan to offer HCV treatment free of charge could be seen, in part, as a form of collective responsibility to redress harm.

Discussion

These four scenarios represent a range of unintended harm—and response. We now discuss, in the context of global health programs: (1) barriers to acknowledging and disclosing unintended harm when it occurs; (2) challenges to offering apology and reparation; and (3) legal perspectives and human rights approaches to acknowledging and addressing unintended harm.

Barriers to acknowledging unintended harm in global health

Several features of global health practice contribute to the difficulty of acknowledging and adequately

addressing unintended harm, including inadequate surveillance for unanticipated harm; fears of liability or perceived threats to programs; imbalances of power; and the self-image of practitioners and their organizations.

Inadequate surveillance for unanticipated harm. Before public health interventions such as vaccines and medicines are implemented at scale, they typically undergo rigorous clinical testing for safety and efficacy. However, the sample size of clinical trials and pilot projects are usually too small to detect rare adverse events or to ensure safety in areas where the intervention has not been tested, as was the case with ivermectin and *Loa loa*. With health promotion efforts that may result in stigma or other social disruption, differences in culture and legal environments can lead to dramatically different results depending on the setting or population. Robust surveillance for unanticipated harm can be quite difficult in remote areas with limited public health infrastructure. Further, for rare events or complex social phenomena, data are often inadequate to reliably infer a causal link between an intervention and a harm. With interventions that are believed to be safe and effective, public health programs typically allocate their limited resources to delivering the benefits of those interventions to the populations who need them, rather than investing in surveillance systems to detect harm.

Liability and perceived threats to programs. When unintended harm occurs in the context of large-scale interventions intended to protect the health of populations, there may be concern that disclosing it could threaten the program in question, result in unwanted negative publicity, and jeopardize the substantial public health benefits that the program delivers. These effects, although initially limited to a single program, can quickly undermine trust in public health institutions more broadly. Apologizing where causality is uncertain (as in scenario 2) could imply acceptance of responsibility and increase liability, especially for international donors and corporate partners, which are vulnerable to lawsuits.

Power imbalances. Solidarity with those from whom we are separated by geography, income, culture, or power is a core value of global health.[36] Even so, it may be difficult for persons who occupy positions of power and wealth to recognize the impact of unintended harm when it occurs in someone who is already marginalized, geographically distant, and with limited resources and means to demand attention or compensation. In global health practice, therefore, imbalances in power can predispose program implementers to the same blind spots that contribute to ethical lapses in clinical trials, which arise from a lack of awareness, understanding, or concern for the impact of one's decisions on the lives of human beings.

Self-image. To truly apologize requires vulnerability, as the apology may not be accepted. When one's identity is wrapped up with doing good or rescuing others, acknowledging harm represents a threat to self-image. Physicians take an oath to "do no harm." When their best efforts result not in healing, but in injury or harm, their personal identity and professional reputation may be threatened. This also holds true for global health organizations, which align themselves with altruistic values and principles. Over-identification with self-narratives of "helping" or "doing good" creates powerful internal incentives for discounting evidence that one's actions have had unintended adverse consequences. Such over-identification also makes it difficult to effectively recognize and navigate dual loyalties.

Challenges to offering apology and reparation

Several features of global health practice contribute to the difficulty of offering apology and reparation, including the global scale of the enterprise; lack of clarity regarding blame or responsibility; discordant values; and inadequate attention to relationships of trust.

Scale. Global health operates simultaneously at multiple levels and across huge geographic, cultural, and economic distances. Interventions may be designed in the boardrooms of international organizations,

but they are ultimately implemented in local communities.[37] On the one hand, the global nature of the field requires that interventions, to some degree, be standardized and delivered in collaboration with international programs to achieve global goals. On the other hand, global programs are enacted at the local level, requiring the engagement of affected persons and communities. Inevitable tensions arise between unified "cookbook" approaches to achieve global targets and a multitude of divergent realities on the ground. Despite lip service to "stakeholder engagement," we still don't practice it consistently or particularly well.[38]

At the community level, where personal relationships are at stake, it is likely that apology *is* offered when health interventions are associated with actual or perceived harm. In our second scenario, the investigators realized that a breach in trust with the community could signal the end of their project. The causal relationship between the drug and the miscarriage was uncertain. The investigators believed that they had asked the woman about the date of her last menstrual period, which is the recommended approach for excluding pregnant women from receiving mass treatment for lymphatic filariasis. But this had not been documented.

The apology in this case was relatively private—similar to what might happen in medical settings. The project team acknowledged the uncertainty surrounding causality, as well as the possibility that they had committed error in not asking the woman about her last menstrual period. They were not official representatives of the global program to eliminate lymphatic filariasis but rather a team of researchers and local collaborators—persons who would likely function as community drug distributors when mass drug administration was implemented. They resided in the local communities and could readily understand and "see the faces" of their study subjects. The apology was apparently accepted and allowed the investigators to proceed, even in the absence of reparation.

The researchers' motives likely included a sincere desire to restore human relationships, but they also needed the cooperation of the community to continue their work. In addition to being the "right" thing to do at a human level, the apology had practical implications for the project. We lack information from the perspective of the woman and her family, but the project team reports that the woman found some comfort in knowing that the miscarriage may have had an external or medical cause.

As scale increases, so do social distance, ambiguity with regard to responsibility, and the personal and organizational stakes in assuming "blame" for unintended harm. Indeed, it may not always be clear exactly what a given individual in global health should apologize for, on whose behalf, or whether an apology is "authorized." Consequentially, apology and restoration of relationships are often more difficult than in scenario 2. The latter two scenarios describe unintended harm that occurred over a period of years in the context of major public health programs involving national governments and external partners. While personal apology at the individual level may be offered more often than we think in such situations, formal apology that addresses all affected persons is uncommon. The political, legal, and organizational complexity of global health partnerships makes it difficult. More often, when unintended harm or error *is* acknowledged in global health practice, the response focuses on the future—in other words, preventing repeated harm rather than addressing the rift in relationships or rebuilding trust.

At the local level, community health workers straddle this global-local divide. They function as cultural translators and intermediaries between a global program and its local implementation; they are agents of a global enterprise, while also members of the local community. Recent evidence indicates that attending to these different roles can involve considerable stress, particularly in addressing unintended harm.[39]

Lack of clarity for responsibility. As already noted, responsibility for harm in global health programs is often multifactorial and diffuse, dispersed among a host of local, national, and international actors. The responsibility for offering apology does not necessarily coincide with responsibility for reparation.

An example of the difficulty of assigning re-

sponsibility for unintended harm in global health comes from mass drug treatment programs for soil-transmitted helminths, or intestinal worms. More than 150 million preschool-age children receive deworming medicine every year through mass treatment.[40] A small (but unacceptable) number have fatally choked on the tablets.[41] The limited evidence available suggests that this occurs primarily when children are frightened or fussy and resist taking the tablets. In such cases, who is responsible? Is it the health care worker or parent who administered the medicine to the child with the intention of improving the child's health, the nongovernmental organization (NGO) that sponsored the deworming, the national and provincial ministries of health that authorized it, the World Health Organization and global health experts who encouraged high drug coverage to achieve important public heath goals, the pharmaceutical company that manufactured the medicine—or no one?

In addition, while individual physicians are licensed (and subject to sanction) by the state, and the actions of public health officials are authorized by the government (and can include police powers of detention and quarantine), global heath as a field lacks a corresponding authorizing agency. Each global health organization is charged by its governing board with advancing a certain agenda or serving specific functions. For example, the World Health Organization acts on behalf of its member states, and the US Agency for International Development is authorized and funded by US Congress. Global health governance remains fragmented and chaotic: an amalgam of diverse interests, sectors, and influences ranging from faith-based organizations to the military.[42] Consequently, authority for program implementation and for addressing unintended harm is often shared and is sometimes ambiguous. Individuals working in global health rarely question their "authority" to act, relying on personal values and motivations or their institution's operational guidelines. This "devolution to individual moral latitudes," as described by Petryna, provides global health practitioners with little clear guidance and can lead to ethical variability.[43]

Lack of consensus on core values. While Solomon Benatar and others have written on the core values of global health, in practice these values are assumed and implicit.[44] The degree to which core values are actually shared and understood across all partners is uncertain. Further, the priorities of organizations engaged in global health can diverge significantly, especially during times of social unrest or fear, or in relation to interventions addressing criminalized populations or stigmatized behaviors. For some interventions—for example, those targeting open defecation or tobacco control—stigma may be both the strategy and the intended result. The lack of an explicit collective understanding of, and commitment to, core values complicates both the recognition of unintended harm and the response to it. Particularly in cases where political determinants of health (such as repressive laws and policies) lead to harm, health interventions may counter these harms or unintentionally be complicit with them.[45]

Trust. At all levels, the success of global health programs depends on a high degree of trust and social capital among individuals. When these are present, stakeholders and representatives of specific institutions can transcend partisan interests and work together toward a shared vision of health for *all* peoples.[46] It is easier to maintain (or assume) this trust when things are working well. In times of stress or crisis, however, or when unintended harm occurs, it is natural for individuals and organizations to want to avoid blame and protect their own interests and strategic objectives. The resulting retrenchment undermines trust—and hurts programs.

Legal issues, human rights, and apology for unintended harm in global health

At first glance, apology seems disconnected from the notion of human rights. While there is not a *right* to apology per se, public apologies, particularly on behalf of states, are increasingly common in an effort to heal social rifts resulting from systemic human rights abuses. However, they are often criticized as insincere, half-hearted, and lacking adequate reparation.[47] To be effective, public apologies must be carefully planned, sincerely offered,

and accompanied by reparation.[48]

Because global health operates at local, national, and global levels, unintended harm, when it occurs, must be acknowledged and addressed at all of these levels. Global health actors—whether funded by states and acting in quasi-state roles or privately funded—work within legal frameworks at the local and national levels, even if they are ignorant of this fact and see themselves as separate from them. They also operate within a global legal framework, which is conceptualized and enacted through the language and principles of human rights, specifically the right to health. These principles are enshrined in the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, and other relevant conventions, such as the Convention on the Rights of the Child.[49]

How might a human rights approach inform acknowledgement of harm, apology, and reparation in global health practice? First, it is important to recognize that global health programs and human rights frameworks share key norms and standards of practice, as well as legal duties, including informed consent, community engagement, monitoring, and reporting. Since the state is obligated to respect, protect, and fulfill the right to health, the state—and, by extension, non-state actors working under the authority of the state—have obligations to ensure the protection and promotion of key rights, including participation and non-discrimination in all health interventions.[50] When this link between global health goals and human rights obligations is openly acknowledged, it is easier to imagine global health practitioners looking to human rights standards and authorities to address harm when it occurs, either as breach of duty (whether intentional or unintentional) or as a result of unforeseen circumstances, despite meeting standards of care.

The United Nations Committee on Economic, Social and Cultural Rights, in its General Comment 14, provides an authoritative interpretation of states' obligations with respect to the right to health.[51] There is no mention of apology in this general comment. The document does, however, discuss "remedies and accountability" (paras. 59–62), emphasizing "access to effective judicial or other appropriate remedies at both national and international levels" and "adequate reparation, which may take the form of restitution, compensation, satisfaction or guarantees of non-repetition" (para. 59). Specific mention is made of "national ombudsmen, human rights commissions, consumer forums, patients' rights associations or similar institutions" to address violations of the right to health. The general comment also describes the equivalent obligations of non-state actors (paras. 63–65).

Meanwhile, the United Nations Human Rights Committee, which provides authoritative interpretation of the International Covenant on Civil and Political Rights, has noted that, "where appropriate, reparation can involve restitution, rehabilitation and measures of satisfaction, such as *public apologies*, public memorials, guarantees of non-repetition and changes in relevant laws and practices, as well as bringing to justice the perpetrators of human rights violations" (emphasis added).[52]

The United Nations Basic Principles and Guidelines on the Right to a Remedy and Reparation for Victims of Gross Violations of International Human Rights Law and Serious Violations of International Humanitarian Law provides another resource for examining the basis for remedies in the case of unintended harm in global health interventions. These principles were the result of a 15-year process of study, negotiations, and drafting on the part of the United Nations Sub-Commission on the Promotion and Protection of Human Rights and the United Nations Commission on Human Rights. They represent the first comprehensive codification of the rights to reparation by victims of mass human rights violations. The Basic Principles acknowledge that appropriate reparations depend on the gravity of the violation and the harm suffered, as well as the circumstances of each case, but they also state that forms of reparation that must be considered include restitution, compensation, rehabilitation, satisfaction, and guarantees of non-repetition.[53]

Notwithstanding these human rights obli-

gations, within the United States, international organizations such as the United Nations and its programs and specialized agencies such as the United Nations Children's Fund and the International Finance Corporation (IFC), enjoy immunity from lawsuits. The extent of that immunity was recently challenged in a case before the Supreme Court involving environmental harm that affected a community of farmers and fishermen whose lives and livelihoods were negatively affected by the construction of a coal-fired power plant partially funded by the IFC in Gujarat, India.[54] The Supreme Court rejected the IFC's claims of absolute immunity and, without judging on the merits of the case, pointed to the IFC's failure to respond to its own internal audit, which found that the institution had not adequately monitored or responded to the project's environmental and social impacts.[55]

Notwithstanding the recent IFC case, the difficulty of realizing rights protections and the limits of courts to redress claims suggests the need for other means of accountability, such as quasi-judicial mechanisms. For example, in 19 countries, review boards can offer financial compensation to persons who suffer serious adverse reactions following vaccination.[56] In doing so, vaccine injury compensation programs recognize the low—but present—level of risk that individuals inherently accept on behalf of the public good. These programs also acknowledge a societal obligation to recognize and address unintentional harm when it occurs.

Challenges and implications

Worldwide, more than US$150 billion is invested annually in international health and development assistance.[57] Given the sheer volume and complexity of this effort, mistakes sometimes happen and unintended harm occurs. We presented four scenarios from neglected tropical disease control programs, but examples can be found throughout the field of global health. The challenge remains: How do these accounts get acknowledged, reported, addressed, and incorporated into a global health system that ensures accountability and redress? How can we learn from our mistakes, even if unintended, and prevent them in the future? Our goal in this paper has been to consider how examples of unintended harm can help global health practitioners learn and grow, rather than seek to forget and move on.

We have explored several challenges and barriers to acknowledging harm and to offering apology and reparation in global health, which include structural, psychological, economic, legal, and cultural factors. Given the enormous complexity of global health, it is not surprising that apology is so difficult. At the heart of apology lies human relationships, whether among individuals linked together by shared interests or friendship, organizations with contractual agreements, or governments bound by international obligations. Too often, our relational assumptions and agreements in global health are implicit and assumed rather than explicit. Further, power dynamics complicate decisions about apology and compensation for harm. Within these networks of relationships, who determines what is "fair" and when compensation is warranted? Apology—and even compensation—can be misused, offered prematurely to avoid a much-needed conversation, or used as a risk-management strategy. In such cases, the person harmed or whose rights have been violated may desire neither apology nor restoration of the relationship.

The great challenge and paradox of global health is that it is simultaneously global in scope and, of necessity, undertaken at the community level. What is appropriate at the global level may be inappropriate or ineffective at the local level, and vice versa. In writing about the complex process of peacebuilding, John Paul Lederach notes that true reconciliation takes place in communities.[58] Peace treaties mean little if neighbors remain estranged and in fear. While public ceremonies of remorse, apology, and even reparation have an important—albeit underutilized—role in global health, they do not replace the need for private apology at the individual or community level.

This leads us back to the necessity of community engagement in global health programs. When programs are designed and implemented with full community engagement, deciding whether and how to apologize can be considered in partnership

with community leaders. We suspect that in such cases, apology may be more natural, easier, and less frequently needed. Top-down approaches tend to increase the likelihood of breaches in trust and the subsequent need for apology. They also make it more difficult for apology to be effective because, in the words of Bill Foege, "the faces" of affected individuals have not been fully seen.[59]

Recommendations

We close by offering a few reflections and suggestions on how we in global health might better address unintentional harm at three levels: individual, organizational, and global.

At the individual level, developing relationships of trust, grounded in respect for human rights, is critical. Global health practitioners should develop the capacity to recognize when trust has been breached and actively monitor for unintended harm. Skillfully applying the art of apology requires a high degree of self-awareness, the ability to connect with others, a commitment to solidarity and other core values, a willingness to question our assumptions, and humility. It also requires awareness of, and respect for, the personally corrosive effects of unacknowledged harm—including moral distress and moral residue.[60] Knowing when and how to disclose error and offer apology is much easier when one's actions are not clouded by compulsion, one is not over-identified with specific outcomes, and one is open to learning of one's ethical blind spots.

At the organizational level, a commitment to acknowledging and addressing inadvertent harm is essential for sustained programmatic excellence. Organizations implementing global health programs should become more aware of human rights frameworks and their ethical and legal obligations as non-state actors.[61] Practitioners and students would benefit from training in apology, as is increasingly provided for medical students and residents.

Ethics in global health is rarely about "getting it right" once and for all. Rather, human rights and ethical principles demand that we continuously monitor our programs to maximize their benefits and minimize any harm that they might cause. Organizations engaged in global health practice would benefit from the type of self-evaluation processes that the Research Fairness Initiative recommends for research institutions.[62] Additional approaches could include specific consideration of apology and reparation within memoranda of understanding and accountability frameworks between governments and NGO partners. Program plans, research protocols, and institutional review boards could more specifically address the responsibilities of individuals, as well as institutions, for responding to unintended harm.

At the global level, acknowledging and satisfactorily addressing unintended harm remain difficult. As we have noted, global health programs are more likely to respond with efforts to prevent future harm than they are to look backward to make reparation. National vaccine injury compensation schemes offer an interesting exception to this rule and provide a model that could be adopted by other countries, as well as expanded to the global level, as proposed by Sam Halabi and Saad Omer.[63]

Further work is needed to develop a framework for addressing unintended harm in global health. This framework should draw on and link to the United Nations declarations, covenants and other legal documents mentioned above. It should also be informed by a wide range of examples of unintended harm and developed through a participative process that includes government agencies, donors, NGOs, and communities. The role of apology and reparation in specific global health situations will likely vary depending on several factors, including the severity of harm; whether harm is caused by an individual, an organization, or a diffuse network of organizations; and whether it results from error, either technical or in judgment, moral wrongdoing, incompetence, negligence, failure to act, or some unforeseeable event.

The year 2020 represents a milestone for many global health programs. The global health community will rightly celebrate the impressive progress and health benefits that have been realized. Yet, along the way, some individuals have suffered harm. While celebrating success, might we also remember those who have been inadvertently harmed despite

our good intentions? Even if personal apology and reparation for affected individuals are not possible, acknowledging unintended harm could provide opportunities to attend to the relational dimensions of global health, promote human rights, foster human dignity, and minimize harm while pursuing the highest attainable level of health for all peoples.[64]

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