

Virtual Mentor

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Clinical case

Pragmatic principles of pharmaceutical donation

Commentary by Richard Currie, MD, and Ronald Pust, MD

Dr. Green, a family practice resident, participated in a program sponsored by his hospital that sent physicians and medical supplies to an urban clinic in Haiti for two weeks every summer. One year, on the last day of his trip, Dr. Green saw a patient in the clinic who had been seen earlier in the week by one of his Haitian colleagues. Reviewing the patient's records, Dr. Green saw that the doctor had put the patient on five different antibiotics to treat his cellulitis. The patient reported that the previous doctor told him the reason for so many pills was that he "wasn't sure which one would work." Each of the medications came from the stock brought in by Dr. Green and the other visiting physicians. The patient had come in that day because of diarrhea that Dr. Green suspected was a result of the inappropriately prescribed antibiotics. In addition, the patient's cellulitis had not improved markedly since his visit earlier in the week. Dr. Green put the patient on the appropriate treatments for his complaints and sent him home.

After the visit, Dr. Green reviewed the clinic records and found that patients were routinely placed on multiple antibiotics, usually unnecessarily. In addition, the number of cases of antibiotic-resistant organisms had been steadily rising since Dr. Green's medical center began donating medications to the clinic five years before.

Commentary

Dr. Green is faced with a dilemma: the antibiotics that he donated to the Haitian clinic have been used inappropriately by a local physician, and patient care has been compromised as a result. On review of clinic records he uncovers a more extensive pattern of harm, including recurrent examples of inappropriate prescribing and the subsequent development of drug resistance in the community. For Dr. Green, now approaching the end of his trip to Haiti, the discovery is surely disheartening. Should he have foreseen the unintended consequences of his donation and taken steps to avert it? Has he neglected an educational dialogue with his Haitian colleagues? Was it irresponsible to bring these unfamiliar new medicines to Haiti?

Because medical students and physicians are increasingly volunteering for short-term projects abroad, the questions raised by Dr. Green's dilemma seem increasingly prescient [1]. The practice of clinical medicine is, in theory, a universal language, so it is tempting for Dr. Green to assume that his donation of time, knowledge and Western medicine will always be useful and welcome, irrespective of how limited

the supply, how relevant his skill set or how fleeting his visit. These are assumptions born of altruism and grounded in the principle of beneficence, and, as such, Dr. Green's intentions are commendable. This case reminds us, however, that in our zeal to address unmet needs we may, at times, unwisely neglect our primary duty of nonmaleficence [2]. While enthusiastically preparing for his trip to Haiti, Dr. Green would have been well served by a simple reminder: First, do no harm.

Beware the medical student tourist: a framework for principled action

In addressing the issue of ethical drug donation, it is helpful to consider Dr. Green's scenario in a broader framework. An international volunteer is, first and foremost, a guest in the host country [3]. Back at home, when invited to participate in patient care, we do not begin by directing clinical management in the absence of input from those we aim to treat. Ideally, we first listen, then we counsel and, ultimately, we respect the autonomy of our patients. Our hosts in the developing world are worthy of the same respect. A welcome and productive volunteer is one who is mindful of the pre-existing customs, wishes and expectations of their hosts. Who invited me? For how long? What is my role during this time?

There are, we believe, some general perspectives that lead to principled, purposeful action in any international humanitarian collaboration. As a guest in the host country, a medical volunteer may aspire to serve in one or more of four primary roles: colleague, coach, critic and citizen. The volunteer who is available for only a few weeks may do well as a clinical colleague, learning from local counterparts while serving alongside them within the existing health care framework. As knowledge, relevant skills and mutual trust develop, the volunteer may become a coach and cheerleader, gradually making the transition from learner to teacher. Eventually, over longer commitments, the lifelong learner earns the right to ask critical questions, challenging his or her collegial equals in the mutual pursuit of systemic improvement. Ultimately, if such systemic changes are to be forged, the role of world citizen must emerge. When the individual guest and host counterpart join minds and hearts to advocate change, only then does sustainable development become a possibility. Let's use this framework to address Dr. Green's drug donation dilemma.

Drug donation and access to essential medicines

What would motivate Dr. Green to collect and carry these newest antibiotics to Haiti at a cost of time, effort and, perhaps, personal expense? More than likely his decisions are influenced by his prior experiences in that country, fueled by a growing global awareness of the scarcity of pharmaceutical resources in developing nations. According to the World Health Organization (WHO), 60 percent of deaths in the developing world are attributed to diseases that are treatable in industrialized countries, a sad consequence of the fact that 2 billion people—one-third of the world's population—do not have any regular access to essential medicines [4]. As we critique Dr. Green's donation, we do not wish to distract from these alarming statistics. We believe there is an ethical mandate to provide equitable access to life-sustaining therapies to the world's poor and marginalized populations. Prohibitive

drug pricing, indiscriminate patent protection and the disproportionate allocation of research funding for categories of drugs that maximize profits all demand immediate collective action by advocates worldwide [5]. We recommend specific overviews of these subjects [4, 6-8]. The issue here is not whether drugs are needed in developing nations, but rather which drugs, where and from whom?

When poorly planned or delivered, the donation of pharmaceuticals can have significant adverse consequences for recipients. At a national level, donations of large quantities of inappropriate or expired medications can burden the recipient with the unwelcome task of sorting, storing and properly disposing of unusable donations, necessitating the regrettable investment of scarce money and manpower. In a review of drug donation practices in Bosnia and Herzegovina between 1992 and 1996, Berckmans et al. estimated that 50 percent to 60 percent of all donations (17,000 metric tons) were unsuitable for use, with an associated disposal cost to in-country agencies of \$34 million [9].

Smaller private donations can be equally perilous. As Dr. Green has discovered, patient care can be compromised when donated pharmaceuticals are irrelevant to the local disease pattern, are poorly labeled or are unfamiliar to community clinicians. Such donations also impact the local health care delivery model negatively by altering prescribing habits and thereby undermining existing national drug policy. The uncoordinated introduction of newer, more expensive medications—erroneously assumed to be superior by recipient and donor alike—compromises government efforts to develop a pertinent, affordable and sustainable drug supply system.

To address the growing problem of inappropriate, burdensome and counterproductive drug donation, WHO now has guidelines for ethical donation [10], based on four core principles. The donated product must be of maximum benefit to the recipient, addressing a clearly expressed need directly relevant to local disease prevalence. The recipient's authority must be respected; donations must comply with existing drug policies. Where a national drug policy does not exist, donors are referred to the WHO's Model List of Essential Medicines, an international consensus list of efficacious, safe and cost-effective medicines for priority diseases [11, 12]. There must be no double standards in drug quality: medications that are unacceptable for use in the donor country should not be sent abroad. Lastly, effective communication between the drug donor and recipient is essential to appropriate distribution and clinical use. The highlights of the WHO's key guidelines for drug donations are:

- All drug donations should be based on an expressed need and be relevant to the disease pattern of the recipient country.
- All donated drugs should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Medicines.
- After arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year.

- All donations should be labeled in a language that is easily understood by health professionals in the recipient country; the label on the container should include the generic name, batch number, dosage form, strength, name of manufacturer, quantity, storage conditions and expiry date.
- Recipients should be informed of all drug donations that are being considered, prepared or actually under way.

Could this scenario have been avoided?

Let us assume that Dr. Green's residency program has established a sustainable, mutually productive program, embedded in a long-term coordinated effort incorporating professional Haitian input. If these visits are truly collaborative, one would expect local Haitian counterparts to define which drugs would be useful in Haitian health care. These decisions would be influenced by evidence-based international protocols, such as those of WHO's Integrated Management of Childhood Illnesses [13, 14] or Model List of Essential Medicines, supported by continuing medical education programs provided via the Haitian Ministry of Health in collaboration with progressive, locally respected nongovernmental organizations [11, 15-17]. In such a setting of planned, sustainable health care development, any role for Dr. Green's program or its pharmaceutical donations would be defined by Haitian host counterparts.

The imperative to provide urgent access to life-sustaining medicines in developing nations is compelling, but should not be viewed as an open invitation for indiscriminate donation. The WHO Guidelines for Drug Donation [10] can inform both Dr. Green and his hosts. Are his drugs the most appropriate to treat local diseases [12]? Is he responding to a specifically defined need? Does his donation comply with the existing national drug policy? We can only speculate as to the overall content and context of Dr. Green's donation, but based on the confusion generated among his Haitian colleagues, it seems apparent that at least some of the key criteria for an appropriate, ethically responsible donation were not fulfilled. In retrospect, the resulting negative clinical outcome and the emergence of antibiotic resistance seem regrettably avoidable.

Take the long view

Dr. Green is an educated clinician, an altruistic volunteer and a welcomed guest in Haiti. As such, he has an ethical responsibility to conduct himself in a fashion that respects and facilitates the autonomous development of the local health care system, while honoring his primary duty of nonmaleficence. In preparing to serve abroad, Dr. Green, like any volunteer, should first examine his potential roles as clinician, coach, critic and world citizen and then plan to serve in this context with his Haitian hosts. Rather than rushing to the rescue, we would all do well to internalize the prayer often attributed [18] to Archbishop Oscar Romero (1917-1980), who was martyred in his native El Salvador: "It helps, now and then, to step back and take the long view... We are workers, not master builders, ministers, not messiahs. We are prophets of a future that is not our own" [19].

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