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## AMA Journal of Ethics®

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## **FROM THE EDITOR**

## **Building Ethical Global Health Care Systems**

In 2015, 87 countries had less than 1 physician per 2,000 people [1]. And in 2014, 24 of 207 independent states had no medical school; 50 had only 1 [2]. Yet there are places where 1 in 4 people have HIV [3], where tuberculosis is resistant to almost all available treatments [4], and where the average person will never celebrate his or her 50th birthday [5]. The lack of a robust health care workforce is both a symptom and a propagator of these health inequities. Disparities in global health care reveal the most blatant violations of the rights to live, succeed, and be happy—because to do any of those things, one needs to have access to health care.

Two of the biggest questions confronting the global health community are these: Who should be leading the charge to build or rebuild health care systems in resource-poor countries? Given the diversity of populations and plurality of needs, what's the "right" way—in terms of policy and infrastructure design, for example—for a system to meet unmet health needs? In this issue of the *AMA Journal of Ethics*<sup>®</sup>, we explore these fundamental questions.

One major point of contention is top-down versus bottom-up models of developing health systems' capacities to respond to health needs. Does successful health systems strengthening come from national policies and wide-reaching programs that are implemented through intergovernmental collaboration? Or does it depend on the input of the very people it is meant to help by addressing—organically and incrementally—smaller, communal problems through a patchwork of different but interconnected projects? We seem to often fall somewhere in between these two camps. Ranu S. Dhillon, an expert in health systems design and advisor to the president of Guinea during the Ebola response, and Pranay Nadella examine this tension in their commentary on a case of a US physician working in Mozambique who is urged by state medical workers to join their strike for better wages and working conditions.

But do physicians and other health care workers from resource-abundant regions (the global North) who work in resource-poor regions (the global South) really know what is best for people whose backgrounds and health and illness experiences are unlike their own? Anita Chary and medical anthropologist Carolyn Sargent explore the need for cultural sensitivity in their commentary on a case of a US physician working in Thailand who seeks to change local healing practices that lack scientific support and might even be harmful.

Cases of physicians working abroad raise the question—which the poor living in the global North might well ask—Why do physicians volunteer or work abroad when we have so many of our own problems at home? Samuel G. Ruchman, Prabhjot Singh, and Anna Stapleton discuss how medical <u>systems and innovations developed for resource-poor countries</u> can improve health care delivery at home—and in turn pay dividends abroad—drawing on the second author's experience devising local health care solutions for resource-poor communities in New York City.

Strains on health systems in resource-poor countries are inevitable, given finite resources, but how we react to and address these strains is of utmost importance to building health systems that are ethically sound and just. South Africa's transition from "vertical" health systems development (focused on specific illnesses) to "horizontal" health systems development (focused on integrated infrastructure) illustrates the potential tradeoffs involved in building just health systems: in 2010, financial support for HIV/AIDS through the United States President's Emergency Plan for AIDS Relief was called into question [6]; this money was potentially to be used in more general health systems strengthening [7] to help prevent other illnesses that were killing as many people as HIV/AIDS (e.g., malaria, TB, diarrheal disease, malnutrition) and to improve maternal and child health [8]. Nicoli Nattrass, an HIV expert from South Africa and a leading activist in the HIV/AIDS movement, and her colleagues Rebecca Hodes and Lucie Cluver discuss the challenges of integrating HIV/AIDS programs with general medical care in sub-Saharan Africa and the importance of AIDS activist organizations in sustaining access to antiretroviral therapy in their commentary on a case involving conflicting obligations to individual patients and donors.

Strains on health systems, however, are not only a result of shifting funding priorities. The growing concern over brain drain, which describes the transfer of physician and health worker talent from the global South to the global North, shows that poor nations' health systems are weakened by forces beyond their own borders. What role do countries in the global North play in attracting physicians who are trained in the global South and desperately needed in their home countries? How can the tension between self-advancement and communal obligation be reconciled in a way that is ethically justifiable? I and my co-authors Daniel DeUgarte and Michele Barry analyze responsibility for and possible solutions to <u>"brain drain"</u>—one kind of which refers to migration of health care workers from the global South to the global North—in our commentary on a case involving a surgeon who has come to the US for skills training and is tempted to remain.

Although brain drain focuses attention on the loss of physician talent, this month's issue also examines a countervailing force: medical education and the creation of more physician leaders within the global South through the building of medical schools and other developments that contribute to health workforce growth. Tracy L. Rabin, Harriet Mayanja-Kizza, and Asghar Rastegar discuss their ten-year experience with the Makerere University-Yale University (MUYU) collaboration in Uganda, an equity-focused global health education partnership. Similarly, Peter Drobac and Michelle Morse present the framework for a novel educational endeavor through Partners in Health in Rwanda, the <u>University for Global Health Equity</u>. These articles highlight the potential of global North-South partnerships to improve medical training and practice if we make equity a priority.

Health systems are also affected by global policies. Jing Luo and Aaron Kesselheim discuss the impact of the <u>Trans-Pacific Partnership</u>—a major trade agreement made between the US and 11 other countries in Asia and South America intended to promote trade and encourage innovation—on access to medicines, particularly for the poor, in signatory countries.

In addition to exploring many of the current tensions and hurdles facing health systems today, we also reflect on the past and the future of health systems strengthening. In her historical analysis, Helen Tilley shows that <u>medical research and treatment programs in</u> <u>colonial Africa</u> brought harm to participants. Recognitions of these harms can help motivate understanding of some patients' continued reliance on African therapeutics and resistance to Western biomedical models of care. This issue also looks forward: where are health systems headed in countries with limited resources, in places where the poor continue to die of diseases that don't kill the wealthy? In <u>the podcast</u>, Agnes Binagwaho, the minister of health of Rwanda and an international leader in health systems strengthening, outlines many challenges that Rwanda overcame to improve health outcomes significantly while highlighting that what worked well in Rwanda might not work elsewhere.

This issue of the *AMA Journal of Ethics* brings to bear the perspectives of several disciplines—law, public health, medicine, economics, philosophy, business, anthropology, and history—in presenting, framing approaches to, and addressing ethical problems of global health care systems. It forces us to ask: Are we building health systems ethically and justly? Are we fully demonstrating respect for the people they are meant to serve? Are the builders the right people? Could we be doing this better? The answer to this last question, most certainly, is yes, and we hope that this issue allows us to take one step closer to doing so.

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### **ETHICS CASE**

## Medical "Brain Drain" and Health Care Worker Shortages: How Should International Training Programs Respond?

Commentary by Abraar Karan, MD, Daniel DeUgarte, MD, and Michele Barry, MD

#### Abstract

The movement of health care workers from countries with resource scarcity and immense need ("source" countries) to areas of resource abundance and greater personal opportunity ("destination" countries) presents a complex set of decisions and relationships that affect the development of international health care systems. We explore the extent to which ethical quandaries arising from this movement are the responsibility of the said actors and the implications of these ethical quandaries for patients, governments, and physicians through the case of Dr. R, a surgeon from Nigeria who is considering working in the United States, where he is being trained to help develop surgical capacity in his country. We suggest how Dr. R, the United States, and Nigeria all contribute to "brain drain" in different but complementary ways.

#### Case

As part of an international medical partnership, you are assigned to help train Dr. R, a Nigerian physician who is visiting the United States to learn surgical techniques that he can then take back to his country to help bolster the surgical capacity there. About halfway through his two-month stay, Dr. R tells you in confidence that he does not believe the health care system in his country will improve; there is too much government corruption and an incapacitating lack of infrastructure. Instead of returning home, Dr. R hopes to obtain a better job through the United Nations or in Ghana so that he can earn more and provide for his family, including his two young children.

Stories like Dr. R's cause us to ask whether global health training programs attempting to counter "brain drain"—the phenomenon of resource-poor areas losing their best practitioners—might actually be facilitating it. How should physicians confront brain drain at a systems level? Is it fair to expect that, upon completing training in the United States or another wealthy nation, physicians like Dr. R from resource-poor areas will pursue their careers and practice mainly in the areas of the nation or world from which they came? If a resource-poor country subsidizes the medical education of a physician who leaves to train—and possibly practice—in a wealthier country, which considerations are most relevant from ethics and justice perspectives?

#### Commentary

The ethical dilemma in this case has much to do with the rights of an individual physician (or health care worker) with respect to his or her own life, personal needs, and goals compared to that person's obligations to his or her community and country. Moreover, it brings to light the possibility that current frameworks in the United States for health systems strengthening might have unintended consequences.

Movement of health care practitioners from areas of resource scarcity (referred to as the "source" areas), where they are assumed to have great impact on public health, to resource-abundant areas assumed to offer more financial and personal benefit (referred to as the "destination" areas) is a complex trend affecting health systems globally. This movement is colloquially referred to in the public health community as <u>"brain drain"</u> and has been occurring for several decades. Recruitment of physicians from less-industrialized countries began in the 1960s, coincident with the advent of universal health care coverage in a number of industrialized nations, which created a relative physician shortage [1]. This trend has continued through today, accounting for the migration of several hundred thousand clinicians from poorer to wealthier nations [1]. Currently, in the US alone, 25 percent of the physician workforce consists of graduates (including US citizens) of international medical schools [2].

An ethical challenge with "brain drain" is that the transfer of human capital from the source to the destination area occurs at great cost to the former, but with minimal cost—and appreciable benefit—to the latter. The relationships that dictate this phenomenon are highly complex; while the source and destination countries both contribute to workforce migration, individuals' decisions are also significant and introduce their own moral uncertainty. The contributions of various actors to brain drain and what these actors might do to ensure social justice will be explored in this article.

#### An Ethical Dilemma Training Programs Create for International Physicians

To contextualize the importance of the problem, the World Health Organization (WHO) estimates that 23 health care workers per 10,000 people is the minimum ratio needed to maintain a health system—and as of 2013, 80 countries worldwide fell short of this threshold level of care [3]. The disparity is most pronounced in sub-Saharan Africa, which is home to 14 percent of the world's population but only 3 percent of its health care professionals [3]. A study of the world's medical schools found that the majority of countries with the greatest need for physicians (almost all of which were in sub-Saharan Africa) had only one medical school [4]. Perhaps the most concerning aspect of medical brain drain is its self-reinforcing impact on health care systems that are already weak: as a health care system weakens, bright physicians and health care workers tend to leave; the more who leave, the more the health care system is weakened.

A number of studies have quantified factors that propel physician migration from source countries: access to better training opportunities, higher salaries, need to escape political instability and corruption, poor quality of facilities and equipment, and plans for raising children [5-8]. Conversely, factors that influence physician retention in the destination countries include strong and robust health systems and political stability, which tend to facilitate improved lifestyles and opportunities for physicians and their families.

Presumably, Dr. R's US-based training program invests in him to improve his surgical skills not only for his individual benefit but also for the benefit of his home community and his country. As part of his participation in the program, there might be an expectation, if not an obligation, that he will transfer his medical skill acquisition to other surgeons and surgeon assistants in Nigeria. Sub-Saharan Africa is currently afflicted by a significant dearth of surgeons, which is exacerbated by surgeons' emigration and the limited training capacity for surgeons who stay in the region [5]. An analysis by Tankwanchi et al. using the 2011 American Medical Association Physician Masterfile of residency and graduation data from all US trainees found an increase in physician emigration to the United States from every sub-Saharan African country except South Africa [9]. Figure 1 shows the number of physicians per 100,000 people worldwide, based on data from the WHO's 2006 report [10]. Given this evidence of disparities in access to physicians, one might argue that the investment of Dr. R's home country in his training suggests an obligation, both contractual and ethical, on the part of Dr. R. not to exacerbate that disparity.



**Figure 1.** Physicians working. Territory size shows the proportion of all physicians (doctors) that work in that territory. Reprinted from Worldmapper, © Copyright 2006 SASI Group (University of Sheffield) and Mark Newman (University of Michigan) [11].

Note. Data from the World Health Organization's 2006 report [10].

However, Dr. R's case is not quite as straightforward as that of an individual obliged to a particular program or community. Although Dr. R might have applied to participate in the program with an intention to return and practice in Nigeria, we cannot ignore the impact that his experience in the United States could have on his perceptions of his professional potential. After being exposed to a health system with many opportunities, advanced technologies, high salaries, and fair patient burden, Dr. R's vision for his own career might reasonably shift. If the training experience contributes to his possibly changing personal and professional goals, might we consider those goal changes to be ethically fraught? This is another important question in the case.

#### Medical Brain Drain as Exploitation of Wealth Disparities

Particularly problematic is that public investment in health care professionals in resource-poor countries tends to be greater than in wealthier ones, probably due to the relative cost of educating each individual physician. A study in Kenya estimated that the total cost of educating a physician from primary school until earning a medical degree was nearly \$66,000 USD and the loss of return on investments if the physician did not return to the source area to practice was over \$517,000 USD [12]. Estimates suggest that, annually, emigration of health care workers from sub-Saharan Africa costs the region \$2.17 billion USD [13]. While it is important to account for the remittances that are sent back to the source country by emigrants, it is difficult to quantify how much of this money is recirculated in the home economy [13]. By contrast, the areas to which these doctors move are spared the cost of their medical education, benefiting instead by the influx of an educated health care workforce. These consequences suggest that medical brain drain is an important kind of exploitation of wealth disparity and a source of ethical and justice-based concerns [14].

#### Analyzing Potential Sources of Responsibility for Medical Brain Drain

Given that power dynamics inherent in medical brain drain, intentionally or not, amount to exploitation, an important ethical question is this: Do destination areas (the largest of which are the countries in the Organisation for Economic Co-operation and Development) have an ethical obligation to alter systemic practices and conditions that contribute to medical brain drain? Moreover, do duties fall on the destination areas alone, or do source areas bear some responsibility for helping reduce workforce migration? One could also ask whether ethical responsibility falls principally on either of these actors or on individual clinicians. Regardless of whether the actors—programs and clinicians—are behaving ethically, a critical outcome of migration is harm to those source areas struggling to maintain their health care workforces. Table 1 summarizes some of the ethical challenges facing actors involved in medical brain drain.

Table 1. Examining Ethical Challenges among Actors Involved in Medical Brain Drain

Level	Ethical Challenge
Destination Country	How should destination areas provide much needed training to international physicians without contributing to brain drain?
	Is active recruitment of physicians unethical? Is passive recruitment unethical?
	Does the fact that source areas lose an educational investment play into the ethical obligation of the relationship?
	Is there a duty to address primary care shortages and other factors in one's own area to reduce demand from destination area health systems?
Source Country	Are source countries responsible for improving the context in which the health system operates, especially as it relates to corruption, political instability, working conditions, and career opportunities, to attract homegrown physician talent?
	Should source areas reduce the burden on their health systems through strategies such as task shifting and locally relevant training?
Individual Physician	Do the rights of the individual physician to freedom of movement outweigh the moral and contractual obligations he or she faces in his or her place of origin after participating in an international training program?

*Individual physician*. A solid argument can be made that a moral responsibility for medical brain drain falls principally on individual physicians. Committing to being a clinician, particularly in a resource-limited setting, carries with it some responsibility to the community that invested in the training. This is particularly true in health professions because medical care can be considered a "special" good, one that civil society values, sometimes more than a material good or commodity, because it is essential to a person's ability to pursue society's other goods. Moreover, locally trained physicians not only have local understandings of suffering in their communities, but also can be best equipped to alleviate that suffering, given their cultural and linguistic familiarity with those communities; this relationship adds some weight to the moral obligation of the

individual physician from that area. Physicians who are trained in their place of origin thus might have a responsibility to their country not only because of their country's investment in them but also because they are best suited to treat patients in that setting. Nonetheless, as previously mentioned, the question stands: Is it fair for physicians to be held to their commitments prior to international training in a destination country when they cannot predict the impact that such an experience might have on their long-term decision making?

*Destination areas.* From a macroscopic perspective, an ethical argument has been made here that not to oppose brain drain actively is the moral equivalent of supporting it and, hence, supporting a violation of a human right—namely, access to an adequate level of health care for all people as stated in Article 25 of the <u>Universal Declaration of Human</u> Rights [14, 15]. Support for, or complicity in, medical brain drain suggests a responsibility on the part of the destination area. Although Dr. R's training program does not intend to worsen brain drain by hosting Dr. R, we in the United States and other resource-abundant areas must be cognizant of the moral relevance of this possible consequence.

So is recruitment of clinicians or trainees from resource-poor areas ever justifiable? If so, under which conditions? Qualitative studies from Canada of international health care recruiters attribute continuing <u>recruitment of physicians</u> internationally to an unmet labor need in destination countries [16]. Recruiters distinguished between passive and active recruitment, saying that only the latter was unethical. We suggest that an important difference between the two is that, in passive recruitment, international physicians indicated their interest to move first, while in active recruitment, physicians were approached by recruiters who offered them opportunities in resource-abundant areas. Nevertheless, we argue next that actions should be taken to reduce both.

One general line of thought has been that, because destination areas tend to invest less in the preliminary education and training of professionals from source countries, they should procure physicians and other health care workers from within their own areas. In the United States, for example, we could work to alleviate our notable <u>primary care</u> <u>shortage</u> by providing educational loan forgiveness or other incentives to clinicians working in underserved areas. The suggestion has also been made that destination areas pay a commensurate fee for the predicted or actual economic losses to a resource-poor area if they choose to actively recruit physicians from these areas [14].

*Source areas*. Source areas are responsible for migration largely because the inherent poor conditions and intense health system strain could reasonably dissuade talented physicians from practicing within the system. While one might argue that this increases physician responsibility and obligation to remain, the fact that there is a high level of political corruption and relatively meager investment in public health systems in many

(though not all) source countries could lessen an individual physician's sense that acting on such an obligation would actually benefit people in need.

In 2001, the Abuja Declaration called upon countries in sub-Saharan Africa to commit 15 percent of their annual budget towards the health care sector and source countries to allocate 0.7 percent of their gross national income (GNI) toward official development assistance (ODA) [17]. As of 2011, only two countries (South Africa and Rwanda) had met the 15 percent benchmark, and overall dollar value of ODA has actually decreased since 2001 in part due to the global financial crisis [17]. This suggests a failure of some source countries to commit and maintain agreements, which could factor into some physicians' emigration decisions.

For their part, if source areas address the drivers of migration we've considered above namely, educational and practice opportunities, standard of living, and political instability—then incentives to emigrate might offer less appeal [18, 19]. Source areas might ease their internal workforce shortages through task-shifting and using less skilled workers to complete health care tasks that optimize their scope of practice in an attempt to make some clinicians' work more expansive and, perhaps, rewarding. However, addressing issues of corruption within health and political leadership is a much more difficult task without an apparent or immediate solution.

#### Funding and Policy Solutions to Medical Brain Drain

To support much needed global health systems strengthening, Mackey and Liang have proposed the creation of a combined WHO-World Bank special agency that would provide, through a global North-South partnership, funds earmarked for health systems strengthening in low- and middle-income countries with health care worker shortages [18]. The fund would weight a given country's or entity's fee based on recognition of the type and number of workers recruited, the proportionate impact of brain drain on the country, and existing health care infrastructure capacity and disease burden [18]. Initiatives such as the US-funded \$130-million Medical Education Partnership Initiative (MEPI) are already helping build training capacity and are bound to have long-term effects on reducing migration [20]. Unfortunately, the five-year MEPI funding has ended, and renewal for educational health systems strengthening is threatened despite in-country success indicators of the program [21].

In 2010 the WHO adopted a global framework, known as the Global Code of Practice on the International Recruitment of Health Personnel, to address the ethical dilemma of workforce movement from the global South to the North, particularly in sub-Saharan Africa [22]. Studies have shown, however, that this policy implementation has had no effect on slowing down migration to the United States—in contrast, the rate of migration from sub-Saharan Africa has actually increased, especially among physicians under the age of 35 [23]. The code is voluntary and only applies to WHO member states; destination countries have not yet implemented any domestic policies in accordance with the recommendations in the code [18].

Locally relevant training has been proposed by Eyal and Hurst [24] as a potential retention practice that policy makers in source countries should consider. This would entail customizing medical curricula to be more locally relevant, which, the authors suggest, could increase the prestige of staying local, reduce burnout, make skills acquired through the medical curricula more appealing to local employers and less so to international ones, and increase opportunities for career advancement [24]. Given that most medical education funding in source areas is governmental and intended to train physicians to address the health of the public, it is likely reasonable to direct medical trainees to respond to local health system demands.

#### Conclusion

Dr. R's decision to attempt a professional career move after his training in the United States is a symptom of the significant conundrum posed by medical brain drain, namely, that his medical skills are being transferred from where they are most to least needed due to a multitude of factors involving his individual decision making and conditions propagated by both his home country and the United States that encourage his emigration. Many factors contribute to workforce migration globally, including failed global health policies, destination country incentives, and the limited ability of source countries to retain physician talent. The ethical responsibility falls on all actors—the individual physician and the source and destination countries. If Dr. R reneged on a contract he made, he would violate his contractual obligation; if he had no contract but left Nigeria with the understanding that he would return, he would violate what we might consider a communal obligation. But to ignore the systemic root causes for his decision—the roles that we in the United States play and that his own health care system has played—would be to miss an important opportunity to combat medical brain drain.

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## **ETHICS CASE**

A Framework for Assessing Responsibility in Intergovernmental Partnerships

Commentary by Ranu S. Dhillon, MD, and Pranay Nadella

## Abstract

Advancing the health of the poor requires aligning a wide array of interests, all of which influence how health care is delivered. Global health professionals often face difficult decisions that can affect their working relationships with government officials, local colleagues, nongovernmental organizations (NGOs), and private sector interests. This article proposes a "compass-based" framework that urges global health professionals to act in a way that is both morally sound and pragmatically effective. Global health professionals must follow their "moral compass" and act in alignment with the interests of the communities they seek to serve while, at the same time, utilizing their "effectiveness compass" to navigate complex situations in ways that ensure achievement of practicable change that can motivate better health outcomes for those in need.

### Case

You are a physician working at a public hospital in Mozambique through an intergovernmental partnership. Recently, many of your Mozambican colleagues have been complaining that their pay is insufficient and that their working conditions are poor. They suspect this situation is directly due to government policies that are also exacerbating the poor health of the country's residents. In response, these colleagues have decided to strike; they will not see patients until the government increases their wages and invests more resources in the nation's health care sector. One of your colleagues invites you to join the strike. You know that if you do, you will jeopardize your relationship with local government officials, possibly putting at risk the entire program you've been maintaining in partnership with your colleagues, they are likely to feel that you have not supported their struggle; thus you might well be jeopardizing your relationship with them.

How should you respond? What are the best strategies for balancing the need to establish and nurture personal and professional relationships with local colleagues and the need to maintain allegiance to political forces that enable effective partnerships

among governments, health care organizations, health care workers, and members of the public?

#### Commentary

Advancing the health of the poor and fighting for equity is not as simple as investing resources and implementing programs. As this case highlights, achieving health improvements, especially across entire countries and through government systems, requires aligning a wide array of actors with a diverse set of interests, all of which influence how health care is delivered. Because so many of these factors are location specific, there is no comprehensive handbook for global health practitioners to use in situations like the one sketched out above.

#### A Compass-Based Framework for Global Health Interventions

Those involved in global health must develop a framework, or a set of navigational tools, for assessing the forces at play in any given situation and for making decisions that are morally sound yet pragmatically effective in promoting the health of the poor.

Moral compass. In quandaries like the one presented above, global health practitioners should be guided by a "moral compass" that aligns with whatever is best and right for the people whom they seek to serve. Global health professionals find themselves in a wide range of roles, from advising or running a program in partnership with the national or local government to collaborating intimately with a single physician or implementing programs with colleagues. They should seek to have productive relationships with all these agents, but their ultimate obligation is to the intended beneficiaries of their efforts. The well-being of these beneficiaries must come first. For example, when one of the authors (RSD) was advising the president of Guinea during the Ebola epidemic, he emphasized that he was there to advocate for the communities suffering through the horrors of the epidemic. To the extent possible, he attempted to align the interests of the president, the president's administration, and his colleagues—from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and other agencies who were partners in the Ebola response—with those of the communities. No matter how important other relationships and partnerships are in delivering health care effectively, the global health practitioner must always put first the interests of those for whom he or she is ultimately working.

*Effectiveness compass.* At the same time, a global health practitioner needs an "effectiveness compass" to navigate the messy political and social realities that can undermine health care delivery. While working in India, one of the authors (RSD) found that collaborating with the government health system was complicated by competing interests, corruption, and chronically absentee officials. Remaining above the fray, so to speak, would have meant carrying out only the few trivial projects that were free of controversy and neglecting deeper, more important issues because they were morally

and tactically difficult to manage. When RSD visited an Indian village and spoke to a poor woman living there, he could not tell her that while his group *could* intervene to improve her health and the health of her children, the bureaucracy at play was too difficult to work around, and so they would not be intervening at all. Instead, his group jumped fully into the labyrinth of political complexities in order to push for the reforms needed to see gains in health, despite the mess and complexity of doing so. If we are to advocate for the poor, it is our responsibility—while never compromising our moral integrity—to be savvy and find ways to get real, palpable results for the people we aim to serve. Therein lies one of the greatest <u>challenges of global health work</u>: coordinating the multiplicity of interests involved in health care delivery so that programs and interventions adhere to the highest moral standards and are still effective in advancing the health of the poor.

#### Applying the Compass-Based Framework to the Case

This case provides a concrete example of a situation in which the twin compasses of morality and effectiveness must serve as a guide. The conundrum is clear: on the one hand, supporting the health worker strike would damage relationships with the government that in turn could jeopardize not only the program but also, if the strike were unsuccessful, the global health practitioner's positioning to potentially broker changes that could resolve the health workers' demands and advance the people's health. Moreover, were the public hospital health workers to strike, the most vulnerable patients would be penalized the most since they are without reasonable access to health care. On the other hand, not to stand in solidarity with your colleagues, who have legitimate and ultimately important demands, would undermine your relationships with them and thus your ability to advance health care in the hospital. Finally, not to join the strike might be to miss a prime opportunity to push for the policy changes and investments needed to more meaningfully improve the health of the poor.

Managing this situation in a way that is morally sound and practically effective requires taking a step back from an oversimplified "either-or" dichotomy and considering afresh what would most benefit the people being served. It seems that without a change in health worker pay and working conditions, the current system remains untenable and results in overworked, demoralized health workers with inadequate resources. Policy reforms seem both morally sound and practically necessary for improving the health of the people long term.

If both of the health worker issues cited in the case are legitimate—if, that is, their demands for more pay and better working conditions are appropriate—the next consideration is whether the visiting physician's joining the strike is the most ethical and effective strategy for improving pay and working conditions for Mozambican health workers. From a moral standpoint, a strike seems problematic in the short term, since it will leave some of the most vulnerable patients without access to care. By joining, the visiting physician is tolerating this risk while potentially forfeiting an opportunity to

mediate a solution. Is striking—something of a nuclear option in this scenario—really the best way for the visiting physician to help compel policy changes and greater investment? The answer is difficult to discern from the case alone, but in many similar instances such a drastic move, even if it forces short-term reform, can engender long-lasting hostility between health workers and government officials. Even if immediate changes are adopted, seeing them through to a stronger health system requires an ongoing, collaborative relationship between these two actors, which might not exist in the aftermath of a strike.

Whether or not the visiting physician's joining the strike is indeed the most moral and effective strategy is also contingent on a better understanding of the government's current reservations about making the health workers' requested changes. Is the government well-intentioned but simply without the required resources, or is it misallocating funds due to corruption or poor management? Are government officials so unwilling to discuss and find ways to implement these measures that only drastic moves will get them to act?

This analysis of the players, their relationships, and possible motives provides a more thorough and nuanced understanding of how to benefit the people being served in the case scenario. Furthermore, it elucidates the wider set of options that exist beyond a needlessly simplistic "either-or," "with us-or-against us" dichotomy. Increased wages and investments would advance the ultimate goal of improving health for Mozambicans living in destitution, but given the moral and tactical limitations of striking to achieve this end, what other strategies might be more sound morally and just as effective, if not more so? If your colleagues are on the verge of striking, you can assume that some of the other options have already been exhausted, but, depending on the specific reasons the government has been reluctant to concede to any of the health workers' demands, more constructive possibilities should be considered. If the government has the resources and ability to push through reforms for the betterment of the people's health but is resisting for self-serving reasons, then there might be bigger challenges ahead for advancing health equity, and you might need to consider whether, pending changes in government, building programs with nongovernmental partners and with communities directly might, in fact, be the more morally sound and pragmatically effective route.

Based on this assessment, you might determine that the best course of action is not necessarily to side with your colleagues or with the government but to see whether you can fight for the greater good of the general public in such a way that your colleagues' demands are realized without a strike. You could use your unique position as a global health practitioner who is an "insider," but who also has the perceived neutrality that neither your colleagues nor government officials have, to exert leadership in this situation and help broker a more constructive resolution. To favor one side or not act at all in an effort to remain neutral could alienate you from one or both sides, so even

though diving in to mediate a standoff is messy, complicated, and potentially ugly, doing so might ultimately best serve the health of the people.

#### Conclusion

There are no straightforward "rules" or formulas for navigating the broad array of forces that often make or break health care delivery to the poor, but aligning the twin compasses of morality and effectiveness provides a useful framework. Remaining clear-sighted about the ultimate objective—serving the interests of the poor—and assessing how different actors' interests relate to this goal—to generate the greatest good—can guide the global health practitioner in resolving dilemmas like the one presented in this case in an ethical and effective manner.

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### **ETHICS CASE**

#### Changing Donor Funding and the Challenges of Integrated HIV Treatment

Commentary by Nicoli Nattrass, DPhil, MSc, MA, Rebecca Hodes, DPhil, and Lucie Cluver, DPhil

#### Abstract

Donor financing for HIV prevention and treatment has shifted from supporting disease-specific ("vertical") programs to health systems strengthening ("horizontal") programs intended to integrate all aspects of care. We examine the consequences of shifting resources from three perspectives: first, through a broad analysis of the changing policy context of health care financing; second, through an account of changing priorities for HIV treatment in South Africa; and third, through a description of some clinical consequences that the authors observed in a research study examining adherence to antiretroviral therapy (ART) and sexual health among adolescents. We note that AIDS responses are neither completely vertical nor horizontal but rather increasingly diagonal, as disease-specific protocols operate alongside integrated supply chain management, human resource development, and preventive screening. We conclude that health care programs are better conceived of as networks of policies requiring different degrees of integration into communities.

#### Case

You are an infectious disease physician from the United States leading a partnership with a group of local clinics in Southern Africa in providing antiretroviral medications as well as HIV testing and education. Recently, though, there have been discussions among donors about reallocating money to build primary care systems rather than directing resources to respond to specific diseases, such as HIV. Some donors have suggested that building health care infrastructure might be more cost effective and save more lives in the long run and that it is unethical to favor responding to one disease over another. A drawback of the infrastructure-building approach is also acknowledged in these discussions: thousands of people with HIV will lose access to antiretroviral medications within the next few months if resources are shifted. You consider that some increase in mortality might be acceptable if benefits are conferred upon a larger number of patients, but you also worry that some of the patients you've been treating will be directly affected by these policy changes. How should you and other physicians working in this context balance ethical obligations to their individual patients and to donors who must

approach health systems macroscopically? How should these tensions be managed effectively?

#### Commentary

Financing for health care is in perpetual flux. Physicians and nurses working in resourceconstrained contexts might develop their own tactics to optimize treatment and care for their patients. But how should health care workers respond when changing priorities of donors and developmental agencies threaten to disrupt supplies of essential medicines for chronic diseases like AIDS? Should they counsel lifelong adherence to <u>antiretroviral</u> <u>therapy (ART)</u> as a prerequisite for survival, even if ART might no longer be available? This is a core question posed by the case. But, in stating that "thousands of people with HIV will lose access to antiretroviral medications within the next few months if resources are shifted," the hypothetical case constitutes a clear violation of global, national, and bilateral commitments to sustaining HIV treatment for patients for whom treatment is already initiated [1-4].

Our focus here is on the more subtle ways in which changing donor priorities can impact health resource allocation and clinical care provision. We examine some of the consequences of changing resources from three perspectives: first, through an analysis of developments in the political economy of health care financing; second, through an account of changing priorities for HIV treatment in South Africa; and third, through a description of clinical consequences. Our perspective on the ethical dilemmas that health care workers might confront in the aftermath of shifts in donor funding for health care is based on our research on the socioeconomic and experiential aspects of HIV treatment in South Africa; we run the largest known longitudinal, community-based study on medicines-taking and sexual health among HIV-positive adolescents [5-8]. And with an HIV-prevalence rate of 18.9 percent among adults aged 15 to 49 [9] and approximately 5.9 million South Africans who are HIV-positive, South Africa has the world's largest HIV epidemic [2].

#### The Changing Policy Context of Donor Funding for ART Programs

Donor financing for <u>HIV prevention</u> and treatment has shifted from supporting diseasespecific ("vertical") programs to health systems strengthening ("horizontal") programs intended to integrate disease-specific care. Since the World Health Organization (WHO) Declaration of Alma-Ata of 1978 [10], there has been a strong current in public health in favor of primary health care and on general health systems as the most efficient way of delivering health care to the greatest number of people. The contemporary push towards horizontal health systems support and primary health care as an alternative to vertical AIDS funding is sometimes framed as a revival of Alma Ata. The horizontal restructuring of health care services, however, does not necessarily result in treatment disruptions for HIV-positive patients. Nevertheless, if health care services are not integrated cautiously—in response to the needs of local patients, clinicians, and services—this could be detrimental at the individual and systems levels [11, 12].

The AIDS epidemic galvanized one of the most effective health activist efforts of the twentieth century. This movement emerged among gay men in the metropolitan centers of the United States and Europe in the mid- to late-1980s and grew into a broader international response among health care activists. Key scientific advancements followed, particularly the development of the first ART in 1987 and then generic formulations in the 1990s [13]. Nevertheless, the exorbitant cost of ART was an impediment to treatment delivery in resource-poor countries, inspiring new forms of social mobilization and policy changes in line with global commitments to providing universal access to ART [14].

The ethical core of the international AIDS response was the demand for ART as a human right [11] rather than as a good available only for citizens in well-resourced countries. In the late 1990s and early 2000s, influential US officials, including a former head of the United States Agency for International Development (USAID), opposed the public provision of ART in the global South, citing patent laws, the high costs of branded medicines, and the perceived inability of patients in resource-poor areas to adhere adequately [15]. Through advocacy and evidence, however, this stance began to change. In 2003, President George W. Bush pledged \$15 billion to AIDS through the President's Emergency Plan for AIDS Relief (PEPFAR) [16]. In 2005, the Group of Eight (G8)—France, Germany, Italy, the UK, Japan, the US, Canada, and Russia—promised Africa \$25 billion to provide universal HIV treatment by 2010 [17]. Humanitarian agencies, such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), and philanthropic agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, started investing in the global rollout of ART. Partnerships among donor agencies, government health departments, local health care workers, and nongovernmental organizations (NGOs) flourished [18, 19]. Investment in ART was motivated not only by the development of cheap generic formulations of ART, but also by the international focus on HIV as an issue of global security [4, 12].

The unprecedented international response to HIV/AIDS helped fund national ART programs in developing countries. Although funding increased globally for health initiatives from the mid-2000s, donor funding for AIDS rose faster than other categories of health spending [20]. Rather than "crowding out" other health spending, the international AIDS response helped mobilize additional resources for health systems [12]. Because of their explicit commitment to funding ART, national health departments in sub-Saharan Africa, in collaboration with donor agencies such as the <u>Global Fund</u> and PEPFAR, could use HIV-specific funds to strengthen health care systems more broadly [16, 21-22].

The vigorous AIDS response supported patients and health care workers, strengthened distribution networks for medical services, pumped essential resources into pharmacies and diagnostics, and helped reduce the rate of new HIV infections and AIDS-related mortality and morbidity [12, 21, 23-25]. These initiatives also strengthened health systems more broadly [16, 21-22].

After the financial crisis of 2008, however, there was growing concern among physicians and program leaders that funds dedicated for ART would be reapportioned, leaving patients in the lurch. At the XVIII International AIDS Conference held in Vienna in 2010, Ugandan physician Peter Mugyenyi described how past arguments concerning the cost effectiveness of ART had resurfaced:

Once again, we are facing some of those prospects which we faced in the mid-1990s. We are beginning to hear this language once more, that universal access is too expensive and that we can't do it.... We need commitment from our governments, from the international community, and from the leadership of rich countries. The emergency has not gone away. We have a financial crunch. AIDS, more than anything else, requires that resources be increased so that we can continue to solve the century's most devastating health problem [26].

Without access to ART and support in adhering to it, patients face the threat of return to a pre-HIV treatment era. Not only would this violate their <u>human right to health care</u> [27], it also would place momentous strain on health care systems, as wards would again be filled with HIV-positive patients with advanced opportunistic infections and precarious prospects for recovery and survival.

#### **Changing AIDS Policy in South Africa**

Political responses to HIV in South Africa over the last decade have been the focus of much public attention [28, 29]. The AIDS denialism of President Thabo Mbeki and Health Minister Manto Tshabalala-Msimang is one of the most contentious issues to have arisen during the post-apartheid era [30]. The protracted battle for public ART access was waged between South Africa's HIV activist movement and political officials during the late 1990s and early 2000s. However, this did not stop health care workers and bilateral partners from piloting programs to treat and manage HIV in keeping with advancing evidence [18]. Donor-funded projects helped support ART programs from the early 2000s, but it was only after 2005 that ART began to become accessible beyond these individual programs [28]. As donors and bilateral agencies such as UNAIDS, the World Health Organization, the Global Fund, and PEPFAR honed their focus on ART provision, the scope of South Africa's HIV treatment program expanded rapidly. By September 2005, 85,000 people had initiated ART in South Africa's public health sector

[31]. By 2015, South Africa had the world's largest ART program, with 2.6 million people on HIV treatment [32].

South Africa's public provision of ART is the result of a vast mobilization of patients, health care workers, government officials, NGOs, bilateral agencies, and international donors, who have worked together to provide and sustain public access to HIV treatment [19]. To help shoulder the weight of AIDS clinical care, cohorts of <u>community health care</u> <u>workers</u> were employed and clinics began to promote HIV treatment [17]. Mobile HIV testing sites also offered blood sugar testing and contraceptive counseling. Clinic infrastructure was improved, both to host HIV testing and treatment programs and to better capture epidemiological and clinical data [19, 33].

South Africa is one of the states whose national HIV treatment programs helped strengthen health systems and save lives. South Africans on ART can now expect relatively normal life spans [34]. But, as we suggest below, this success is vulnerable to changes in donors' and governments' health care priorities and practices [20, 34].

#### **Donor Decisions, Clinical Consequences**

The effects of changing donor commitments and of governmental reapportioning of resources are evident in our research with HIV-positive adolescents in the Eastern Cape, one of South Africa's poorest provinces with among the highest rates of infant mortality. Many of the adolescents in this research (aged 10 to 19) were born during the era of President Mbeki's AIDS denialism, prior to the establishment of a national program to prevent mother-to-child transmission of HIV. Thus, their mothers could not access medicines to reduce perinatal HIV transmission.

Our research, constituting over 1,000 hours of observation at South African public health care facilities over the course of three years, has shown the importance of carefully considering, as the case scenario suggests, the chasm that can develop between neatly defined donor objectives and their real-world implementation.

This chasm can be seen in one of the health care facilities specializing in the treatment of multidrug-resistant tuberculosis (TB) in which we worked and where many patients are co-infected with HIV and TB. Prior to the drive to integrate HIV services with general care, a dedicated HIV clinic and patient "folder depot" served these patients. To solve the problem of relevant clinical information being kept in separate parts of the clinic, which could potentially add hours to a patient's waiting time, the "folder depot" enabled adolescent patients to fetch their folders from a consolidated data source, see a nurse for a medication refill, and complete their clinical visit within three to four hours.

In the second half of 2015, however, the policy imperative to try to integrate services according to the model of a streamlined, "horizontal" service disrupted the clinic's own

model for optimizing the treatment and management of HIV-positive patients. This model had been developed slowly, by a team of nurses, pharmacists, data capturers and—critically—expert patients who received their own ART at the clinic. The result of this change was not necessarily a shorter waiting time for patients in general, but a longer waiting time for patients on ART, who were combined with patients receiving general services. For adolescents participating in our research who needed ART, this meant that they had to arrive early in the morning and be prepared to wait all day. They reported missing days of school (for which they could be punished) and were further at risk for stigmatization if their HIV status became known to teachers. For the patients' caregivers, this could mean the loss of a day's wages or make it more difficult to maintain a regular job, threatening a reduction in family resources and worsening poverty and food insecurity. For the families reliant on this health care facility, horizontal services integration has not reduced HIV stigma or improved equality; instead, it has exacerbated the challenges of living with HIV and AIDS.

#### Conclusion

Although the provision of ART in developing countries like South Africa was facilitated by donor support, retreat of donors from their commitments to funding ART programs could portend harmful consequences for patients, as is evident in our study of HIVpositive adolescents in South Africa's Eastern Cape. The shift in health care spending from disease-specific interventions to the more general provision of services is being justified with reference to the equity considerations of the Declaration of Alma-Ata [10]. Yet we have seen that AIDS responses are neither completely vertical nor horizontal but, rather, increasingly *diagonal*, as disease-specific protocols operate alongside integrated supply chain management, human resource development, and preventive screening [35]. In the decades after Alma-Ata, research has shown that health care programs are better conceived as networks of policies requiring different degrees of integration into communities [36]. The success of integrated health care, especially in countries with high HIV-prevalence, depends on the sustained provision of HIV treatment [37]. A strictly horizontal approach is blind to the challenges of managing ART programs and to the broader public benefits (fewer new HIV infections, lower morbidity and mortality) of a strong ART program. A weak ART program will harm patients and risk a resurgent AIDS epidemic. In South Africa, political obstructions to ART have subsided in the wake of successive government commitments and ambitious plans for the provision of HIV testing and treatment programs. The difficulties of sustaining ART provision, and of developing patient-led strategies to support adherence to ART, are the next challenges that frontline health care workers will confront.

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### **ETHICS CASE**

#### **Blending Western Biomedicine with Local Healing Practices**

Commentary by Anita Chary, MA, and Carolyn Sargent, PhD

#### Abstract

Western allopathic physicians working internationally might encounter allopathic colleagues who endorse local healing practices that are not scientifically supported and, hence, might pose harm to patients. Respect for the autonomy of local physicians and patients thus can conflict with the ethical principles of beneficence and nonmaleficence. In such a situation, it is advisable for Western allopathic physicians to communicate their concerns to local colleagues as equal partners. Making an effort to understand local meanings associated with a traditional therapy demonstrates one's respect for local cultural ideas and practices, even if one disagrees with that therapy, and is crucial to tailoring messages about clinical practice change. A realistic approach to cross-cultural clinical practice change seeks to reduce, rather than eliminate, harm.

#### Case

Maria is a US physician who has been assigned to teach a six-month course on cardiovascular and respiratory pathology to medical students in Thailand. While there, she notes that some of the local clinical professors, who are also physicians trained in allopathic medicine, endorse a traditional naturopathic herb for treatment of congestive heart failure. This herb does not have scientific support in the allopathic literature, and some studies suggest that it might even be detrimental to health. Furthermore, Maria worries that availability of the herb could dissuade patients from using Western medicines. On the other hand, she acknowledges that some interventions that do not have scientific validity from a Western allopathic perspective can have ethical, cultural, social, personal, and clinical value in other contexts.

How should Maria—and Western allopathic physicians working to develop health systems internationally—respond to valued local health practices that could be harmful to patients based on scientific evidence generated within Western allopathic models of healing?

#### Commentary

The above scenario is quite familiar to health care professionals working in international

settings, where a variety of healing modalities that are distinct from those of Western allopathic medicine are part of the local approach to treating illness. Importantly, this case of clinical practice conflict concerns not only direct patient care and health outcomes, but also relationships with colleagues in the setting of health systems development. In other words, in this situation, more is at stake than the health of a single patient or population of patients; also at stake is a collaborative relationship between a US-based practitioner and local Thai colleagues, all of whom share the goal of educating medical students and improving the local health system. If Maria expresses concerns about the herb for treatment of congestive heart failure, will the Thai clinical professors perceive it as disrespectful? Is it ethical for Maria to attempt to <u>change a culturally</u> meaningful practice by condemning use of the herb? How can Maria show respect for local healing modalities and for the autonomy of local clinicians and patients while also abiding by ethical principles of beneficence and nonmaleficence?

In this situation, we believe it is important for Maria to voice her concerns to local physicians about the naturopathic herb. However, she must use her authoritative allopathic knowledge carefully, recognizing that imperatives—i.e., "don't use the herb"—could alienate Thai patients and clinicians alike. During fieldwork as medical anthropologists in Latin America, Asia, and Africa, we have often witnessed an unfortunate consequence of allopathic practitioners' demands that local health practitioners and patients stop using a traditional medicine: local rejection of Western allopathic medicine altogether.

One thing we've learned is that cross-cultural medicine should instead involve respectful dialogue, listening, and the willingness to compromise. Maria's development of a solid appreciation for the context of local clinical practices will be imperative if she is to <u>communicate sensitively</u> with the clinical professors. For Maria, promoting a change in clinical practice will take time and most likely require many conversations with her Thai colleagues. In what follows, we discuss key considerations for successful communication promoting such change.

An important consideration for Maria is recognizing how power differentials within the local practice setting might affect the way her Thai colleagues perceive her actions, intentions, and concerns. In health systems development, local practitioners—those from the global South or from low- and middle-income countries—and allopathic physicians—particularly those from Western nations—are often not on equal footing. Funding institutions for international projects are typically based in high-income Western countries and do not always involve local practitioners as equal partners in setting priorities. Local practitioners might be under pressure to comply with the requests of their collaborators from Western countries to ensure continued funding of projects, even if it means sidelining local priorities [1]. In attempting to encourage a change in clinical practice, Maria must ensure that her concerns about the naturopathic

herb are perceived not as a top-down demand or condemnation from an outsider but rather as the beginning of a mutually respectful conversation between equal partners.

Maria should raise the topic in a way that demonstrates her regard for her Thai colleagues' and patients' knowledge, experience, and opinions. Maria might first choose to discuss the herb with a trusted local colleague with whom she has developed rapport before bringing it up to the group or department as a whole. During initial conversations, rather than voicing her immediate concerns that the herb could be inefficacious and even pose harm to patients, she might employ open-ended questioning: "Tell me more about this herb I've been hearing about for congestive heart failure. What are your observations about its effects? And what do patients think about this herb?"

Maria must also strive to understand the local particularities of the Thai practice of Western allopathic medicine, sometimes referred to as biomedicine, which is present as a healing system all over the world. In the US and high-income countries, biomedicine is associated with several core features. First, the mainstay of the biological and clinical sciences' knowledge base is derived from human subject research from clinical trials. Second, the focal subject of Western allopathic medicine tends to be an individual human body, rather than a set of social relations, an environment, or an ecosystem affected by illness. Third, Western allopathic medicine dominates clinical practice in the US and many high-income countries, and the majority of biomedical practitioners, are unlikely to practice or endorse other healing modalities with the exception of alternatives such as chiropractics and acupuncture [2].

However, variations on these themes are present in the practice of biomedicine throughout the world. As discussed by physician-anthropologist Arthur Kleinman, multiple forms and cultures of biomedicines exist [2]. In low-resource contexts, particularly in rural areas or at underfunded universities with limited access to cuttingedge clinical literature, <u>evidence-based paradigms</u> tend to become less important as physicians rely on expert opinion and individual empirical experience to guide practice [3]. Additionally, in non-Western settings, it is not uncommon for biomedical practitioners to incorporate aspects of local or <u>traditional healing systems</u> into Western allopathic practice, as seen with Ayurvedic healing in India, classical Chinese medicine in China and Southeast Asia, and traditional medicine in Thailand [4-8].

Understanding not only the local variations in Thai biomedical practice but also its context is key for Maria if she is to communicate successfully about the clinical situation in which she is practicing. First, she must become familiar with the drivers of change at the local medical school. For example, do the Thai clinical professors and students have access to clinical literature, and are they accustomed to reading it? Are continuing medical education courses available, and do health care professionals anticipate changing their practice over time based on such courses? Do Thai physicians look to

particular institutions, such as professional associations or the Ministry of Public Health, for practice guidelines? Do physicians learn largely from apprenticeships with other physicians? Which sources of knowledge are respected and which are suspect? Understanding what drives change in Thai biomedical practice can help Maria determine how best to tailor information to her audience, whether this involves presenting professors and students with primary sources about the herb, reviewing treatment guidelines from governing health agencies, or offering to work with other professors and students to see patients with congestive heart failure.

Maria might also explore factors that lead the Thai clinical professors to integrate naturopathy and biomedicine. Traditional healing systems can contribute to national identity by serving as points of pride and cultural uniqueness. Indeed, for this reason, some governments in the global South make traditional remedies available through public health institutions and integrate traditional healing systems into national health care systems [9-12]. Clinicians' prescription of nonallopathic remedies thus might form part of nationalist projects. Syncretism of biomedicine and traditional healing can also serve local social purposes, such as indicating a physician's religious or ethnic affiliation and, accordingly, attracting a patient base with shared identities [13, 14].

Maria must also attempt to understand the cultural meanings associated with the naturopathic herb. In much of the world, local, complementary, and alternative healing modalities offer health seekers goods, services, and approaches to wellness and illness that Western allopathic medicine does not. For example, in many traditional healing systems, the focus of clinical intervention is not only the individual body, but also—for patients and families—something larger, such as solidarity within extended kinship groups and the well-being of local communities [2]. Has knowledge about the herb been passed down from generation to generation? Is growing, harvesting, procuring, and preparing the herb a social process thought to benefit many rather than a single patient with congestive heart failure? Use of locally grown herbs can have social and cultural heft because they can signify one's connection to a specific ethnic group or village, particularly in times of social and cultural change. If locals see long-standing social and cultural practices as at risk from competing paradigms, they might use a local herb as an expression of commitment to family, community, ancestors, or a way of being [13, 14].

Considering the local context of biomedical practice as well as social or cultural rationales for using an herb can better position Maria to discuss with her Thai colleagues the use of an herb for a particular purpose. As medical anthropologists, we have seen diverse results of such conversations. At times, traditional healing modalities serve too many social functions and play too many important cultural roles to be supplanted. At others, local practices are phased out in favor of an allopathic practice. And sometimes, when patient populations strongly favor traditional healing, clinicians compromise by suggesting a symbolic dose of an herb or medicine, small enough to avoid interactions
with biomedical treatments. Seeking to reduce rather than fully eliminate the potential for harm often seems to be a realistic approach.

In summary, we offer the following general advice for those involved in cross-cultural health systems development who find themselves in Maria's dilemma:

- 1. Communicate with local colleagues as equal partners.
- 2. Understand what drives change in biomedical practice locally and tailor messages about practice change accordingly.
- 3. Make an effort to understand local meanings associated with a traditional therapy to demonstrate respect for local cultural ideas and practices, even when disagreeing with the safety or efficacy of that therapy.
- 4. Seek to reduce rather than eliminate potential for harm.
- 5. Recognize that change takes time but that an individual can introduce an innovative idea and, with support from others, encourage modifications to clinical practice over the long term.

# Conclusion

We would like to close with a story. When one of the authors (CS) was beginning her career as a scholar of reproductive health, she was conducting fieldwork in a rural West African village. After deliveries there, birth attendants would place dung on the newborn's umbilical stump to dry it out. The author felt conflicted, as this practice is known to be dangerous in Western medicine [15, 16]. As a foreigner to the community, she pondered whether to say something to the midwives about what she knew from an allopathic perspective. Would they see her comments as disrespectful? When she described her dilemma to an elder woman, who was a respected community leader, the elder responded, "Your duty is to convey what you know. And the family's duty is to decide what they think is best." The elder's statement encapsulates the heart of the challenge posed by the concept of autonomy: sometimes we must respect—at least in the short term—decisions that we might not fully support.

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# THE CODE SAYS

**The AMA** *Code of Medical Ethics*' Opinions on International Health and Research Danielle Chaet, MSB

Although the AMA *Code of Medical Ethics* provides guidance primarily to physicians practicing in the US, these physicians are expected to uphold the *Code*'s standard of professionalism when working internationally. Accordingly, the *Code* specifically addresses ethical issues related to physicians' conducting <u>biomedical or behavioral</u> <u>research outside the US</u>. By the same token, physicians practicing in the US are expected to uphold the *Code*'s standard of professionalism regardless of their patients' national origins, and the *Code* specifically addresses <u>safely discharging patients</u> who are noncitizen immigrants.

Opinion 2.077, "Ethical Considerations in International Research" [1], provides guidelines for physicians participating in research in countries with differing cultural traditions, health care systems, and ethical standards. Physicians have ethical obligations to ensure protection of research participants in several ways: first, they must ensure that the research protocol has been developed according to a sound scientific design. In fact, with certain exceptions, US investigators must obtain approval for such protocols from institutional review boards (IRBs) [2]. What are the specific participant protections addressed by Opinion 2.077?

Opinion 2.077 specifies that IRBs—particularly, physicians who serve on them—must determine that the "ratio of risks to benefits is favorable to participants." The opinion states that when making this evaluation, the IRB "should obtain relevant input from representatives from the host country and from the research population." As with any research protocol, IRBs are required to protect the welfare of individual participants by ensuring that an appropriate and effective informed consent process will take place. In order for the information presented to be meaningful to the participants, it needs to be communicated in ways that are consistent with local language and customs. Opinion 9.121, "Racial and Ethnic Health Care Disparities" [3], while not discussing research per se, also touches on this point by noting that

Participatory decision making should be encouraged with all patients. This requires trust, which in turn requires effective communication. Physicians should seek to gain greater understanding of cultural or ethnic characteristics that can influence patients' health care decisions. Physicians should not rely upon stereotypes; they should customize care to meet the needs and preferences of individual patients.

Finally, Opinion 2.077 explains that IRBs must protect from exploitation the population from which participants are recruited by ensuring that the research corresponds to an actual medical need in a region. The research should also have <u>potential for lasting</u> <u>benefits</u> for the population from which participants are drawn, particularly if the region lacks health care resources. Moreover, physicians conducting human subjects research must encourage research sponsors to continue to provide interventions found by the study to be beneficial to all participants at the conclusion of the study.

#### Safe Patient Discharge

The *Code* also speaks to international health in cases in which noncitizen immigrant patients are being cared for in US hospitals. Opinion 9.141, "Safe Patient Discharge" [4], provides guidelines for physicians who might face conflicting demands in discharging patients. When a nonpaying, noncitizen patient is being cared for in a US hospital, physicians at that hospital must balance the needs of the patient with those of the greater community. While resources at the US hospital might be limited (e.g., beds, clinical staff, and money), physicians still may not ethically discharge any patient to a resource-poor environment where the patient's health would be at risk. Similarly, a patient who is ready for discharge may be released into care that is safe and adequate for his or her clinical situation but possibly not ideal. (For example, an ideal care setting might include 24-hour daily care though only 18 hours daily can be provided.) The background report on the opinion explains the factors a physician should consider in these types of circumstances.

Throughout the discharge process, physicians should listen to the concerns of future caretakers and to the preferences of a patient who is not a citizen or legal resident just as they would when planning the discharge of a citizen patient. The physician should consider the caretakers' and patient's understanding of the standards of care in their country of citizenship and the social attachments (such as employment or other support systems) that the patient may have in the US, for example. These considerations may be important when physicians assess the adequacy of future care arrangements for the patient. Moreover, the caretakers' and patient's involvement in the discussions may very well lead to a helpful consensus about what ought to be done [5].

The background report acknowledges that occasionally, despite the best efforts by a physician and the discharge team, there may be no ethically satisfying decision. If no consensus can be reached about how the patient's care ought to be handled, a physician

should support the patient's right to seek input from an <u>ethics committee</u>. Should stakeholders continue to fail to reach consensus, a physician should support a patient's right to seek arbitration before a legal body. Consultation with the embassy of the patient's country of origin might also be helpful. It is extremely important to note, as the report does, that "forcing an immigrant to leave the US is a prerogative of the federal government, and should only occur following due process. Physicians should decline to authorize a discharge that would result in the patient's involuntary repatriation, except pursuant to legal process" [5].

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# **MEDICAL EDUCATION**

# Medical Education and Global Health Equity

Peter Drobac, MD, MPH, and Michelle Morse, MD, MPH

# Abstract

Recent efforts to expand medical training in resource-constrained settings are laudable, but change that transforms health systems will require new educational approaches. Today's physician-leaders need to leverage clinical and global health knowledge with a nuanced understanding of the social forces that impact health, the ability to marshal political will, and the capacity to manage dynamic programs and institutions. In establishing the University of Global Health Equity, we have identified three reform principles. First, equipping medical schools with the tools and technology to deliver is imperative. Second, the mismatch between the skills taught in most medical schools and those needed to improve fragile health systems must be addressed. Finally, medical schools that strive to eliminate health inequities should "walk the walk," adopting progressive practices to institutionalize equity.

Profound <u>shortages of skilled health personnel</u> are both a cause and a consequence of the fragile health systems that plague much of the world. The recent Ebola outbreak in West Africa, which has claimed over 11,000 lives, illustrates this phenomenon [1]. Years of civil unrest and displacement, coupled with chronic underinvestment in health care services and health education, severely depleted the health care workforce. In this setting, there was little to stop the rapid <u>spread of Ebola</u>. Frontline health care workers, without adequate training or personal protective equipment, were particularly vulnerable. In Liberia, which had only 1 physician per 100,000 people before the epidemic [2], an estimated 8 percent of the country's health care workers died in the epidemic [3]. With the remaining workforce unable to safely deliver basic primary health care services, thousands of additional preventable deaths among mothers, infants, and children under five are projected to occur [3].

Many countries have responded to health care personnel shortages with increased investment in education. The number of medical schools in sub-Saharan Africa has more than doubled since 1990 [4]. But is simply training more physicians and other health care workers an adequate response? We argue that physicians cannot serve impoverished communities effectively without understanding the structural forces that drive inequality and concentrate suffering disproportionately among the poor. Moreover, we believe that

educational institutions have a responsibility to train health professionals to actually improve the health systems in which they will be working.

#### A New Paradigm: The University of Global Health Equity

Founded in 2015, the University of Global Health Equity (UGHE) is a private, not-forprofit university established by <u>Partners In Health (PIH)</u>, a Harvard-affiliated global health and social justice organization, in collaboration with the government of Rwanda and other partners [5]. UGHE is located in Rwanda because of the country's impressive track record of health care delivery innovation, success in health systems strengthening, and commitment to reducing social, economic, and health inequalities [6]. Over the past 15 years, <u>Rwanda's approach to health care reform</u> has driven perhaps the most dramatic improvements in population health and prosperity in the world [6]. Through progressive education programs, experiential learning, and research, UGHE—which will enroll its first cohort of medical students in 2018—aims to become a global hub for advancing and disseminating such innovations in health care delivery science and for cultivating a new generation of global health leaders.

Although other medical schools often struggle to enact incremental reforms, as a new institution UGHE has a rare opportunity: a blank canvas upon which to reimagine medical education. Three principles are relevant to medical schools that endeavor to strengthen health systems in resource-constrained settings. First, equipping medical schools and their clinical training sites with the tools and technology to deliver high-quality health services is not only a necessary prerequisite for quality education but also a justice issue. Second, there is a mismatch between the skills taught in most medical schools and those needed to practice effectively within—and to improve—fragile health systems. Medical educators need to rethink both what they teach and how they teach. Finally, <u>diversity in health professions training</u> may both improve the quality of education and remediate disparities in health care access for underrepresented minority groups [7]. Therefore, medical schools with a social mission that strive to eliminate health inequities should "walk the walk" by adopting progressive admissions standards—which consider the full potential of the student—and other practices to address inequities in access to quality higher education.

## Access to Information and Technology

It is virtually impossible to improve fragile health systems without first ensuring that basic infrastructure and resources are in place. Paul Farmer has called these the four S's, referring to "staff, stuff, space and systems" [8], which are discussed briefly below. The technical term for this is *health system readiness*. Like the health systems they support, medical schools in resource-constrained settings cannot be expected to thrive without critical resources and technologies.

What, then, should be the "medical school readiness" package in resource-constrained settings? Surely it should include sufficient numbers of qualified faculty (staff), adequate educational and clinical infrastructure (space), research opportunities and robust accreditation systems with global minimum standards (systems), and access to information and technology (stuff). The latter is worth emphasizing. Access to digital information does not require sophisticated technology. A stable Internet source and access to a connected device is adequate if coupled with open access to the medical literature and online clinical resources, such as UpToDate<sup>®</sup>, that many of us take for granted.

But consider the reality for medical students in many parts of the world. In Haiti, for example, only 6 of 10 teaching hospitals in the country have reliable Internet access and only half have medical libraries (ME Morse, unpublished data, 2015). Imagine trying to learn and practice twenty-first century medicine in a setting where the dominant education technology is the chalkboard and modern medical knowledge is out of reach in expensive, elite medical journals. In our experience, lack of access to technology, so critical in the rapidly changing field of medicine, exacerbates inequities in medical education.

UGHE benefits from a visionary development policy of the Rwandan government, which has laid fiber optic broadband cable throughout the country. This allows UGHE faculty to blend curated online classes from Harvard and elsewhere with vigorous classroom discussions, creating more diverse active learning experiences. Students, who can be scattered at their workplaces and clinical sites during the week, have formed a tightly knit virtual learning community that extends beyond the classroom—one that in coming years will connect students around the world and, perhaps, motivate better understandings of health inequalities and how to respond to them.

## Transformative Leadership Begins with Transformative Learning

American medical education has seen pockets of innovation and a groundswell of calls for reform in recent decades [9]. Nevertheless, for a discipline evolving as feverishly as medicine, it is remarkable that the dominant paradigm for physician education is over a century old. Many of the defining features of the twentieth century medical school as identified by the 1910 Flexner report [10]—a heavy emphasis on the basic sciences, a largely didactic "preclinical" phase, and clinical training that is concentrated in hospitals—stubbornly persist. Moreover, the professionalization of medicine catalyzed by the Flexner report resulted in the closure of many medical schools that accepted minorities and women [11, 12], an exclusionary trend that still demands solutions.

In our opinion, this model is inadequate for training physician-leaders whom we need to respond to health injustices. Today's physician-leaders need to leverage clinical and global health knowledge with a nuanced understanding of the social forces that impact

health, the ability to marshal political will, and the capacity to manage dynamic programs and institutions. These competencies are not typically developed in today's medical school curricula [13].

UGHE's approach to training physician-leaders begins with a paradigm shift from a purely biological to a biosocial understanding of health and disease. Social medicine examines the social, economic, and political determinants of health and highlights the moral and epidemiologic dimensions of health disparities. Think of it as an expanded "diagnostic" toolkit. The biosocial orientation to medicine can be coupled with pragmatic skills and praxis to create more equitable and effective health care delivery systems. This "therapeutic" toolkit, or social medicine prescription pad, draws from principles of leadership, management, ethics, public policy, social science, activism, and design thinking.

These principles form the basis for UGHE's Master of Science in Global Health Delivery (MGHD), currently a part-time degree program for working health professionals from diverse disciplines. The MGHD will be woven into the medical school curriculum to produce a unique joint degree program. UGHE's approach is consistent with what Julio Frenk and colleagues describe as a "third-generation" approach to health professional education, one that uses global knowledge to inform the transformation of health systems by change agents whose competencies mirror health system needs and priorities [14].

At a time when graduates of health professional schools struggle to understand structural violence—systemic forces that prevent people from achieving their full potential [15]—the root causes of poor health, and how to remediate these problems, only a radical departure from educational norms will suffice. Frenk and colleagues [14] have called for educational reform to generate transformative learning, an evolutionary concept that builds upon informative learning (acquisition of skills and knowledge) and formative learning (socialization and professionalization). Transformative learning aims to develop leadership competencies through shifts "from fact memorisation to searching, analysis, and synthesis of information for decision making; from seeking professional credentials to achieving core competencies for effective teamwork in health systems; and from noncritical adoption of educational models to creative adaptation of global resources to address local priorities" [16].

Our experience in Rwanda, Haiti, and the United States suggests that experiential learning is a powerful tool to shift from formative to transformative learning. Through home visits, mobile clinics, and direct engagement with community health workers and communities, medical trainees begin to experience the lives of the people they serve. This brings trainees closer to understanding the root cause of illness in ways that will allow them, in partnership with their patients, to find solutions to this world's most

pressing challenge, <u>achieving health equity</u>.

As educators who believe in fostering critical thinking that empowers students to be more than passive receptacles of knowledge, we believe that the best classroom is the lived experience of our patients. According to education theorist and activist Paulo Freire, "teachers and students (leadership and people), co-intent on reality, are both Subjects, not only in the task of unveiling that reality, and thereby coming to know it critically, but in the task of re-creating that knowledge" [17].

#### Institutionalizing Equity

In the United States, well-documented racial, ethnic, and economic disparities in health care access and outcomes coexist with <u>underrepresentation</u> of these same groups among medical school faculty and students [7]. Moreover, institutional bias in academic medicine and the culture of medicine itself—in both the training of health professionals and the organization of health care delivery systems—can reinforce health care disparities [18]. Without a commitment to a social mission, health professions education institutions can themselves become perpetrators of structural violence. Progressive admissions standards, which consider the full potential of the student rather than promote a simplistic focus on test scores and grades, have the potential to systematically elevate those whose voices have been silenced and are a vital step towards correcting the mistakes of the last generation's institutions. Mullan and colleagues have proposed a social mission composite score that ranks medical schools according to the percentage of graduates working in primary care, practicing in underserved communities, or who are underrepresented minorities [19].

New universities like UGHE have an important opportunity to provide models for institutional reform by implanting an equity agenda into their institutional DNA. This will require significant investment and imagination. Progressive admissions practices alone will not truly create opportunity for young women and men from extremely impoverished backgrounds. Because many children lack access to quality primary and secondary education, an educational bridge program may be required to prepare students for a rigorous university education. Creative tuition financing models are needed to eliminate financial barriers for the majority of potential students. And community engagement strategies are needed to ensure that the university catalyzes local development and creates an ethos of leading through service.

Already, such aspirations to deliver world-class health professions education in settings of resource scarcity are raising questions of cost and sustainability, echoing many of the debates in global health over the past two decades. Not long ago, antiretroviral therapy (ART) for HIV/AIDS was deemed too complex, too expensive, and not cost-effective for millions suffering from the disease in poor countries. Today, over 15 million people worldwide are on ART [20], the positive economic impact is well documented, and there

is even discussion of the potential to achieve a "grand convergence" of health outcomes in rich and poor countries [21]. Viewed through the lens of value for health systems and economies, we believe that high-quality, progressive health professions education represents an equally sound investment.

Paulo Freire called education "the practice of freedom" [22]. It can also be a tool for justice. At its best, medical education can do more than improve health—it can create a better world.

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# **MEDICAL EDUCATION**

# Medical Education Capacity-Building Partnerships for Health Care Systems Development

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## Abstract

Health care workforce development is a key pillar of global health systems strengthening that requires investment in health care worker training institutions. This can be achieved by developing partnerships between training institutions in resource-limited and resource-rich areas and leveraging the unique expertise and opportunities both have to offer. To realize their full potential, however, these relationships must be equitable. In this article, we use a previously described global health ethics framework and our ten-year experience with the Makerere University-Yale University (MUYU) Collaboration to provide an example of an equity-focused global health education partnership.

## Introduction

In global health collaborations between institutions in resource-rich and resource-limited communities, money and expertise typically flow in one direction. <u>Research relationships</u> have built significant capacity—in infrastructure and human expertise—for basic science and clinical investigation over time. More recently, there has been increasing emphasis on translating this research into improving health outcomes in the study communities [1, 2]. <u>Global health educational relationships</u>, on the other hand, often develop out of the desire of academic institutions in resource-rich environments to provide their trainees with clinical experiences in resource-limited environments. These experiences are intended to provide trainees with exposure to globally relevant diseases and health care systems challenges that are uncommon in their home institutions, with the expectation that this perspective will enhance their clinical skill and knowledge as well as their understanding of the complexity of delivering care in resource-limited environments [3, 4]. Benefits to the partner institutions, however, are not as well defined [5]; this is, in part, due to lack of scholarly attention to this issue, although how benefits are defined would also depend heavily on the framework of the relationship.

As noted in the 2010 Lancet Commissions report, "Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World" [6], there is a gross mismatch between population needs and provider capacity as a result of major global gaps in current postsecondary training programs in medicine, nursing, and public health. The report called for a social movement within the health professions—with professional educators, students, and young professionals serving as key players along with other stakeholders—to promote a common, global, cross-disciplinary strategy to address health systems strengthening needs. Among a host of other reforms, this strategy sets the stage for a new philosophy of global health educational partnerships, one that demands grounding in the "principles of non-exploitative and non-paternalistic equitable sharing of resources to generate mutual benefit and accountability" [7]. One key component of bidirectional partnership involves leveraging the experience of academic institutions to <u>develop medical faculty for resource-limited regions</u>. More than simply a training-of-trainers focus, the development of academic faculty serves to enhance capacity for both clinical reasoning and critical thinking and, thereby, the local human resources available to address health systems issues. In this model of partnership, the institutions in resource-rich regions also benefit by enhancing the breadth of their training and research capacity.

In order to achieve their goals, however, these collaborations must first and foremost be equitable relationships. Within this framework, equity requires that more resources be directed toward the less advantaged partner, thereby ensuring that the outcomes of the relationship will place both parties on an appropriately enhanced footing. This article will discuss such a framework, using the example of the Makerere University-Yale University (MUYU) Collaboration, a global health education capacity-building project between Mulago Hospital (MH)-Makerere University College of Health Sciences (MakCHS) in Kampala, Uganda, and the Yale School of Medicine (YSM) in New Haven, Connecticut.

#### An Equity-Focused Global Health Education Collaboration Model

MUYU was launched in 2006, with the Yale portion of the partnership having grown out of the global health program in the Department of Internal Medicine at the YSM. The Yale program had been sponsoring ongoing international clinical health elective rotations for residents since 1981, making this one of the oldest such programs in the United States [8]. As has been previously described [9], Mulago Hospital, operated by the Ministry of Health, is the main Ugandan National Referral and Teaching Hospital, with a very high volume of patients that typically exceeds its 1,500-bed capacity. Mulago Hospital also serves as the primary clinical training site for MakCHS undergraduate medical and nursing students as well as postgraduate medical and surgical trainees. Although MakCHS has many ongoing international research collaborations and has an office dedicated to hosting international clinical trainees and faculty, MUYU is one of very few educational collaborations with a focus on *bilateral* capacity building.

The concept for MUYU was born in 2002, when faculty from the Yale Global Health Program joined together with MakCHS faculty leadership to develop a vision of a mutually beneficial relationship with a primary focus on improving the quality of patient care on the wards of Mulago Hospital. It was agreed that the primary transformative mechanism would be training of key clinical faculty in areas identified by the leadership at MH-MakCHS. Faculty training would in turn enhance the quality of training of MakCHS postgraduate (residents) and undergraduate trainees while providing opportunity for Yale students, residents, and faculty to participate in MH-MakCHS clinical, educational, and research activities.

From this foundation has grown a robust collaboration that involves five elements: (a) an organizational structure headed by co-directors (one from MakCHS and one from Yale); (b) administrative offices to support visiting trainees and faculty at both institutions; (c) a faculty exchange program (as described elsewhere [9]) to support the development of junior Mulago Hospital physicians and MakCHS faculty in areas that are identified as priorities for the leadership at MH-MakCHS; (d) a Yale-to-MakCHS exchange program for short-term clinical and research experience for faculty, residents in various specialties (i.e., internal medicine, emergency medicine, neurology, and obstetrics and gynecology), and senior medical, physician associate, nursing, and public health students; and (e) a MakCHS-to-Yale senior medical student exchange program for selected students to participate in short-term and often transformative clinical training in internal medicine, funded by the Yale School of Medicine in reciprocity for the resources devoted by MakCHS faculty to hosting and educating Yale students in Kampala.

In addition, MUYU has given rise to a host of offshoot capacity-building initiatives in Uganda. These include a program within the MakCHS structure that specifically supports the education of postgraduate internal medicine trainees; the development of the Uganda Initiative for Integrated Management of Non-Communicable Diseases (a multisectoral partnership with the mission of building capacity in the realms of prevention, care, training, and research to enable the provision of effective and integrated care) [10]; capacity building within teaching laboratories at MH; and MakCHS medical library enhancement. Of note, the MUYU Collaboration developed at the same time that specific global health education ethics recommendations were emerging; it is instructive, therefore, to have this concrete example in mind during the subsequent discussion of two of the key guidance documents.

## Ethics and Equity in Global Health

In 2010, a geographically and professionally diverse group of leaders in global health education and ethics came together as the Working Group on Ethics Guidelines for Global Health Training (WEIGHT). The resulting guidelines [11] provide a framework to support the multiple stakeholders in global health training programs (identified as sending and host institutions, trainees, and sponsors) in developing ethically responsible training experiences and programs. The group drew a clear link between the ethics of global health collaboration and the concept of equity, stating:

Global health training that benefits the trainee at the cost of the host is clearly unacceptable; mutual and reciprocal benefit, geared to achieving the program goals of all parties and aiming for equity, should be the goal [12].

Acknowledging the Western philosophical bias and focus on the individual patientphysician relationship of the classic four principles of biomedical ethics (autonomy, beneficence, nonmaleficence, and justice) [13], Pinto and Upshur have proposed an additional set of ethical principles that may be more useful in the setting of global health endeavors that aim for equity [14]. Although these principles were articulated as guidance for individual students or health practitioners, we find that introspection, humility, solidarity, and social justice can also be useful in framing an equity-focused global health educational collaboration.

*Introspection.* The first step is to openly define one's motives in becoming involved in such a collaboration. This mutual understanding, in conjunction with a shared vision for the partnership, will then drive the structure for implementing the vision. It was critical for YSM participants in MUYU to recognize that the major strength of the YSM lies in faculty members' expertise as educators and investigators, coupled with the availability of other resources that could enrich collaboration. We therefore hoped to improve the quality of care provided to patients at MH through training of junior and mid-level physicians and faculty in the areas of need identified by the MH-MakCHS leadership, which would have a magnified downstream effect on the training of future clinicians, researchers, and leaders. In return, this partnership would provide a rich environment for Yale faculty, residents, and health professions students to enhance their knowledge and skill in areas relevant to their clinical or investigative interests.

*Humility.* Humility requires that resource-rich institutions enter into relationships with institutions in resource-limited areas, recognizing that partners are best positioned to identify their own core problems and solutions. This necessitates a willingness to hear partners' ideas with an open mind. The leaders at MH-MakCHS defined a primary need for increased capacity in noncommunicable diseases and asked that the collaboration focus on training faculty in these fields. The partnership was, therefore, structured to clearly respond to this need.

*Solidarity*. The concept of solidarity is best crystalized in the following question: Are the partners working in a unified manner toward a common goal? The YSM partners felt strongly that—by virtue of engaging with MH-MakCHS—Yale had the responsibility to help strengthen MH and MakCHS, two institutions that are ultimately responsible for providing care and training a significant portion of the health care workforce for Uganda. The MUYU co-directorship, an administrative model involving leadership from both institutions, was devised to further strengthen commitment to this goal. The result of

these decisions is that—since 2006—the partnership has facilitated the bilateral and ongoing exchange of more than 400 faculty, residents, and students, including 15 Ugandan attending physicians and faculty trained in specific subspecialty areas identified as high priority by the leadership at MH-MakCHS.

*Social justice*. The concept of social justice is exemplified by this question: Is the collaboration designed to decrease human suffering in the resource-limited region? In the case of MUYU, the Ugandan consultants and faculty have, thus far, all returned to Uganda, and 12 of 15 have assumed MH-MakCHS positions in which they have used skills and concepts learned at Yale to develop new systems of education, applied research, and clinical care. This partnership thus has had significant impact on the training of students and residents as well as on the care of patients in the national referral hospital. This partnership has also enriched the education of trainees and students at Yale and has begun to provide a template for joint applied research endeavors. The process of sensitization to specific issues that are faced by Ugandan patients and clinicians, and the development of academic partnerships between Ugandan and US trainees and providers, has allowed MUYU to serve as a launching pad for collaboration on scholarly activities aimed at raising global awareness of these issues, with the goal of further improving patient care in Uganda and the region [10, 15-17].

## Conclusion

In considering the Lancet Commission's call for educators to join health systems strengthening efforts in resource-limited areas of the world, the idea of equity in partnerships is central to the development of ethically sound global health education endeavors. The WEIGHT guidelines and global health ethics framework proposed by Pinto and Upshur [14] help to demonstrate how MUYU serves as one model of an equity-focused educational partnership. Importantly, the last ten years have shown how this collaboration has both thrived and laid the groundwork for the evolution of additional projects that may have even greater impacts on the Ugandan health system and individual patient care. Our hope is that the description of this global health ethics framework and collaborative model will be taken up and adapted for educational partnerships in other settings as a means of empowering educators to move health systems forward, independently of policymakers and special interest groups—a true social justice mission.

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## **HEALTH LAW**

## **Pursuing Justice in Haiti's Cholera Epidemic**

Richard Weinmeyer, JD, MA, MPhil

## Abstract

In 2010, the nation of Haiti was leveled by a shattering earthquake that killed thousands and devastated its already fragile infrastructure. During relief efforts to aid Haiti's suffering population, the United Nations sent troops to Haiti to assist the rebuilding of country's most basic services. But those troops unknowingly carried with them the bacteria that cause cholera, and through the UN's negligent actions, it triggered a horrifying cholera epidemic that continues to harm the Haitian people. Those injured by the cholera epidemic have sought relief in the US federal court system to obtain justice for those killed or sickened by the cholera outbreak. The UN has declared legal immunity for causing the epidemic, yet the litigation on this matter is ongoing.

## Introduction

On January 12, 2010, a devastating earthquake struck the island nation of Haiti. The seismic event and its aftermath killed more than 200,000 people [1], displaced close to 1.5 million residents [2], and left the poverty-stricken country in an even more precarious state. And another catastrophe would soon bear down on the Haitian people. In October 2010, Haitian health officials found an unusually high number of cases in which people presented symptoms of acute diarrhea, vomiting, and severe dehydration in two different regions of Haiti [3]. Stool samples from symptomatic patients confirmed the presence of *Vibrio cholerae*, the bacterium that causes <u>cholera</u> [4]. Within a few weeks, new cases of cholera were found in other parts of the country, including the capital, Port-au-Prince [5]. By the end of November 2010, every region of Haiti had positive cases of cholera; over 16,000 Haitians had been hospitalized with acute diarrhea and over 900 were dead from the disease [6].

The cholera epidemic in Haiti is still ongoing. Over the course of nearly six years of the outbreak, it has been estimated that more than 9,200 people died from the disease, with more than 770,000 Haitians having been infected [7]. Historical records indicate that, prior to this epidemic, cholera had not been present in Haiti for at least 150 years [4], which gave impetus to several independent investigations seeking to unearth what caused this public health crisis. All of the studies that have been conducted point to the

same source: peacekeeping troops deployed by the United Nations (UN) to a UN base in Haiti.

Although systematic failures in establishing a UN peacekeeping base in Haiti is the culprit behind the Haitian cholera epidemic, as will be explained below, calls from the international community that the UN quickly address and rectify the damage caused by the epidemic have garnered little response from the intergovernmental organization. Advocates seeking just compensation for victims of the epidemic, as well as <u>humanitarians</u>, have taken to the courts as a means by which to hold the UN <u>accountable</u> for its negligence in failing to screen UN peacekeeping troops for cholera and failing to enact proper sanitation practices. This article will discuss the tricky legal challenge that exists in charging one of the most prominent humanitarian organizations in the world with dereliction of its duties.

#### The United Nations—the Proximate Cause of the Haitian Cholera Epidemic

Since the early 1990s, the UN has deployed several peacekeeping and <u>humanitarian</u> <u>missions</u> to Haiti in order to address political unrest and socioeconomic instability [8]. In 2004, following the removal of Haiti's president during a contentious political struggle, the UN established the UN Stabilization Mission in Haiti (MINUSTAH) to provide a military presence, oversee civilian affairs, and offer humanitarian and development assistance [6]. During the 2010 earthquake, MINUSTAH troops played key roles in the immediate response to the disaster as well as in long-term humanitarian efforts, including clearing debris, rebuilding local infrastructure, leading security assessments, and ensuring that the rule of law and administration of justice were being carried out [6]. But between October 8 and 21, 2010, a battalion of Nepalese MINUSTAH troops arrived in Haiti to provide further support for ongoing earthquake relief efforts [6], and it is during this timeframe that the first cases of cholera began to appear.

Considerable evidence from several investigations points to the Nepalese troops as the source of the disease. Epidemiological studies have shown that the Nepalese troops sent to MINUSTAH had been exposed to cholera while training in Nepal, likely during an outbreak of the disease in the Kathmandu Valley [9]. Cholera is endemic in Nepal, and although medical examinations revealed no reported symptoms among the troops, the bacteria can be carried asymptomatically, and none of the troops were tested specifically for *V. cholerae* before leaving for Haiti [10]. More tellingly, epidemiological research on the Haitian cholera epidemic has repeatedly shown that the *V. cholerae* strain in Haiti is closely related to the bacteria strains from Southeast Asia [3]. Different specimen samples from the Haitian cholera outbreak have pointed to a common genetic source, and genetic sequencing of the Haitian bacteria has demonstrated that it is nearly identical in its genetic makeup to the *V. cholerae* strain that was found in Nepal during the summer of 2010 [3].

Moreover, analyses of the cholera outbreak reveal that the epidemic originated in the area of Méyè where the Nepalese troops were stationed, near the MINUSTAH base [11], where poor sanitation measures acted as a catalyst. The MINUSTAH base is located near the Méyè Tributary, a waterway that then flows into the Artibonite River—the largest river in Haiti and one of the main water sources used by Haitians for drinking, bathing, and cooking [6]. Even before the outbreak had begun, local residents complained that the UN was dumping sewage into the river, and reporters visiting the base in the throes of the outbreak described seeing an overflowing sewage tank and a dark foul-smelling liquid pouring from a pipe into the river [12]. An environmental survey conducted by a UN independent panel of experts found the MINUSTAH base to have an inadequate waste infrastructure that allowed for a "significant potential for cross-contamination" because of poor pipe connections, broken pipes, and a faulty waste disposal system wherein water contaminated with fecal material was dumped into a septic pit near the Méyè Tributary [11]. By giving Nepalese MINUSTAH troops entry into Haiti without screening and treating them for cholera, the UN allowed a dangerous contagion to be introduced into an impoverished and vulnerable nation. Furthermore, the reckless construction of the MINUSTAH base sanitation and waste disposal systems, together with the UN's failure to address these systemic breakdowns, fueled the proliferation of a deadly cholera outbreak that was entirely preventable.

#### **Response by the United Nations**

The UN's willingness to take responsibility for the Haitian cholera epidemic and to help with further relief efforts has been poor. Although the UN's culpability has been confirmed through scientific studies [9], expert reports [3], and the very investigation that was commissioned by the Secretary-General of the UN [11], the organization has denied any role in starting the epidemic [13]. In response to advocacy groups seeking compensation for victims of the cholera outbreak and demands that the UN establish and fund a nationwide program to properly address the outbreak and prevent further destruction, the UN has stated that the outbreak was "caused by a confluence of circumstances and was not the fault of, or deliberate action of, a group or individual" [14]. Furthermore, the UN will not review the legal claims of injured Haitians because "consideration of these claims would necessarily include a review of political and policy matters" [14]. This stance means that the UN considers the roles the MINUSTAH peacekeepers and the base played in contaminating the waterways and the troops' negligent actions to be a matter of public policy instead of an actionable legal claim under tort law and, therefore, outside the duties owed by the UN to the Haitian people [15]. Although the UN has launched the Initiative for Elimination of Cholera in Haiti—a \$2.27 billion plan to address the epidemic in partnership with the <u>Centers for Disease Control</u> and Prevention, the World Health Organization, and other bodies—the UN has only committed to providing \$23.5 million, or less than 1 percent of the needed funding [6]. Given the UN's refusal to concede its role in the Haitian cholera outbreak, Haitians

sickened during the outbreak and the families of those who died have taken to the federal courts in the United States to seek justice from the UN.

#### Federal District Court

On October 9, 2013, a class action lawsuit was brought by five named plaintiffs—Haitian and US citizens—against the UN, MINUSTAH, the Secretary-General of the UN, and the former Under Secretary-General of MINUSTAH. The case was brought in US federal district court in New York because the UN is headquartered in New York State [16].

The brief filed with the court served three core functions. First, it laid out the argument that the case should be considered a class action suit so that the five named plaintiffs could represent and obtain relief for "at least 679,000 individuals, including the representatives of the more than 8,300 people who contracted and died from the cholera epidemic that was introduced into Haiti" [17]. Second, the 67-page complaint set forth detailed evidence demonstrating that the UN knew or should have known that the Nepalese MINUSTAH soldiers were exposed to cholera and that the troops should have been tested and treated for the disease; that the UN knew or should have known about the base's reckless sanitation systems and poor waste disposal practices, which posed a high risk to the Haitian people; that the UN consciously disregarded these risks; and that the actions culminated in the cholera epidemic [18]. Third, the plaintiff's brief asserted that because the UN did not establish a venue or mechanism for plaintiffs to seek legal remedies, the UN waived its legal immunity, thereby allowing those harmed to seek damages for personal injury, wrongful death, emotional distress, loss of use of property and natural resources, and breach of contract [19].

The UN did not respond to this legal challenge. Instead, on March 7, 2014, the US government filed a statement of interest with the court stating that "all of the defendants in this matter are immune from legal process and suit" [20]. Given that the UN chose not to oppose the complaint submitted by the plaintiffs, the US federal court intervened because of the "United States' obligations as host nation to the UN and as a party to treaties governing the affairs and immunities of the UN" [21]. According to the US government, the UN and its officials are immune from prosecution unless they have expressly waived their right to immunity [20]. The UN's immunity, it is argued, stems from two multilateral agreements to which the US is a part: the Charter of the United Nations and the Convention of the Privileges and Immunities of the United Nations [20]. Specifically, article 105, section 1 of the UN charter states that the UN "shall enjoy in the territory of each of its Members such privileges and immunities as are necessary for the fulfillment of its purposes" [22]. Article 3, section 2 of the convention states, "The United Nations, its property and assets wherever located and by whomsoever held, shall enjoy immunity from every form of legal process except insofar as in any particular case it has expressly waived its immunity" [23]. For the individually named UN officials, the US argued that they were also protected by the Vienna Convention's article 32 that provides legal immunity to "diplomatic agents" [24]. The US government grounded its argument in case law supporting the immunity of the UN, its subsidiaries (here, MINUSTAH), and its officials, noting in particular that immunity had not been expressly waived by any UN body or official [20]. As a result, from the US government's perspective, immunity from prosecution remained in place, and, given this protection, the US government concluded that the federal court lacked the jurisdictional authority to hear the case [20].

The court was not convinced by the arguments asserted by the plaintiffs and concluded that the UN was immune from prosecution and, as a result, that the court lacked subject matter jurisdiction to hear the case [25]. In finding that the UN, MINUSTAH, and their officials did not expressly waive their immunity as required by the Convention on the Privileges and Immunities of the United Nations, the court based its reasoning primarily on the case of *Brzak v. United Nations* [26], wherein the plaintiffs argued "that the UN's dispute resolution mechanism was inadequate to resolve their case, and that this inadequacy stripped the UN of its immunity" [27]. In Brzak, the court also found the UN to be immune because it did not expressly waive its immunity [28]. Without an express waiver of immunity, the UN could not be sued for its role in the Haitian cholera epidemic and the federal district court in New York could not hear the case.

#### **US Court of Appeals**

In February of 2015, the plaintiffs appealed the decision of the district court to the US Court of Appeals for the Second Circuit. Based on the reasoning used by the district court in its opinion and the arguments asserted by the US federal government, the plaintiffs distinguished the present case from Brzak and argued that the UN's inability to comply with another section of the Convention on the Privileges and Immunities of the United Nations effectively revoked its immunity [29]. Although the issue at hand in Brzak dealt with section 2 of the convention and the immunity afforded to the UN, the plaintiffs argued that section 29 of the convention was controlling in the present case. Under section 29, the convention states, "The United Nations shall make provisions for appropriate modes of settlement of: (a) Disputes arising out of contracts or other disputes of a private law character to which the United Nations is a party" [30]. According to the plaintiffs, section 29 is a condition precedent to section 2, and with the UN's failure to establish an "appropriate mode of settlement" to address the claims of injured Haitians, the UN had materially breached the convention, removing its immunity [29]. To support its argument, the plaintiffs urged the court to review the legislative history of the convention's drafting, the intent of the drafters, norms in international law, and the court decisions from other countries where the UN has been legally pursued for failure to provide access to remedy mechanisms [31]. As those cases have shown, the plaintiff's argued, "international organizations, including the UN, are entitled to immunity only when they comply with their obligations to provide access to an alternative remedy" [32].

Once again, the UN did not respond to the notice of appeal. However, the US federal government did contribute to the case on appeal by submitting an amicus curiae brief (i.e., "friend of the court" brief) to urge the court of appeals to affirm the lower court's ruling and find that the UN and its officials have immunity and, therefore, that the court does not have the jurisdictional authority to hear the case [33].

## Conclusion

In 2013, the *New York Times* referred to the ongoing litigation against the UN for its role in the Haitian cholera epidemic as "one of the most organized legal challenges to United Nations assertions that it is immune to such litigation" [34]. As the case continues to be pursued by the plaintiffs and discussed widely by experts, journalists, international humanitarian organizations, and other interested parties, its importance in seeking redress for those harmed during times of crisis cannot be overestimated. Oral arguments before the US Court of Appeals for the Second Circuit took place on March 1, 2016, and the international community is surely watching closely to see how the court will rule and just what the implications will be for the UN and the people of Haiti who continue to deal with the dangerous and unpredictable circumstances ensuing from the 2010 earthquake and continuing cholera epidemic.

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## **POLICY FORUM**

Protecting Pharmaceutical Patents and Test Data: How the Trans-Pacific Partnership Agreement Could Affect Access to Medicines in the US and Abroad Jing Luo, MD, and Aaron S. Kesselheim, MD, JD, MPH

## Abstract

The Trans-Pacific Partnership (TPP) Agreement is a proposed free trade agreement between the US and 11 other countries in Asia and South America covering many consumer goods, including prescription medicines. This review describes how the TPP could affect international laws governing intellectual property rights for prescription drugs, focusing on patents and exclusivity protections for test data, including their effect on reimbursement decisions by national health care authorities responsible for health priority setting. We conclude that the TPP could affect low-income patients' access to medicines in signatory countries.

On February 4, 2016, trade ministers from 12 Asia-Pacific countries (the United States, Canada, Mexico, Peru, Chile, Australia, New Zealand, Singapore, Brunei, Malaysia, Vietnam, and Japan) accounting for approximately 40 percent of global trade met in New Zealand to officially sign the Trans-Pacific Partnership (TPP) Agreement [1]. The agreement cannot become effective until at least six countries with a collective GDP of more than 85 percent of the GDP of the original 12 signatories ratify the text using domestic legal procedures [1]. Although President Barack Obama and the Office of the US Trade Representative have repeatedly emphasized the importance of this agreement in contributing to economic growth and jobs creation [2], foreign policy experts believe that it will take substantial political effort to get the trade agreement through the US Congress. For example, the leading Democratic and Republican candidates in the current presidential race have come out strongly against the TPP, expressing concern that the agreement might offshore jobs and reduce American wages [3, 4]. Pushback in the US against signing the TPP has also been endorsed by US-based special interest groups in labor, environment, and health [5]. These groups are concerned about the ability of corporations to use new procedures created by the TPP to challenge regulations aimed at protecting the environment, labor rights, or public health [6].

Although the TPP covers traditional areas of trade policy such as tariffs, financial services, and telecommunications, one of its 30 chapters relates to intellectual property [7], including an entire section devoted to pharmaceutical products. Thus, the TPP has

the potential to affect signatory countries' citizens' access to medicines in a number of ways.

#### **Paying for Medicines**

Citizens living in TPP member countries who rely on <u>lower-priced prescription medicines</u> are poorly served by the particular portions of the agreement that favor the financial interests of pharmaceutical manufacturers and, more specifically, by language within the agreement that targets how drug reimbursement decisions are made by national health care authorities.

Currently, the systems used to determine prescription drug reimbursement vary widely across TPP member countries. To give a concrete example, let us consider how two member countries, Australia and the US, deal with the problem of providing reimbursement for high-cost chemotherapy agents for advanced-stage breast cancer using widely differing approaches to pharmaceutical pricing. In the US, while most women who have HER2/neu receptor-positive metastatic breast cancer might receive coverage for prescription drug treatment with the chemotherapy agent trastuzumab through their health insurers, many are also responsible for substantial out-of-pocket payments [8]. This type of breast cancer is a good example to consider in the context of prescription drug costs because breast cancer affects a large number of women who live within TPP member countries [9] and because overall survival can be improved with targeted treatments such as trastuzumab [10]. In 2014, the average Medicare beneficiary paid \$5,971 out-of-pocket for a year's supply of trastuzumab [11]. By contrast, under Australia's national Pharmaceutical Benefit Scheme (PBS), the maximum patient copayment for trastuzumab was A\$38.30 (approximately \$29.60 in US dollars) [12]. Australia's PBS leverages its single-payer status to negotiate substantial discounts for expensive drugs like trastuzumab.

The TPP might alter how individual member countries make national reimbursement decisions for pharmaceutical products [13], possibly leading to higher prices in countries with strong pharmaceutical price regulation policies and practices. A provision called the "Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices" allows manufacturers opportunities to challenge reimbursement decisions made by national health care authorities. For example, if a national health care authority decides that a new drug product is not a good use of national resources and recommends against listing the product on the national formulary, the drug's manufacturer could request an internal or independent review [14]. Critics of the TPP believe that this annex is directed at member countries with centralized national institutions that set <u>pharmaceutical prices</u>, such as Australia and New Zealand. For example, if the TPP were to be implemented in its current form in Australia, manufacturers of prescription medications with very high list prices could have another way to challenge unfavorable listing recommendations made by the Pharmaceutical

Benefits Advisory Committee, which makes reimbursement recommendations based upon a drug's comparative effectiveness and safety, overall budgetary impact, and value [15].

Similarly, the TPP's "Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices" might be invoked if the US should ever decide to establish a comprehensive national formulary or central authority to negotiate prescription drug prices on behalf of its citizens. For example, if future Congressional authority were to be granted to allow the Centers for Medicare and Medicaid Services (CMS) to use its collective market power on behalf of all <u>Medicare Part D</u> prescription drug plan sponsors, CMS would also have to provide manufacturers two opportunities to challenge unfavorable reimbursement decisions. First, an internal review could be requested. If the unfavorable recommendation remained valid after the internal review, the TPP could guarantee manufacturers the ability to request an independent review of CMS's decisions by some external body (the composition of the body and its standards for review are not currently defined under US or international law) [14].

The "Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices" also contains language that favors manufacturers over governmental or other payers in negotiating drug prices. For example, while the rules, methodologies, principles, and guidelines used in listing decisions must be publicly disclosed, information considered confidential or proprietary by manufacturers will remain undisclosed [14]. This type of information could include measures of the costs associated with research and development—i.e., clinical trial or manufacturing costs—as well as proposed discounts or rebates on international list prices. Therefore, while the annex might make it easier for manufacturers to navigate the various reimbursement processes in TPP member countries, its protection of manufacturers' marketing information does not help ministries of health or other national health care authorities obtain lower drug prices.

#### **Generic Competition**

The TPP would hamper access to lower-priced medicines in member countries by delaying generic competition through expansions in patent-based and non-patent forms of intellectual property protection. The TPP would allow a greater variety of patents stemming from the original pharmaceutical patent in countries that might otherwise not permit them. It would also extend existing patent terms and other intellectual property protections such as those on clinical trial (test) data.

*Expansion of patentability*. First, the agreement specifically expands the scope of patentability to include new methods of use for existing pharmaceutical products [7], allowing patent systems to extend market exclusivity for six or seven years after the patents on the active ingredient expire [16]. Methods of use patents are widely employed in the US to try to forestall generic competition on brand-name drugs. For

example, one review of patents relating to the HIV protease inhibitor combination ritonavir/lopinavir in the US found 210 patents and applications relating to peripheral aspects of the product, including 31 covering methods of use [17]. Such patents, obtained at various points after the drugs were in development, had the potential to delay generic competition on the drug for more than 12 years after the expiration of the original patent on the active ingredient.

*Extension of patent terms.* Additionally, the TPP agreement requires member countries to grant patent term extensions for "unnecessary" delays by the local patent office and for delays associated with the drug approval process [7]. In the US, patent term extensions were enacted into law as part of a compromise agreement negotiated under the 1984 Hatch-Waxman Act [18], in which brand-name manufacturers received market exclusivity extensions for up to five years to account for time spent in drug development, while generic manufacturers were allowed to file abbreviated applications for drugs to streamline their market entry. This finely struck balance between the interests of brand-name and generic manufacturers has been credited with helping stimulate the remarkable growth and success of the US pharmaceuticals market for both branded and generic products over the subsequent decades [19]. While the TPP imposes on other member countries portions of US pharmaceutical law intended to protect brand-name innovation, it does not provide to all member countries incentives similar to the US's abbreviated process for generic drug approvals, thereby favoring patent exclusivity over broad access to lower-priced generic drug products.

*Extension of non-patent forms of intellectual property protection.* The TPP would require signatory countries to consider as trade secrets all <u>clinical trial data</u> submitted to regulatory agencies supporting a drug product's claims of safety and efficacy [7]. The practice of protecting test data generated from clinical trials (sometimes called data exclusivity) is controversial because it reinforces prescription drug patent monopolies. Since the term of data protection runs independently of the term of patent protection, a prescription drug product may therefore remain insulated from competition due to data exclusivity despite the expiration of the patent. Test data protection can also prevent generic competitors from "inventing around" pharmaceutical patents and offering lower-cost versions of the drug.

Some public health proponents also oppose data protection for pharmaceuticals because the costs of clinical trials are often subsidized by public sources. For example, in the US, 50 percent of qualifying clinical trial costs for drugs intended for rare diseases (designated by the Food and Drug Administration [FDA] as <u>"orphan drugs"</u>) are subsidized by tax credits to manufacturers [20]. The purpose of the Orphan Drug Act was to incentivize the development of new treatments for rare diseases. However, in recent years its scope has broadened as the number of new prescription drugs approved under orphan indications grew. In 2014, 18 of the 41 newly approved FDA drugs were for
orphan indications, as were 7 of the 10 bestselling drugs that year [21]. Under the TPP, most if not all of these drugs will receive some form of test data protection, even though US taxpayers directly supported the critical clinical work on which the data were generated. Manufacturers seeking to sell lower-cost generic versions of these drugs in member countries will be unable to do so until the data exclusivity term expires.

Trial data protection has important implications for generic competition and patient safety. In the US, under the Hatch-Waxman Act, generic manufacturers may receive marketing approval for their products after demonstrating bioequivalence against a reference product, while relying on the original product's previously submitted trial data as proof of safety and efficacy [18]. Being able to reference previously conducted trials allows generic manufacturers to offer their products less expensively and in a more timely fashion than if they had to repeat costly clinical trials demonstrating safety and efficacy. The need to repeat clinical trials because of data protection rules for the sake of generic drug approval is also ethically questionable [22]. The Declaration of Helsinki [23] protects human subjects from unnecessary risk during experimental research; this is particularly applicable to patients if the trials require a placebo or control arm. Thus the TPP might impede access to drugs for lower income people by increasing the costs associated with generic entry.

Although previous international agreements, such as Article 39 of the Trade Related Aspects of Intellectual Property Protections (TRIPS) Agreement [24] have also required trial data protection, the TPP establishes a higher international standard by requiring specific numbers of years of trial data protection for pharmaceuticals. More specifically, the TPP requires five years of data protection for each new pharmaceutical product, three years for data requiring new clinical information, and between five and eight years for data relating to biologic products [7]. The TPP defines biologics as products containing, at a minimum, "protein[s] produced using biotechnology processes" for use in humans [7]. Such products include insulin, erythropoietin, filgrastim, growth factors, and monoclonal antibodies such as trastuzumab or infliximab. Although the US currently protects test data for biologics for 12 years [25], a majority of TPP member countries have no pre-existing regulations protecting trial data specifically for biologic drugs [26]. Thus the TPP creates a new norm in many countries with regards to test data protection for biologics and may contribute to maintaining high biologic drug prices in the future [26].

## Conclusion

Although the TPP was originally intended to enhance countries' economies and reduce international tariffs, the agreement could reduce access to medicines by extending effective patent terms and reducing generic competition. It extends portions of US pharmaceutical and regulatory laws to the other 11 member countries, while omitting some important public health safeguards with respect to streamlining generic competition. From disclosure requirements to trial data protection, the agreement seems to favor manufacturers and inventors' rights over public health needs. If the TPP is implemented in its current form, it will be more difficult to get generic drugs or followon biologic products to the market in signatory countries while, at the same time, it may make brand-name medications more expensive.

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# **MEDICINE AND SOCIETY**

# Why US Health Care Should Think Globally

Samuel G. Ruchman, Prabhjot Singh, MD, PhD, and Anna Stapleton

# Abstract

Why should health care systems in the United States engage with the world's poorest populations abroad while tremendous inequalities in health status and access are pervasive domestically? Traditionally, three arguments have bolstered global engagement: (1) a moral obligation to ensure opportunities to live, (2) a duty to protect against health threats, and (3) a desire to protect against economic downturns precipitated by health crises. We expand this conversation, arguing that US-based clinicians, organizational stewards, and researchers should engage with and learn from low-resource settings' systems and products that deliver high-quality, cost-effective, inclusive care in order to better respond to domestic inequities. Ultimately, connecting "local" and "global" efforts will benefit both populations and is not a sacrifice of one for the other.

Despite its excellence in many places in clinical care, research, and innovation, the United States' health care system is marked by pervasive <u>disparities in health status</u> and by systemic obstacles to equitable health care service access. In recent years, for example, the infant mortality rate among non-Hispanic blacks (12.67 deaths per 1,000 live births) was estimated to be more than twice the rate for non-Hispanic whites (5.52 deaths per 1,000 live births); the infant mortality rate among non-Hispanic whites in Alabama (7.67 deaths per 1,000 live births) was estimated to be more than twice the rate for non-Hispanic whites in Alabama (7.67 deaths per 1,000 live births) was estimated to be more than twice the rate for non-Hispanic whites in New Jersey (3.78 deaths per 1,000 live births) [1]. That tremendous health inequalities associated with race and geography begin even before the moment of birth attests to the lack of health justice or fair opportunity in accessing health care. Given this reality, the United States cannot afford to ignore the poorest, either at home or abroad. Instead, our health care system's players—clinicians, organizations, and governments, for example—must engage global health as a means to building stronger health care systems both at home and globally.

We seek to dispel the notion that <u>global health engagement</u> must come at the expense of local service by arguing for a new understanding of a supposed border between "local" and "global" work. Breaking down this false dichotomy requires de-emphasizing geographical distances or differences and focusing programmatic decisions instead on the common and communal challenges we face across contexts. First we review three prevailing perspectives that necessitate high-income countries' global health involvement: that these countries have (1) a moral obligation to ensure basic opportunity for all people, (2) a duty to protect themselves and others against health threats, and (3) a desire to ensure global economic prosperity. Then we introduce a fourth perspective, which is potentially most relevant to daily decision making among clinicians and organizations, yet too often overlooked: engaging in thoughtful global health efforts offers us vital opportunities to learn about innovations in low-resource systems. These insights can inform and improve health care service delivery and health care reform efforts in our own communities, which, in turn, can generate new lessons for domestic and international applications. Ultimately, in our experience, global and local engagements with marginalized countries and people constitute complementary and connected, rather than exclusive or isolated, efforts. In time, what we see as "locally" productive can merge with our sense of what is "globally" productive.

### High-Income Countries' Obligations to Become Involved in Global Health

Ethical, security-focused, and economic arguments have traditionally informed engagement in global health efforts. However, arguments based on mutual learning are potentially more relevant to everyday programmatic decision making.

*Ethical*. Philosophers such as John Rawls and Henry Shue argue that basic equality of opportunity (Rawls) and standards of <u>human rights</u> (Shue) must be ensured by the international community, especially where governments fail to guarantee fulfillment of those rights and opportunities for their own people [2]. Extreme deprivations of basic necessities—such that mortality for infants and children under five years of age ranges from roughly 100 to 160 deaths per 1,000 live births in the world's eight worst-off countries—are all too common and demand the attention of clinicians everywhere [3].

*Security-focused*. Building capacity with global partners to monitor, prevent, and respond to emergent and existing threats is a crucial line of defense against <u>pandemics</u>, first-line pharmaceutical obsolescence (e.g., emergence of drug-resistant strains of tuberculosis or malaria), and global environmental perils. The expanded range of insect disease vectors, for example, is already proving to be one of the most visible public health consequences of climate change, blurring national and continental boundaries and extending the range of historically "tropical" diseases [4]. And systemic weaknesses, such as lack of capacity for diagnosis, information sharing, and locally appropriate response contributed to the emergence and longevity of the 2014 Ebola outbreak in West Africa [5].

*Economic*. Global health risks impact macroeconomic growth and recession. Guinea, Liberia, and Sierra Leone—all relatively small economies—lost \$2.2 billion in economic growth due to the Ebola crisis [6]. Conversely, a health crisis of similar scope and severity in the United States would likely have global economic ramifications.

Importantly, investments in health care can contribute to poverty alleviation, which opens new markets and generates new models of local economic development [7]. If local health crises can contribute to global economic downturns, then improving the health of the world's poorest people could also have far-reaching implications for domestic economic conditions.

*Reciprocity.* Most relevant to clinical practitioners, institutional stewards, and researchers is their recognition that policies and innovations from settings abroad have the potential to transform health care in the United States. This recognition has consequences for their daily decisions, such as introducing new best practices for interactions with marginalized patients, creating opportunities for partnerships with institutions in lowincome countries, and setting innovation agendas that focus on equity and community engagement. Successful health care systems in low-resource settings are designed to target and serve the poor in ways that are contextually appropriate—addressing social, cultural, and economic barriers to care—and make efficient use of limited resources. Among numerous public health innovations, Rwanda has tested performance-based financing to improve the use and quality of child and maternal health services [8]; piloted antiretroviral treatment led by nurses rather than physicians [9]; and deployed various local interventions to increase health insurance coverage, even in poor communities, and so reduce out-of-pocket expenditures [10]. As soaring costs increasingly threaten to make health care unaffordable, causing the greatest harm to the disenfranchised, the United States should look to systems that serve difficult-to-reach populations and deliver quality care—and do so efficiently. For example, community health workers have become integral to health care systems across sub-Saharan Africa and India, providing a model of low-cost care delivery [11]. And, in fact, US-based organizations that bridge hospital systems and their neighborhoods are beginning to implement community health worker models inspired by counterparts abroad [12]. A recent review of studies of community health workers in the United States found that such interventions improve cancer prevention and cardiovascular risk reduction and are cost effective for marginalized populations [13].

Similarly, products and methods of outreach that are developed for or in low-resource settings—where economic constraints and emerging markets can create incentives for innovation—can be useful for addressing inequities in health care knowledge, access, and quality in the United States. Examples of products developed for low-resource countries include low-cost ventilators [14] and mobile-phone-based flow cytometers used to diagnose some infections and cancers [15]. These and other innovations could be implemented within the US to lower costs of, and improve access to, health care. Methods of engagement and outreach developed for specific issues abroad can also be adapted to domestic problems. Effectively working with local faith-based communities, for example, has been central to implementing behavioral or attitude-based interventions in maternal and child mortality in Sierra Leone, the Democratic Republic of

the Congo, Mozambique, and elsewhere [16]. Civic technologies, such as mTrac, which empowers health facility workers to report on medicine stock-outs [17], or U-report [18], which empowers young Ugandans to engage in public affairs and information sharing, enable improved targeting of issues and accountability, creating novel efficiencies even in low-bandwidth environments. In our experience, systems improvements and innovations like these have optimal impact when they are exchanged, adapted, and implemented across contexts. Disengaging from the global ecosystem of knowledge production is foolhardy, particularly for domestic academic medical centers that claim to deliver the next generation of health-improving care.

## Simultaneously Engaging Global and Local Health Care: A Narrative

Once we recognize the importance of global interactions for improving local health care practices, managing tradeoffs can still be daunting. One organization navigating those tradeoffs is City Health Works, a New York City-based nonprofit organization working to implement community health worker (CHW) innovations based on global experience in a domestic context [19]. City Health Works serves patients with one or more chronic conditions such as asthma and diabetes; its patient population is low income and primarily Hispanic or African American. Patients benefit from one-on-one, in-person peer coaching focused on educating and motivating them to lead healthier lives. In designing the intervention, the organization's founders (including co-author PS) drew on extensive experience creating and operating CHW programs in sub-Saharan Africa [12]. By working to identify and neutralize the factors that create crises before they occur, and by using relatively low-cost CHWs rather than the expensive labor of nurses or physicians, the program promises to both improve health outcomes and reduce expenditures on preventable hospitalizations and emergency room visits.

Testing an old model in a new context can reveal challenges as well as opportunities for improvement that will benefit communities around the globe. City Health Works is addressing the core management challenges that face any CHW organization: integrating with local care systems; achieving financial sustainability; and building and maintaining information infrastructures that can provide patients, CHWs, physicians, and other care team members with the right information at the right time. These challenges limit the growth and efficacy of CHW programs everywhere. Yet, as City Health Works develops new technologies to support information collection and sharing between CHWs and primary care teams, for example, these technologies can be adapted and deployed in sub-Saharan Africa and beyond.

Opportunities for the two-way exchange of innovations between US and global CHW programs are not just aspirational but extant. City Health Works and other leaders in global and domestic CHW work are participating in a new task force, led by the Arnhold Institute for Global Health in partnership with the Office of the UN Secretary-General's Special Envoy for Health in Agenda 2030 and for Malaria, which is working to produce a

framework for sustainable, effective CHW programs in the US by drawing on global learnings. Building on a previous report focused on the investment case for CHW programs globally [20], the current task force aims to address the essential and interrelated problems of programmatic, operational, and financial sustainability. In addressing these problems for the domestic context, the task force will contribute new learnings that in turn can be applied to the benefit of CHW programs—and their patients—around the globe.

# Conclusion

A desire to rectify extreme health status and health care access inequities and ensure basic opportunities to live healthy lives bolsters health care workers' aspirations to engage with international public health efforts. Even if one concedes that the United States has a special obligation to prioritize the needs of its domestic poor, recognition of significant epidemiological, economic, and informational connections across contexts should commit us to global engagement. Working towards more equitable health systems worldwide helps us all, morally and medically. Failure to capitalize on opportunities to link "global" and "local" health efforts inhibits the potential of both, to the detriment of those in the greatest need.

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#### Disclosure

Dr. Singh is an advisor to City Health Works and, as noted in his biosketch, director of the Arnhold Institute for Global Health. As noted in her biosketch, Ms. Stapleton is the program manager for policy at the Arnhold Institute for Global Health.

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# **HISTORY OF MEDICINE**

Medicine, Empires, and Ethics in Colonial Africa Helen Tilley, PhD

# Abstract

This essay examines the history of European empire building and health work in sub-Saharan Africa, focusing on four patterns that shed light on the ethics of outside interventions: (1) the epidemiological and bodily harms caused by conquest and economic development; (2) the uneven and inadequate health infrastructures established during the colonial era, including certain iatrogenic consequences; (3) the ethical ambiguities and transgressions of colonial research and treatment campaigns; and (4) the concerted and inadvertent efforts to undermine African healing practices, which were not always commensurable with introduced medical techniques. This kind of historical analysis helps us home in on different kinds of ethical problems that have grown out of past asymmetries of power—between people, professions, states, and institutions—that shape the nature of international health systems to this day.

What do we learn about ethics and international health systems when we look to the past? This essay considers this question by examining the history of colonialism in sub-Saharan Africa, focusing on the harms of conquest and on the treatment and research campaigns sponsored by nascent medical services. At over 11 million square miles, Africa is the second-largest continent (after Asia) and was the last massive region of the world that Europeans colonized (between 1880 and 1910). The timing and scale of European colonization matter. This was a period when germ theories of disease began to predominate in many parts of the world and pharmaceutical treatments and vaccination campaigns were on the rise [1, 2]. It was also a time when hygienic regimes in cities became more uniform [3]. These new ideas and techniques increased people's faith that diseases could be mastered and human lives extended, if only the new knowledge were applied. By exploring the ethical dimensions of medicine in colonial Africa, we can begin to appreciate the moral complexity not only of past interventions but also of international health systems today, given their roots in imperial dynamics. Indeed, historical analysis of the unintended—and the willful—harms produced during the colonial period bring to light various lessons for the present since these patterns linger and continue to affect people's perceptions and practices.

### The Relations among Conquest, Development, and Health

Politicians from several European countries oversaw the conquest of sub-Saharan Africa at the end of the nineteenth century, dividing the bulk of the continent between the governments of Britain, France, Germany, Belgium, Portugal, and Spain. While their motives varied, they tended to be optimistic about the potential wealth of the new territories in terms of both natural resources and labor pools. They also embraced a vague mandate to "civilize," "improve," and "develop" the populations they ruled, setting up governance structures that invested officials, usually unfamiliar with the regions, with far more political and cultural power than most Africans possessed [4]. Health activities took on an exalted role given this ethos of improvement since they were a visible and seemingly uncontroversial way to address the needs of the continent's people. Unsurprisingly, medical projects often received a significant portion of development funds earmarked for social welfare, and medical personnel made up the majority of employees in the technical services of each colonial state [5, 6].

Yet Europeans' efforts to ameliorate the health of imperial subjects were typically beset with contradictions both because disease burdens increased and because health conditions were more difficult to control than officials expected. Conquest was violent and disruptive, radically altering landscapes and lives, and producing what medical specialist Patrick Manson aptly referred to in 1902 as a "pathological revolution" in tropical Africa [6]. Manson had in mind certain epizootics, such as rinderpest, which had swept through Eastern and Southern Africa in the 1890s, decimating cattle populations and leading to massive social and economic upheavals [7]. He was also concerned about an ongoing pandemic of sleeping sickness (*African trypanosomiasis*)—a disease transmitted by tsetse flies and fatal to humans unless treated—that had recently broken out in the territories surrounding Lake Victoria, including the Congo, Uganda, the Sudan, and Tanzania [6]. The flies' habitats had been transformed in the previous decades, bringing tsetses into closer proximity to humans and distancing them from some of the animals, especially cattle, on which they normally fed. Thus, in at least some regions, people became a convenient meal for the flies, increasing transmission rates and spreading the epidemic to new areas [8].

Over the next decade, hundreds of thousands of people in the region died from the disease, causing widespread trauma and fear [8]. As Manson would have known, the Belgian, German, French, and British officials on the ground were no more equipped to handle the outbreak than anyone else, given their uncertainty about its etiology and the fact that there was as yet no cure. The Germans and French focused on developing drug treatments, some of which were arsenic-based and near-deadly in effective dosages [6, 8], while the British often chose to cordon off affected groups, using coercive tactics and forcing large numbers of people to leave their villages [8]. Both methods—drug treatment and forced removal—ultimately stemmed the Lake Victoria epidemic, although questions about its causes lingered as did the endemic foci of the disease [6, 8].

Colonial efforts to create export economies had similar adverse effects on Africans' health [9]. Whether people were enlisted in mining, infrastructure, or agricultural projects, they often had few occupational protections and succumbed to illnesses that resulted from their labors. In the mining regions of Southern Africa and the Belgian Congo, for instance, workers experienced sharp increases in tuberculosis rates [10]. In areas of large-scale plantation agriculture, they became more vulnerable to water-borne, mosquito-borne, and worm diseases, stemming from the altered environments [11]. As demand for industrial laborers increased, it also led to massive migrations of men to expanding urban centers in Southern Africa, indirectly affecting fertility rates and prompting concerns that colonial rule was eroding rather than bolstering population levels [12]. A physician touring the Belgian Congo in the 1920s surmised that "the principal cause of depopulation in the Congo is the European penetration itself." Referring to rising levels of disease, infertility, and border-crossings, he continued: "since all of these causes [of ill health] increase more and more as the economic, commercial and industrial development of the Colony increases, the depopulation becomes equally more and more threatening" [13]. Even as officials trumpeted their benevolent ambitions in colonial Africa, they were forced to grapple with illnesses and debilities they had inadvertently caused or exacerbated, hindering state-building efforts and belying their claims to be helping the populations.

Following Paul Farmer's lead, we could call these injurious consequences a form of "structural violence" [14, 15]. The political and economic systems that underpinned colonial rule not only disrupted people's lives and livelihoods but also created enduring inequalities that laid the groundwork for more damage. Physicians working within colonial territories and taking seriously the ethical principle "to do no harm" had to contend with the health problems imperial governance generated, whether they were conscious of its role in producing them or not.

### **Medical Services in Colonial Africa**

Europeans' lofty ambitions to establish far-reaching medical services in each territory were often stymied in practice. Directors of medical departments found it difficult to communicate and coordinate both within and across their territories, making it harder to find solutions to shared health problems. As they were the first to admit, the scale of their responsibilities was daunting. Money was in short supply and the number of trained personnel was rarely sufficient for the tasks [6]. Colonial rule was expensive and, because most European governments believed colonies should generate their own revenue, seldom were there funds necessary to build health services expansive enough to meet people's immediate needs. For several observers, this situation seemed wrong and unjust because colonial rule obliged those in power to care for their subjects [6].

Although many medical professionals understood the financial and staffing challenges, they could not remedy the situation on their own since they played no part in raising

revenue and only a modest role in setting policy priorities. At a meeting of the directors of medical services from across sub-Saharan Africa in 1935, two health administrators from South Africa called the state of affairs "deplorable" and blamed metropolitan governments for their "neglect of African problems" [16]. While they admired the work of the League of Nations Health Organization (an intergovernmental agency founded after the First World War and a precursor to the World Health Organization), they still lamented that "as compared with what it has done for other parts of the world ... the Health Committee of the League of Nations itself has done remarkably little for the African continent" [16]. Theirs was a fair assessment. They could have said the same about the largest health philanthropy then in existence, the International Health Board of the Rockefeller Foundation, which, up to 1951, spent only 3 percent of its total grants on African projects [17]. The double standards at work were not lost on a small number of critics who pointed out that during the interwar period budgets and personnel considered acceptable in sub-Saharan Africa would be labeled "appalling" or "derisory" in Western Europe [18, 19]. Indeed, European governments' failure to redistribute sufficient funds to African budgets and international organizations' comparative neglect of African health concerns had ethical consequences of their own, including higher mortality and morbidity rates in sub-Saharan Africa than in other parts of the world [6-12, 20, 21].

In the face of these financial constraints, medical services tended to work in triage mode, focusing much of their energy on problems they deemed critical for human health or economic development (and sometimes both), which meant that <u>infectious diseases</u>—such as sleeping sickness, yellow fever, syphilis, smallpox, and malaria—received disproportionate attention compared to public health activities [6]. Yet even in <u>disease-control campaigns</u>, good intentions could backfire. Scholars have recently surveyed the many different colonial-era health initiatives across sub-Saharan Africa, concluding that it is "biologically plausible" [22] that these, combined with increases in blood transfusions, played a role between 1924 and 1955 in facilitating the <u>spread of HIV</u> infections in central and West Africa [22, 23]. Although historians are wary of suggesting a single "smoking gun" for the pandemic since its causes are multifactorial, they do point to the use of unsterile syringes and contaminated blood during the colonial era as being contributing causes [24, 25]. The iatrogenic or accidental nature of these transmissions hardly diminishes ethical concerns about their consequences.

#### Medical Research and Experimentation in Colonial Africa

Establishing medical services tended to go hand-in-glove with launching research programs on a range of subjects, turning the African continent writ large into a vast arena for experimentation [6, 20, 26, 27]. As late as 1955, a senior British physician at Oxford University, Honor Smith, pointed this out with unqualified enthusiasm: "[I]t is the almost unlimited field that Africa offers for clinical research that I find so enthralling ... problems of the first interest abound, [and] clinical material is unlimited" [28]. Smith's

exuberance reminds us of how willing outsiders were to treat Africans as unproblematic research subjects, with few topics off limits. Such attitudes raise important questions about informed consent and autonomy, and go to the heart of power inequalities within colonial empires.

For much of the colonial era, there existed no agreed-upon <u>ethical standards for "human</u> <u>subjects" research</u> [29], nor were there clear methods for how to design and analyze either large- or small-scale trials [30]. Even treatment protocols for both acute and chronic problems, such as infectious diseases and malnutrition, were often developed in an ad hoc fashion with little demarcation between practices considered ethically acceptable and unacceptable [31]. In other words, no consensus existed that crossing an ethical line ought to be a central concern. It is worth recalling, in this respect, that medical research carried out in sub-Saharan Africa was not so unusual or extreme. Only in the decades after the Second World War did European and North American countries begin to establish national and international standards relating to medical ethics, prompted in no small part by the horrors of the Holocaust, but also triggered by a range of <u>biomedical errors and accidents</u>. And not until after mid-century did ethical conversations extend to human subjects research and patients' rights globally [30-33].

For some investigators and clinicians, these open-ended conditions in colonial Africa created an ethos, in both treatment and research campaigns, that the ends justified the means. If they had to deceive, coerce, manipulate, or even threaten in order to achieve their therapeutic or investigative goals, they sometimes would [34]. Likewise, if the effects of their drugs were unknown, if diagnostic tools and treatments caused pain or permanent debilities, they would choose to use them anyway, guided by the logic that doing something was better than doing nothing [35]. In the case of sleeping sickness research, for instance, medical experts conducted painful lumbar punctures to detect trypanosome parasites and provided drugs that managed to save lives but also caused, for 10 to 20 percent of recipients, blindness, encephalopathy (or brain damage), and even death [8, 36]. People adversely affected during these campaigns had little recourse for long-term care and assistance except their existing communities.

This is not to suggest that medical experts lacked morality: examples also abound of medical personnel showing compassion for patients and research subjects and being critical of methods that seemed duplicitous or dangerous [20, 27, 34]. Nor should we presume that they were all-powerful. Administrators and physicians learned fairly quickly that they sometimes had little control over the people among whom they worked. Invasive bodily practices—such as taking blood, collecting stool samples, or even conducting lumbar punctures—and socially disruptive "solutions"—such as forced removals (to distance a population from an insect vector)—or even vaccinations of children could lead, as officials reported, to "the most stringent protest and opposition" [37]. Opting out was one way for African communities and people to object to colonial

investigations. Indeed, given the paucity of medical personnel on the ground across colonial Africa, participants in such programs had a lot of room to maneuver in shaping not only the work that was ultimately done but also the meaning that they attributed to it [34, 38].

There were also instances when health administrators decided that the uncertain effects of an intervention outweighed the possible benefits. Both immunological and ethical concerns, for instance, drove debates about malaria control and eradication across tropical Africa from the 1930s onwards. Would it be right, several leading malariologists asked, to attempt eradication when doing so would interrupt the forms of immunity people acquired through a lifetime of exposure and failure would create the possibility for widespread pandemics, especially in areas of intense endemicity? Those who answered yes saw the issue as a question of short- versus long-term tradeoffs: in their eyes, infant and child mortality from malaria, which in places in the early 1950s approached 25 percent of all childhood malaria cases, was already too high a cost to bear [21]. Ultimately, the potential risks and logistical challenges proved too daunting; Africa was largely left out of the World Health Organization's global malaria eradication campaign (MEP), and a range of smaller pilot studies were initiated instead. By the mid-1960s, the global campaign had failed, leading to resurgent malaria in many parts of the developing world in which eradication had been attempted [39]. Having been largely bypassed by the MEP, most African countries faced no such resurgence, but neither did they benefit from decreases in childhood mortality. For some, Africa's omission was thought to be not just the wisest but also the most ethical path. For others, such an omission was yet another example of neglect, lost opportunities, and ethical disregard [21, 40, 41].

#### Medical Pluralism and the Marginalization of African Healing

A final issue that highlights the thorny nature of medicine across cultures is the way in which colonial states used both civil and criminal laws to challenge and marginalize most forms of African therapeutics. This was true especially for those techniques that fell outside an individualistic and materialist approach to bodily and mental health and stressed connections to ancestors and the spirit world [42]. Yet, no matter how dominant colonial medical systems became in sub-Saharan Africa, they never "entirely usurped other forms of healing practices already present" [43]. In other words, medical pluralism was the norm even when colonial services received the lion's share of resources and legal protections and set the terms of debate for what constituted acceptable medical practice.

Only a small minority of officials and scholars during the colonial era was willing to question imperial policies regarding endogenous forms of healing. These were usually people who had spent considerable time studying such systems—including a number of African professionals and elites—who felt endogenous cultures of care were worthy of

defense [44]. Whether it was right or wrong to undermine African therapeutics, these ideas and practices have endured. Indeed, in the 1950s and 1960s, more and more Africans entered the medical profession and some, paradoxically, became staunch defenders of "folk" medicine because it seemed both cost effective and more appropriate culturally. The resurgence of interest in <u>"traditional medicine"</u> during the second half of the twentieth century arguably grew out of critiques of the limited reach of state medicine in much of the developing world and a burgeoning awareness, in the midst of the global Cold War, that different therapeutic cultures that had long been stifled or marginalized deserved closer scrutiny. By the end of the century, such insights were even incorporated into ethical guidelines related to "externally-sponsored research ... in developing countries," which recognized the different harms that could be done in clinical work that overlooked or ignored "alternative medical systems" [45].

#### Conclusion

The end of colonial rule in sub-Saharan Africa entailed its own forms of structural and real violence. Beyond the military struggles in central and southern Africa, European governments also withdrew medical personnel, cut funding for health services, and allowed disease control efforts to lapse [46]. Political independence intensified people's optimism and yet the economic and epidemiological challenges remained and sometimes increased. This was especially true in the 1980s and 1990s when intergovernmental agencies, such as the World Bank and the International Monetary Fund, imposed new strictures on many African countries' revenue streams, a process referred to as structural adjustment [47].

Examining the history of European empires in sub-Saharan Africa highlights the extramedical factors that have affected health and healing across the continent. Military conquest and economic development were justified on the grounds that they would improve conditions for people in Africa and yet, in many places, they caused considerable harm. State health systems were also typically understaffed and underfunded, making it difficult to fulfill their mandate and raising questions about distributive justice. In research and treatment campaigns, people's consent was rarely sought, and they may have viewed such medical interventions differently from health care professionals, leading to mistrust, misunderstanding, and resistance and reappropriation. Finally, colonial rule marginalized forms of care and therapy that made sense to many people, forcing specialists of African therapeutics to pursue survival strategies of their own. All of these dynamics reverberate into the present and need to be taken into account in any effort to bolster international health systems.

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