ETHICS SEMINAR

Challenges in International Medicine: Ethical Dilemmas, Unanticipated Consequences, and Accepting Limitations

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Abstract

While personal and organizational challenges occur in every area of health care, practitioners of international medicine face unique problems and dilemmas that are rarely discussed in training programs. Health professions schools, residency and fellowship programs, nongovernmental organizations (NGOs), and government programs have a responsibility to make those new to international medicine aware of the special circumstances that they may face and to provide methods for understanding and dealing with these circumstances.

Standard ''domestic'' approaches to such challenges may not work in international medicine, even though these challenges may appear to be similar to those faced in other clinical settings. How should organizations ensure that well-meaning health intervention efforts do not cause adverse unintended sequelae? How should an individual balance respect for cultural uniqueness and local mores that may profoundly differ from his or her own beliefs, with the need to remain a moral agent true to one's self? When is acceptance the appropriate response to situations in which limitations of resources seem to preclude any good solution?

Using a case-based approach, the authors discuss issues related to the four major international medicine domains: clinical practice (postdisaster response, resource limitations, standards of care), medical systems and systems development (prehospital care, wartime casualties, sustainable change, cultural awareness), teaching (instruction and local resources, professional preparation), and research (questionable funded studies, clinical trials, observational studies). It is hoped that this overview may help prepare those involved with international medicine for the challenges and dilemmas they may face and help frame their responses to these situations.

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Much has been written about the development and practice of international medicine.[1–4] These practical descriptions often guide the activities and outreach plans of physicians from the ''most-developed'' countries who seek to work in other, usually resource-poor, countries. However, the complicated, and sometimes ethical, issues that can arise in international medicine have not been as well described in the medical literature. While experiential observations vary from place to place, common themes arise that may present uncomfortable and unforeseen challenges, personal moral conflicts, or classical ethical dilemmas.

Why is this termed international rather than global medicine? While some authors use the terms interchangeably, ''global health'' generally has little relation to geography, implying instead the consideration of the whole planet's health (and often environmental) needs above the concerns of particular nations.[5–8] In contrast, international health has been defined as having five elements: 1) a focus on health issues of countries other

than one's own, rather than those issues that directly or indirectly affect health and transcend national boundaries; 2) the development and implementation of solutions that usually require binational, rather than global, cooperation; 3) the inclusion of both prevention in populations, and clinical care of individuals, rather than health equity among nations and for all people as a major objective; 4) the aim of helping people of other nations (an element shared by both international and global health); and 5) the involvement of a few health care disciplines, rather than interdisciplinary and multi-disciplinary health care/non–health care teams.[9]

For the purposes of this paper, international medicine involves health care professionals (and trainees) from "developed" countries who provide health care, system development, education, or research in "developing" countries. Most physicians and residents have no formal training in the issues, especially ethical issues, raised by working internationally. Yet there has been a steady increase in interest in international work, with nearly one-third of graduating medical students now having international medicine experiences.[10] An increasing number of international medicine fellowships are sending trainees abroad, and many practicing physicians sign up to assist in disaster situations.

In this article, using a case-based approach, we explore physician participation in international health as it relates to four major domains: clinical practice (postdisaster response, resource limitations, standards of care), medical systems and systems development (sustainable change, prehospital systems, wartime casualties, and cultural awareness), teaching (instruction and local resources and trainee supervision), and research (potential bias in funded studies, consideration of local issues in clinical trials and observational studies).

The example cases we selected are those that we feel warrant special mention based on our cumulative experiences, either because they have not been commonly described in previous literature or because they may be generalized to many international medicine scenarios. Most of these challenges occur in resource-poor regions. We gathered these cases from our extensive international medicine experiences, including work in remote, rural, and war-stricken areas of developing and "least-developed countries." They are either actual cases in which we or our colleagues have been involved or representative composites synthesized from several real cases and experiences. Full identifying details or citations of these situations are not included because they might cause difficulties or even hazards for the individuals involved if publicized.

Our goals are to help readers recognize a range of situations in which unforeseen challenges, including ethical dilemmas, may arise and to present some methods and skills to identify and ameliorate such practical and personal dilemmas. Most of these discussions are applicable to all international health care practitioners.

Some of the cases described are true ethical conflicts. Others may appear to be ethical problems at first glance, but upon further inspection, represent examples of unintended consequences, for which the solution is forward-thinking and a commitment to a long-term

strategic goal. Still others describe how clinicians might manage, both personally and professionally, the often tragic cases in the face of what they view as extremely scarce resources.

While many moral and ethical dilemmas in international medicine are the same as or similar to those faced in all clinical settings, the "Western" response to "normal" ethical dilemmas may need to be modified when working in different cultures. Recognizing cultural uniqueness (an aspect of the politically correct term "cultural sensitivity") dictates that some ethical issues need to be approached with an awareness of local mores. Most commonly, these include the release of medical information; a patient or family's refusal of treatment; the determination of futility for patients with terminal conditions; and involvement with group, elder, or family decision-making. While adhering to cultural norms may conflict with Western ideas, it corresponds to the ethical principle of autonomy, that is, a respect for culture, societal norms, and persons.[8]

For most areas of international medicine, the overarching principle is to leave behind sustainable system changes. In this sense, "sustainable" means that local health care professionals can continue to develop any system changes and improvements introduced using local resources. In this case, "system" means procedures established to reach an outcome. Working toward this goal prevents the too-common clinician behavior of doing, rather than teaching. Doing clinical practice (i.e., providing direct clinical care to patients), rather than helping to educate local practitioners and improving the health care system, could be termed "medical adventurism." While often enjoyable and within a clinician's comfort zone, this behavior may undermine local clinicians' confidence, making them dependent on outside aid as well as undermining or competing with local health systems or healers. Rather than imposing the "correct" answer to local problems, sustainability requires that local health care providers are assisted in developing local solutions. In international medicine, ignoring the principle of sustainability can negatively affect the local health care system and providers, violating the bioethical principle of nonmaleficence.[8,11]

CLINICAL PRACTICE

Clinical practice is international medicine's most visible element. It also presents the most obvious and widest range of challenges. International medicine clinicians practice medicine using a variety of methods in diverse circumstances. They can work for pay or, most commonly, as volunteers through nongovernmental organizations (NGOs) or governmental entities (from their home country, a regional or international agency, or the local government) or as individual providers. They also may provide medical care during patient transport to facilities or countries with higher levels of care. International medicine practitioners may also serve as clinical consultants to international hospitals, medical systems, and governments.

Working in an international clinical setting requires understanding and acceptance of local resource limitations and cultural constraints. A core issue is that clinicians

who are not trained or experienced in international medicine tend to bring their traditions with them, often seeking to clone their practice setting or to use diagnostic and treatment algorithms from more-developed countries, even though these may be unrealistic and unhelpful to the local community. Examples include developing a trauma registry in a country that cannot afford to vaccinate its children or performing a hernia repair for an inguinal mass rather than diagnosing filariasis.

The first three cases (below) illustrate resource limitations commonly encountered in less-developed regions and after many acute disasters. Shortages may include the equipment or facilities needed for parenteral drug or fluid administration, endotracheal intubation, mechanical ventilation, prehospital transport to higher-level facilities, and appropriate or sufficient medications. The fourth case highlights what may seem to be an ethical dilemma, but illustrates differing accepted global standards of medical practice.

Challenges arise when available resources, a patient's cultural background, or local standards of behavior force uncomfortable decisions or conflict with personal moral beliefs or ''Western'' ethical precepts. Optimally, international medicine clinicians can decide on ethical approaches to these dilemmas in advance. Using utilitarianism (in short, the greatest good for the greatest number) as the basis for decision-making, decisions may be made to shorten treatment courses or to ration equipment or system use based on the patient's age, total resources needed, or the probability of survival. Strict utilitarianism, however, has its own limitations in individual decision-making and may be socially constrained. When an ethical dilemma occurs, especially one that needs urgent action and has not been anticipated, clinicians must decide how to act in a manner that they believe is ethical and relevant to their personal mores. The Rapid Ethical Decision-Making Model is one tool that can provide guidance on how to act quickly while assessing the ethics of one's behavior. The model, described in detail elsewhere, first asks the user to buy time for deliberation, whenever possible.[12–14] If that cannot be done, the model tests proposed actions against three ethical principles. The Impartiality Test asks clinicians to consider if they would want that action done on them in the same circumstances. The Universalizability Test asks if they think that it would be appropriate for every clinician in the same circumstances to act as they propose to do. The Interpersonal Justifiability Test asks if the clinician would be comfortable having the proposed action made public to his or her colleagues and the public. While it is applicable to some of the clinical cases with ethical dilemmas, it may be difficult to apply to others.

CASE—Postdisaster Response: After a major earthquake and subsequent tsunami occur in a remote but heavily populated area, a small team of physicians and nurses fly there to help. They carry basic personal and professional equipment, but have no logistics plan or support systems.

Responding after acute disasters constitutes the most high-profile international medicine activity. In these settings, the goal is to supplement available health care resources to help save lives and reduce morbidity. Almost by definition these are, at least temporarily, resource-poor environments. In such settings, the underlying ethical principles are utilitarian. That is, fairness or distributive justice demands that the Western standard of maximizing treatment for the individual patient should yield to a standard that maximizes the most good for the population.[15]

It is very appropriate to provide temporary emergency clinical treatment—especially during health care crises, such as postdisaster, war, and refugee situations. The guiding principle is to help local practitioners by bringing knowledgeable, organized, and self-sufficient teams. Because chaos is common after a disaster, it is particularly difficult to predict consequences of individual actions and strategic plans. As a result, unanticipated counterproductive efforts are common. ''Good Samaritan'' volunteers, either unaffiliated with self-supporting organizations or untrained or unprepared for their mission by their organization, often add to the problems by consuming resources that bona fide caregivers or the local population need.[16] Similarly, sending unrequested supplies often overwhelms the supply distribution systems with what may be unusable or unneeded items. Such attempts at beneficent behavior can actually cause harm. In addition, bringing teams to disaster sites requires an exit plan. Upon arrival, teams should begin to plan a transition of responsibility for patients, equipment, and supplies to local providers and health care systems. A difficult ethical issue arises when the local system and economy cannot sustain and rebuild to an adequate level, such as when an acute disaster strikes a chronically resource-poor setting (e.g., the 2010 Haiti earthquake).

CASE—Resource Limitations: One or two children, unconscious from presumed cerebral malaria, arrive each day at the referral hospital in sub-Saharan Africa. The national protocol is to administer intravenous (IV) quinine. In the developed world, this treatment is considered dangerous, and the standard of care is that it be delivered through an IV pump and that patients have constant cardiac monitoring and frequent serum glucose testing for hypoglycemia. However, in this referral hospital, the only one of these monitoring measures available is serum glucose testing, every other day.

In this circumstance, the clinician can either not use the medication needed to treat this lethal condition or improvise in a manner not consistent with the developed world's standard. These types of situations require a combination of improvised and elegant medical treatment.[17] That is, treating these children necessitates working with or adapting whatever resources are available (such as putting the medication in $D_{10}W$ and using pieces of aluminum foil to crimp and control IV fluid drip rates) and doing the fewest possible interventions to achieve maximal patient outcomes.

This is not without danger—some children may develop lethal conditions with this improvised protocol. However, not using what some might consider ''degraded'' treatment standards would do serious harm and cost most, if not all, of these children with severe malaria their lives. Accepting this type of resource constraint is similar to the process used in

wilderness and postdisaster medicine. Neither typical training programs nor normal clinical practice in developed countries prepare clinicians for this type of situation.

Although the situation described may be morally challenging, it does not reflect a true ethical conflict because there is no competition in goals or values. The standard of care is different in resource-rich versus resource-limited practice environments, but the practitioner who is able to acclimate to this restricted environment can retain his or her own beneficence-oriented value system, which is still aligned with the values driving the care of these children with malaria under either standard.

CASE—Standards of Care: A team of international medicine physicians is working with a local hospital, where they witness a precipitous delivery. After a full-term, apparently normal neonate is delivered bradycardic and apneic, standard noninvasive resuscitation measures are used. The child has sputtering attempts at breathing and a normal heart rate over the next 20 minutes. While there is neonatal intubation equipment available, this procedure is never done in this hospital because the nearest infant ventilator is 4 hours away and may not be available. Even if it were, transportation may not be feasible. The Western standard of care for the child's current condition is intubation; the local norm is to let the child die if noninvasive measures fail.[14]

Two standard-of-care situations often arise in international medicine; the first and most common, described above, centers on resource limitations. The second, described in the case below, relates to differing standards based either on a different interpretation of scientific evidence or on tradition- or culture-based medical practices.

What should the visiting international medicine clinician's practice standards be in such a limited-resource setting? One of the most common dilemmas encountered in international medicine clinical work is the need to limit provision of treatment based on medical resource limitations and local practices. Yet clinicians' frustration is evident, with the common comment: "We could have saved her if only she had been in our hospital back home."

While the above case initially implies the need to accept the constraints of limited resources, it actually represents the more common (and more difficult) question of how to allocate limited resources when differing standards of care are, at least potentially, possible. The physician engaged in international medicine must decide whether to agree with the accepted rationing of resources or to try to stretch or alter this allocation to accommodate a more Western standard of medical intervention.

Analogous situations are common among new providers from developed countries who work in resource-limited settings, such as using limited oxygen for an unsalvageable patient, sending an apneic post–cardiac arrest patient several hours away in the only ambulance (with one of the few nurses), or transfusing a trauma patient with a GCS of 5. While all of these actions are possible, they not only strain resource-poor health care systems, but also endanger the lives of other patients who might benefit from those resources.

Commonly, in less-developed countries, patients must prepay for medications, IV fluids, diagnostic imaging, and optional treatments. What is considered "optional" (in some cases, coronary artery stenting that may save a life) depends on the locale and even the specific medical system. For example, in many countries, some hospitals cover all costs (generally for patient groups that have paid into government insurance programs), while others (for those without these benefits) only partially cover services—unless the patient can prepay for them.

In such situations, it seems practical to lean toward strict utilitarianism as a primary ethical system, even while acknowledging the personal and social constraints of such approaches when applied to individual decisions. One caveat: if the decisions are made on the basis of an international clinician or group's faith-based beliefs that are not shared by the patient or local culture, it represents a type of cultural, if not ethical imperialism.[18] Groups (NGOs, universities, governments) sending providers into these situations have a responsibility to educate the providers on how to make these decisions.

CASE—An elderly woman is hospitalized with a hip fracture and awaits surgery. Although she is experiencing significant pain, her physicians only prescribe parenteral NSAIDs. You ask why they are not giving narcotics. They respond that they normally do not do that for fractures.

This case, while it may seem to have ethical implications, actually relates to differing treatment standards. In this case, the clinicians based the patient's treatment both on their experience and on local medical tradition. Since everyone receives the same analgesic treatment (usually with rescue narcotics, if necessary), there are no ethical issues. Similar situations include vaginal deliveries without analgesia, which is common and expected in many areas of the world; basing neonatal resuscitation on "older" gestational age (rather than 20 weeks' gestation as is generally done in the United States); and refusing dialysis for renal failure patients with severe dementia.

These cases do not represent ethical dilemmas—only initial confusion and consternation by those not used to these practices—if the treatment and limited resources are distributed equitably, rather than being allocated based on sex, racial, ethnic, tribal, or caste considerations. Again, new practitioners entering these situations must be forewarned to expect variations from what they consider the standard of care and to understand that good medical practice is not globally uniform.

MEDICAL SYSTEMS AND SYSTEM DEVELOPMENT

International medicine clinicians often work within and help to improve or restore an existing medical system. This may include helping to plan clinical facilities, assisting or consulting on prehospital care systems, or assisting in developing regional or national data gathering (registry) systems. In some instances, they work within their own medical system (such as the military,

an international organization, or an NGO) but must interact with the local system.

Working within the local medical system requires understanding that when resources available to treat patients are limited, every treatment has an identifiable cost to other patients who may not receive necessary interventions. In addition, while not as promotable or dramatic as performing acute procedural interventions, preventative treatment (e.g., vaccinations, HIV treatment for pregnant and lactating mothers, nutrition services) is likely more effective at improving the overall population health. Challenges arise when clinicians feel bound to override mandatory local processes in an attempt to develop or modify existing systems or when local health priorities are overruled in favor of the health care that international medicine practitioners feel they can best deliver.

CASE—Sustainable Change: A U.S.-based mission group sets up a clinic in a rural Central American village. U.S. volunteer health care workers (physicians, nurses, students, etc.) staff the clinic on a rotating basis and provide free health care services for the village. Supplies and medications for the clinic are donated from the United States. After a few years, the local pharmacist goes bankrupt and the only local doctor leaves the area because of the decrease in his paying patients. Patients with chronic illnesses start to complain of lack of continuity in their care. Eventually, the mission clinic closes when its U.S.-based funding is not renewed, leaving the area without any access to health care.

For those delivering international medical care to resource-poor settings, the question is how to deal with a breakdown in or absence of essential health care systems. The provision of direct clinical care by well-meaning ''outside'' or foreign health care personnel may have harmful effects that are unanticipated and unintended. For example, as in the case above, direct health care provision may financially compete with or lower the reputation of local health care practitioners, may cause false expectations and subsequent resentment from the local patients, may not be able to provide extended or follow-up care for chronic medical conditions, and, if it does not include training for local health care workers, may not have a capacity-building or long-term positive effect on the local community.

Standard elements of ethical international medicine programs include working with the community to develop programs they need and want, acting in concert with local providers, and leaving behind sustainable changes.[8,13] To do otherwise, as in this case, places a burden on the population that may far exceed any benefit the short-term medical intervention provided.

CASE—Intrafacility Transfers: A team of visiting academics is observing in a rural hospital in a developing nation when a 12-year-old boy presents after a fall from a tree. The patient has significant pain and swelling around the knee and a distal femur fracture is suspected. An ultrasound examination demonstrates a midshaft fracture. The nearest x-ray and orthopedic surgery facility is an hour away. The ambulance (which takes up to eight patients at a time in a space designed for two patients) has full loads for the next 2 days. Some of

those patients have waited a week or more for radiographs or transfer to a higher level of care.

To the extent that triage is based on ethics, this represents a fairly common ethical situation. Triage criteria, if accepted by the local health care community, can resolve this and many similar cases. Optimally, triage rules provide resources to those who are the most in need and who also would benefit the most.[17]

Common problems in scenarios such as this are that no local triage rules may exist, health care providers disagree about how to interpret any that do exist, or the extended family vehemently disagrees with a triage decision that does not benefit their child. (Of course, other families also will want input about their relatives' positions on the transport list.) Resolving this situation involves getting the health care staff to agree on applicable triage rules, assessing the child in terms of the ability to provide stabilization and analgesia, and fitting the other patients anticipating transport into the triage schema. Fairly applied utilitarian triage rules often can lessen dilemmas that arise due to limited resources.

CASE—Wartime Casualties: Two local civilian patients appear at a military medical facility in a war zone. One has a FAST-positive examination, with a distended abdomen and hypotension after a motor vehicle crash. She needs rapid surgical intervention. The other is a 2-year-old child with congestive heart failure and a ventricular septal defect. As per protocol, neither can be treated at the military facility and must be referred to the civilian hospital, although the woman will probably die before arriving and the local hospital has no medications with which to treat the child.

A unique group of international medicine clinicians are the many military physicians in combat and peacekeeping areas. They face difficult ethical dilemmas when their professional judgment and natural beneficence conflict with military- or government-imposed restrictions about which patients they can treat. The military's rationale for this protocol is that their medical service exists exclusively to treat their own war casualties. If the military facility uses resources on others, then war casualties may suffer.

Local rules in some war zones pose additional ethical dilemmas. These include civilian provisions restricting care for combatants, particularly combatants who are fighting against the local or national government, whether local authorities will be notified about medical care given, and whether health care workers will put themselves in situations where they are exposed to combat risk to provide health care services.

When considering such dilemmas, clinicians may feel conflicted due to their competing sense of fairness (distributive justice). This often places military physicians in a moral bind. However, they also should be aware that they have no obligation to expose themselves to harm (professional, legal, or physical) as they assist others.[19]

CASE—Cultural Awareness: A young patient with no known underlying diseases arrives at the hospital in cardiac arrest. After unsuccessful resuscitation attempts, he was pronounced dead. He had been seen the prior day in the ED and discharged with a diagnosis of gastroenteritis. The clinical history suggests that he might have suffered a massive pulmonary embolus. The country,

however, bans autopsies on a religious basis. The clinicians thus have no way of knowing if they should have treated the patient differently—either during his first visit or during the resuscitation.

This case illustrates a common and frustrating scenario. Both ongoing clinician education and improved patient care suffer when autopsies are forbidden.[20] Yet this is only one of many situations in which international medicine clinicians may believe that the cultural norm directly opposes beneficence. The degree to which a clinician can adapt to local mores, however, will eventually have to be a personal decision. Some value conflicts may be so significant (e.g., performing female circumcision) that a clinician may not be able to continue working in that venue.

International medicine clinicians may face ethical dilemmas due to a wide range of cultural issues. These include restrictions on access to medical care based on sex, religious affiliation, tribal affiliation, age, or the ability to pay for medications, procedures, or timely medical care; language difficulties when communicating with patients, family members, or other practitioners through interpreters of varying abilities; traditional beliefs or treatments (sometimes government sponsored) that delay or interfere with appropriate medical treatments; and religious or burial practices that conflict with institutional rules.

Also important for international medicine clinicians to remember is that health care guidelines and legal contexts differ from country to country and are sometimes absent.[8] Developing medical systems generally lack extensive quality assurance programs. The lack of external oversight from either colleagues or others may lead to medical practices that are beyond individuals' competence or that do not conform to any care standards. A question, if not an ethical dilemma, is whether international medicine organizations should encourage some level of monitoring and analysis of health care delivery, at least for their own clinicians.

TEACHING

International medicine teaching includes helping to develop or instruct in physician or nurse postgraduate training programs, health professions schools, or prehospital training programs. International medicine clinicians may also assist with ongoing or short courses, such as Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support, Advanced Trauma Life Support (ATLS), and ultrasound courses, speak at international venues and provide online educational resources in English or local languages.[18] With the growing number of international medicine fellowships and programs within health professions schools, international medicine clinicians may also teach and supervise students and postgraduates from their own or other countries. All such activities have inherent ethical issues.

Challenges may arise for practitioners relating to how and what to teach. There may also be concerns about international medicine students and postgraduate trainees related to their international medicine preparation, competency, supervision, and benefits to the international medicine students and the community.

CASE—Education and Local Resources: The Health Ministry of a developing country has asked Western emergency academicians to teach an ACLS and ATLS course for the physicians in their district (outlying) hospitals. These local physicians lack electrocardiogram (ECG) monitors, ventilators, most medications needed for cardiac resuscitation, imaging, and surgical capabilities and an organized prehospital system.

In the above scenario, the basic question is: What should the international medicine academics choose to teach? While it is logical to teach practice standards applicable to the local setting, it is easy to forget that teaching higher standards of care such as those of many resource-rich countries will not in itself lead to improved local standards. Do they teach the current "optimal" standards or only those elements that local practitioners can actually perform in their setting? Ethically, the dilemma relates to veracity, that is, telling the truth to the course sponsors, who anticipate that the standard curriculum will be taught, versus beneficence, providing instruction in the material that is actually needed and relevant.

Standard ACLS and ATLS courses were not developed for clinicians in the least-developed countries, and local health care professionals are well aware of their system limitations, even if government administrators are not. Adult learners respond to new information that they need and can use and find such courses frustrating unless they are adapted to the local situation. It behooves international medicine instructors to learn local health care procedures and limitations before they begin teaching. (Local health care professionals also appreciate being able to contribute this knowledge.) While instructors might mention information beyond what local providers can use, the concept of beneficence argues for emphasizing the most effective available techniques, including when and how to transfer patients and how to recognize futility.

CASE—The international medicine programs at a U.S. medical school have sent three medical students, a nursing student, and two residents to the district hospital in a developing country where you, an international medicine physician, are working. They are supposed to participate in educating local practitioners and work clinically, although these instructions are somewhat nebulous.

Academic global health programs are burgeoning. The goal of these programs is to reduce disparities in global health through training, research, and service. In response to the passion and enthusiasm of students, many programs now provide short-term experience in a resource-limited setting.

As international medicine programs rapidly expand, increasing numbers of health profession students and postgraduates are taking advantage of short-term clinical experiences. These visits vary from a few days to a year or longer, are explicitly for training (although most claim to provide service to the host region), and exhibit inconsistent quality.[13,21] Trainees participating in these programs report many educational benefits, including improved clinical acumen, less reliance on diagnostic tests, exposure to a broad spectrum of illnesses, and increased cultural sensitivity.[22–24]

Participants generally assume that their actions are ethical, viewing them (some have said "naïvely") as simple "altruism."[25] Much less attention has been given to the ethical issues associated with education and service initiatives of global health programs, and no formal ethical guidelines are available for global health training experiences, although ethics guidelines do exist for those who establish and run such programs.[13]

While institutions that host international medicine providers may benefit from temporarily increasing what may be a limited health workforce (with various levels of training and experience) and from having opportunities for international collaboration, critics continue to label these trips "medical tourism."[26] Suchdev et al.[27] explained that these visits can be seen as:

- Self-serving: providing value for visitors without meeting the local community's needs.
- Raising unmet expectations: sending volunteer practitioners and trainees who do not have appropriate language or medical training or accountability.
- Ineffective: providing temporary, short-term therapies that fail to address the root causes.
- Imposing burdens on local health facilities: providing culturally irrelevant or disparaging care and leaving behind medical waste.
- Inappropriate: failing to follow current standards of health care delivery (continuity, access) or public health programs (equity, sustainability).

Ultimately, international medicine training must avoid exploiting host countries to benefit trainees. The goal must be mutual and reciprocal benefit.[13,28]

RESEARCH

Fundamental to all research ethics is the protection of human subjects. International medicine research ethics involve the ethical treatment of patients, the ability of the investigator to adapt as needed and in an ethical manner to local research circumstances, and the strict adherence to the study plan to avoid exploitation of the vulnerable.[29,30]

Unique problems arise when considering clinical research in less-developed regions. These include whether a valid oversight body exists that can monitor research-related activities and provide human subjects protection that will define risk limitations for participants, that will be eligible to provide informed consent (or if informed consent will be obtained), and that can determine if and how the study population will benefit from the research. International research dilemmas often revolve around the question of who defines ethical research behavior. Is ethics defined by the culture of the researcher or by that of the subject? Bioethicists do not behave in similar ways throughout the world, nor is there international agreement on fundamental values.[31,32] As ten Have[8] wrote, international medicine "bioethics necessarily reaches beyond the Western individualist perspective of traditional bioethics. [T]he ethical systems of different cultures need to be examined and moral values analyzed and applied in specific contexts."

In developed countries, oversight bodies such as institutional review boards (IRBs) are designed to protect study subjects with scientific and ethical reviews of proposed research projects. In developing countries, similar oversight groups may not be available or may lack the experience or diversity to provide meaningful assessment of such projects.[33] For international medicine investigators, the only available deliberating ethical body may be the investigator's home institution IRB, although it rarely has insight into the community values where the research is to be performed. For instance, in some cultures, it is felt that discussing a negative outcome may cause it to actually happen, so discussing the potential risks of a research procedure with a subject, as required by a Western IRB, may be overshadowed by the concern about mentioning them at all.[34]

In fact, potential research subjects may not be able to distinguish clinical research from medical care, thus making informed consent for research participation meaningless. Moreover, some believe that the concept of individual consent may be a Western, rather than a universal concept, so should not be used in all cultural settings.[26] Controversy exists about whether imposing the individualistic principle of informed consent in community-oriented cultures is a form of "ethical imperialism."[8] Rather, researchers may wish to use community consent, in which the entire community meets to collectively decide about participating in a research project.

Others, however, argue that cultures around the world may be similar enough to justify using individual consent.[35] Limited empirical studies suggest that informed consent is often acceptable to and supported by various populations in developing countries.[36–38]

Ethical international research guidelines have been developed by the Council for International Organizations of Medical Sciences and others to assist in ethical decision-making in international research.[28,39] However, like other established regulations and professional codes of ethics, guidelines cannot anticipate all the circumstances that arise during the application of a research protocol, especially in a developing country. Investigator integrity is therefore the final pathway to ensure effective international medicine research ethics.

CASE—You have an opportunity to be the primary investigator on a placebo-controlled double-blind trial of a new, lifesaving, antiviral agent. The trial is supposed to occur in sub-Saharan Africa. This agent cannot be further tested in the developed world, since the major trial was halted early when the agent was proven to be ideal for treatment. It is now in use throughout the developed world.

Nonexploitation of clinical subjects represents a key element in determining whether a research trial is ethical.[34] The study described above, while seemingly outrageous, was actually funded for nine trials through the CDC and NIH, five through other governments, and one through the United Nations.[40]

For academic clinicians, obtaining a grant for international medicine research and then publishing the results may be vital for career advancement. This may pose an ethical dilemma if the project is either not wanted by or inappropriate for the proposed site or

simply exploits the population. These "double-standard" types of situations repeatedly arise.[41]

Yet someone will apply for the grant, so why not do it, especially if it is not quite as egregious a situation as in this case? Doing so puts one on a slippery slope that compromises integrity, does potential or real harm to patients, and discredits you, your program, and all other international medicine clinician-researchers.

CASE—Postdisaster Clinical Study: At the site of a major earthquake in a developing country, all drinking water sources are destroyed. Survivors are presenting to a field clinic with dehydration. An emergency medicine resident doing an international elective wants to compare the effects of the standard oral rehydration formula with a new formula. She decides to measure how much of each is needed to achieve a favorable clinical response in patients with about the same degree of dehydration.

The potential of misunderstanding the difference between treatment and research is great in countries where participants may lack medical sophistication. International medicine clinician-researchers are obligated to ensure that prospective subjects understand that refusal to participate in research will not result in withholding necessary and available health care. Because international medicine research is often conducted at the same time as the delivery of medical care, it may appear that research participants get deferential and preferential treatment compared to other patients, thus reaffirming the idea that care may be denied if a patient declines to participate in a research project. Perceived priority care for research subjects adds to this therapeutic misperception and, indeed, might be considered a form of coercion.

Most international medicine researchers do not live in the countries in which they perform research. They tend to come for short periods of time, conduct a research project, and leave (i.e., fly-in, fly-out research). Research subjects may have minimal understanding of what happens after study completion. When international medicine researchers leave the site, consideration should be given to the detection and care of potential adverse events, side effects, or delayed complications related to the research intervention. Otherwise, the research enterprise is perceived as abandoning the local participants, thus souring community support for future international medicine research endeavors.

Distributive justice suggests that research done in developing countries should be responsive to the health care needs of the country. Thus, the health benefit of the research should be available to the population in which the research is performed. If the knowledge gained from research is made available only to populations that can afford the resulting health products, then the research could be characterized as exploitive and unethical. For this reason, the researcher needs to ensure that there is some direct benefit to the local populations involved in the research enterprise.

International guidelines for international medicine research ethics require "community benefits" for those being studied.[39] This means projects should focus on important community-identified health needs and priorities and share any benefits from the study with the community.[42–44] Such benefits, which communities may expect post research study, include improvements in individual health, better access to treatment, or improved local medical and research capacity.[8,34,45,46]

CASE—Observational Study: An international medicine research fellow is working in an NGO clinic set up in a refugee camp in an East African country. For her public health master's project, she wants to interview women at the camp to help determine the frequency of sexual and physical assault on refugee women and children so that supportive resources can be defined.

The potential direct benefits of research should justify any emotional discomfort that the data collection process can generate. Maintaining the integrity, dignity, and safety of the study population should be weighed against the importance of any information collected in this study. If there is a possibility of negative aftereffects, such as embarrassment or humiliation, a mechanism should be developed to identify, monitor, and respond to such outcomes. The risk–benefit ratio should be carefully assessed in international medicine research involving displaced and other vulnerable persons, with careful and honest consideration given to why the study is being done and if there is local benefit from the results.

In some cultures, the social conditioning of women makes them especially vulnerable to research misuse and abuse. In no circumstance is it morally acceptable for group, tribal, or village consent to supersede an individual's wishes.[47] However, in many circumstances, an individual cannot provide consent unless his or her family or elders are also included in the decision-making.[48] This should be acknowledged and respected by the international medicine researcher.

In refugee camps, where individuals are forced together by often unpleasant circumstances, confidentiality is at risk. Admission of suffering from physical or sexual abuse, an affiliation with a culturally divergent researcher, or confiding in a medical interpreter who may be coerced to breach confidentiality may put these women at risk of social ostracism or worse. The risk–benefit ratio of the research should be assessed based on the local circumstances, and the local conditions should dictate the appropriateness of the research regardless of the scientific and ethical merits.

Ethical international medicine research should include only that research relevant to the community and with potential direct benefit to the participants. Research should be designed with minimal additional risk to the population, and subject selection should be based on a valid study design rather than convenience.

CONCLUSIONS

Bioethical dilemmas and personal challenges exist in all areas and at all levels of international medicine. The following actions can help prepare international medicine programs and organizations for the bioethical dilemmas and personal challenges that participants may face.

1. Clinical Practice:

- Design well-structured programs with monitoring and analysis of care provided.
- Prepare participants for the cultural and clinical situations they may face.
- Aside from disaster response, have long-term sustainable partnerships with local communities that provide mutual benefits.

2. Medical System and Systems Development:

- Develop programs based on community and national needs.
- Design programs for sustainable outcomes.
- Work with local clinicians to maximize results.

3. Teaching:

- Design programs with clear goals for all parties.
- Provide local benefits to the host institution and health care community.
- Supply adequately prepared providers or students with good supervision.

4. Research:

- Design projects with community input based on their needs.
- Provide participants or communities with tangible benefits from the project.

Focused reading, discussion, and experience help ameliorate some of these dilemmas—or at least provide methods of acting ethically when they arise. International medicine training programs, nongovernmental organizations, and government programs have a responsibility to help those new to international medicine become familiar with the dilemmas they may face and offer methods for dealing with these dilemmas. The ultimate goal of international medicine is sustainable local change to provide improved systems, methods, knowledge, and resources for the delivery of health care throughout the world.

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