Connecticut Debate Association

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Amity High School and Westhill High School

This House Would prohibit the emigration of medical personnel from less developed to developed countries.

This House Would ignore experimental drug testing protocols to fight deadly epidemics.

This House Would implement aggressive screening and quarantines to prevent international disease transmission.

How the U.S. Made the Ebola Crisis Worse

The Wall Street Journal, E. Fuller Torrey 15 Oct 2014: A.19.

Amid discussions of quarantines, lockdowns and doomsday death scenarios about Ebola, little has been said about the exodus of Africa's health-care professionals and how it has contributed to the outbreak. For 50 years, the U.S. and other Western nations have admitted health professionals -- especially doctors and nurses -- from poor countries, including Liberia, Sierra Leone and Guinea, three nations at the heart of the Ebola epidemic.

The loss of these men and women is now reflected in reports about severe medical-manpower shortages in these countries, an absence of local medical leadership so critical for responding to the crisis, and a collapse or near-collapse of their health-care systems.

Although Africa bears 24% of the global disease burden, it is home to just 3% of the world's health workforce. A 2010 World Health Organization assessment of doctors, nurses and midwives per population listed Liberia, Sierra Leone and Guinea in the bottom nine nations in the world in medical manpower.

In Liberia, a nation of four million people, the number of Ebola cases is said to be doubling every 15-20 days. Based on news reports, I've estimated that there were about 120 Liberian physicians in the country prior to the outbreak.

According to an American Medical Association database, in 2010 there were 56 Liberian-trained physicians practicing in the U.S. This number does not include other Liberian physicians who emigrated to this country, were unable to pass state licensing exams, and are employed as technicians, administrators, or in other jobs. Older studies suggest that the number failing such exams is about half of those licensed.

Thus the total number of Liberian physicians in the U.S. is probably about two-thirds the number in Liberia. In addition, Liberian-trained physicians live in Canada, Great Britain and Australia.

The Liberian situation is not exceptional. Altogether in 2010 the U.S. had 265,851 licensed physicians trained in other countries, constituting 32% of our physician workforce, according to the AMA. Among these, 128,729 came from countries categorized by the World Bank as being from low- or lower-middle income countries. These physicians tend to work disproportionately in rural and inner-city jobs less favored by American medical graduates. West Virginia, for example, has the highest proportion of foreign-trained physicians from poorer countries to U.S.-trained physicians.

The U.S. has always welcomed health professionals from other countries. However in 1965, responding to a perceived shortage of physicians for the growing U.S. population, Congress passed landmark immigration legislation giving preference to health professionals. Subsequent legislation in 1968, 1970 and 1994 further opened the door, especially for physicians from poorer countries. The percentage of foreign-trained physicians has steadily increased from 10% of the workforce in 1965 to its current 32%.

Many objections to this policy have been raised over the years. In 1967 Walter Mondale, then a senator from Minnesota, called it a disgrace. It was "inexcusable," he wrote in the Saturday Review, that the U.S. should "need doctors from countries where thousands die daily of disease to relieve our shortage of medical manpower."

A 1974 report on the "Brain Drain" for the House Foreign Affairs Committee noted that the current policy was widening the gap between rich and poor nations, and warned that the policy "has a great potential for mischief in the Nation's future relations with the LDC [less developed countries]."

Despite such complaints, U.S. policy has continued to encourage the immigration of physicians and other health

workers from poorer countries. "There's nothing wrong with a foreign-trained doctor," Casper Weinberger, then secretary of the Department of Health, Education and Welfare, said on TV in 1973. "Of course we're using a lot of them, and will use a lot more."

The consequences of this policy may be more than "mischief." Ebola may be merely the first of many prices to be paid for our long-standing but shortsighted health manpower policy. Surely the wealthiest country in the world should be able to produce sufficient health workers for its own needs and not take them from the poorest countries.

Dr. Torrey is associate director of the Stanley Medical Research Institute and author of "American Psychosis: How the Federal Government Destroyed the Mental Illness Treatment System" (Oxford, 2013).

How to Stop the Spread of Ebola

The New York Times, Room for Debate, October 2, 2014

Introduction

Countries in West Africa have been struggling to stop what has become the largest Ebola outbreak ever recorded. Now, with the first case diagnosed in the United States, health officials are scrambling to prevent the disease from infecting more people.

What needs to be done and what lessons have been learned about containing the spread of Ebola from West Africa?

Much More Vigorous Government Response to Ebola Is Needed

Alexander Garza associate dean of public health practice and associate professor of epidemiology and emergency medicine at St. Louis University College of Public Health and Social Justice, was assistant secretary and chief medical officer of the Department of Homeland Security from 2009 to 2013.

Systems to reduce the risk of infectious disease being imported into the United States are already in place. The Centers for Disease Control and Prevention has trained workers in the countries where Ebola is endemic to screen for the virus and take temperatures of passengers before they can get on an airplane. Customs and Border Patrol agents have been instructed on the signs and symptoms so they can report any arriving passengers who may be infected to the C.D.C. quarantine officer.

But the response to Ebola needs to be more intensive.

Either more needs to be spent to increase the number of screeners and to make their work more rigorous, or workers need to be shifted.

Because of disease's incubation period, an infected person may not be symptomatic until they get on a plane or even after they get off the plane, so more diligence is needed.

And this is no ordinary communicable disease. It is the ISIS of biological agents. The response should mirror antiterrorism efforts.

More screening workers need to be put in airports outside of West Africa. At U.S. airports, people who have come from West Africa should be more actively screened for symptoms and questioned more closely about their possible contact with Ebola.

Flight manifests should be scrubbed for travelers coming from infected areas. This would allow a concentrated secondary screening by trained quarantine officers regardless of whether a passenger exhibited signs and symptoms of Ebola. Questions should include questions about any close contact with a person infected with Ebola and what area of the country they lived in or came from, since the disease is much more prevalent in some areas than others.

Assuming that the patient in Dallas would have answered this question truthfully, he would have been quarantined. Persons denying contact would then be again evaluated for any signs of infection such as a fever and finally customs and border officers could collect contact information for their stay in the United States, including where they were eventually going to stay. This could help local public health officials know where these travelers are in the community and give a heightened sense of awareness.

This could likely require a doubling of the Global Migration and Quarantine office's budget until this disease is under control. And help from other agencies would also be needed.

The military can easily convert artillerymen into infantry if they're needed to fit the fight. It's more challenging for an agency like the C.D.C. to rally a surge of health combatants. But it needs to be done to combat the disease as a whole government effort.

Staff from all agencies within the Department of Health and Human Services can be retooled. And there are health agencies within all of departments that could contribute people to work at screening individuals at the airports within West Africa.

We need to face this disease threat as we have done with other dangerous threats.

Bolster Communication With Health Workers

Thomas Inglesby a doctor, is the director of the U.P.M.C. Center for Health Security and an associate professor of medicine and public health at the University of Pittsburgh Schools of Medicine and Public Health.

There is already one important lesson from the response to Ebola in Texas. The patient was sent home after being examined for a fever, and because of that additional people may have been exposed to the virus. Given the stakes related to even a single case of Ebola, in the time ahead it will be critical for American doctors and nurses to know the right protocol.

American doctors and nurses must know the procedures for gauging whether a patient is likely to have Ebola and know what to do.

The goal should now be that every health-care worker in the United States that comes into contact with patients with a fever understands what questions to ask, how to provide the right care and testing, and how to isolate in cases that call for it it. Right now there is no single emergency health communication system that can reach all doctors and nurses in this country.

Some are plugged into C.D.C. alerts, others receive texts and emails from their state public health agencies or state certification boards. We should fully use these systems and others that exist to ensure that, from this point forward, all health-care providers are fully aware of the risks of Ebola and how they need to respond.

I would probably leave it to the states to figure out how to make sure that happens. Instituting a new single emergency alert system across the country would run into major technical and practical barriers and would take time. It is worth examining whether such a system could be built in the future. There are not that many urgent public health messages that need to be spread across the country at the same time, but this is certainly one of them.

Bar People From Areas Affected by Ebola Until Threat Is Over

Jessica Vaughan is the director of policy studies at the Center for Immigration Studies.

The case of Thomas Eric Duncan, the Liberian man who brought Ebola to the United States, demonstrates how the erosion of effective immigration controls has put Americans at risk, and suggests further steps that must be taken to protect the public from international travelers who are a threat to public health.

Neither the U.S. government nor the airlines nor the Liberian government have effective measures to screen travelers for exposure.

Neither the U.S. government nor the airlines nor the Liberian government established effective measures to screen international travelers for exposure to Ebola. Duncan was apparently tested for fever and questioned by officials but did not disclose his contact with a woman who had recently died, suggesting that he knew he was at risk. Clearly it was folly to expect that we could rely on individuals to self-quarantine in these situations.

The total number of visas issued to citizens of Liberia, Guinea and Sierra Leone is not large relative to other countries. But it's a large enough group to worry about. Based on State Department nonimmigrant visa issuance statistics, I estimate that there are about 5,000 people in Guinea, 5,000 people in Sierra Leone and 3,500 people in Liberia who possess visas to come to the United States today (or who could be in the U.S. right now). Additional steps need to be taken to protect our communities.

Our government must simply deny admission to any non-U.S. citizen who has been in the afflicted countries in the recent past, until the crisis is over. The most fundamental purpose of immigration controls is to protect our homeland, and our leaders must end their chronic reluctance to use them.

To Fight Ebola, the E.R. and Outpatient Clinics Need to Be Prepared

Aubrey Stimola Ryan is a global health fellow at Mount Sinai-St.Luke's and Mount Sinai-Roosevelt Hospitals in New York City, where she practices clinical emergency and tropical medicine. She has studied, written about and trained in infectious diseases, including Ebola, Avian Influenza, and pediatric H.I.V. in Tanzania.

The first case of Ebola in the United States was sent home from a Dallas clinic on Sept. 26, two days after developing nonspecific symptoms and seven days after arriving from Liberia, an epicenter in the current outbreak. If a travel history had been obtained and properly documented at triage, his symptoms should have raised the specter of Ebola resulting in immediate quarantine, not two days later when he returned with worsening symptoms.

A travel history combined with other specific criteria should trigger a chain of events implemented to prevent the spread of suspected cases.

In this era of ease of international travel, obtaining travel histories from a patient in an emergency room or outpatient clinic should be a prerequisite for leaving the triage area. Noncompliance can result in misdiagnosis, delayed treatment

and the preventable spread of a dangerous or deadly communicable disease. In the case of Ebola, a simple travel history can actually be instrumental in stemming an outbreak; even one missed case can perpetuate the chain of infection.

The taking of travel histories can be tailored to specific diseases. For example, in the case of Ebola, travel from an outbreak area or exposure to infected individuals within the two- to 21-day incubation period. Because Ebola's initial symptoms are nonspecific and easily mistaken for a variety of less serious illnesses, including the common cold, such questions are imperative in developing diagnoses.

In the emergency room, a history of travel to a region where there is a current outbreak of Ebola together with other specific criteria, such as a fever higher than 101.5° F should trigger a chain of events implemented to prevent the spread of suspected cases. These events should include patient isolation before further evaluation, flagging patient charts as "high risk," minimizing the number of staff involved in the patient's care, adherence to C.D.C. infection control precautions — including the proper donning, removal and disposal of protective equipment and appropriate collection and transport of laboratory specimens — detailed patient interviews to further elucidate Ebola risk factors, and notification of both hospital infection control and local health departments.

Recognizing Ebola Is the Key to Prevention

Aileen M. Marty is a professor of infectious diseases at Florida International University and the director of its Health Travel Medicine Program and Vaccine Clinic. She was recently in West Africa where she helped Nigeria set up a system to screen passengers arriving and leaving a country.

It couldn't be simpler. The key to preventing an infectious disease from going out of control is to recognize it as soon as possible.

Health care workers throughout the world must recognize that we live in a global society where people travel constantly from one nation to another.

The current Ebola epidemic in West Africa claimed its first victims in Guinea in December 2013, but tragically, no one suspected there was an Ebola outbreak until late February. Why? Because there had never before been an outbreak of Ebola in West Africa. Ebola was a virulent inhabitant of the Congo region, thousands of miles away.

The United States' first Ebola case, a man who had just moved to Dallas from Liberia, also became a victim of this geographic nearsightedness. To reduce the spread of any highly infectious, dangerous disease such as Ebola it is imperative that health care workers throughout the world recognize that we live in a global society where people travel constantly from one nation to another. Even workers at a rural local community hospital in America's Heartland must be acutely aware of any outbreak of any serious contagious disease going on anywhere. At any time, at any moment, an infection with an incubation period of more than 24 to 48 hours can travel to virtually anyplace.

What can be done in the future to contain the spread of a contagion like Ebola? We need public awareness, continuous training, planning, memorandums of understanding and prepositioning of resources, including trained health care workers. Once a health care worker has reason to suspect that an individual may be infected with a dangerous highly infectious disease there must be an established protocol for them to follow that includes knowledge in the proper use of barrier methods, protective equipment and treatment methods.

First and foremost, we must not forget, it is a small world we live in. The bacteria, viruses and other germs have already figured that out.

Experimental Drugs and the Ethics of Fighting Ebola

The New York Times, Room for Debate, December 1, 2014

Introduction

International medical teams this month could begin administering experimental Ebola drugs in West Africa, where the outbreak has killed more than 5,000 people.

But is it ethical for the drugs to be given in randomized, controlled trials — considered the gold standard in methodology — since that would require some patients to take placebos? How can the development and testing of Ebola drugs and vaccines be accelerated while respecting ethical standards?

Trials Tempered by Compassion and Humility

Nancy Kass is a professor of bioethics and public health at Johns Hopkins University. *Steven Goodman*, an associate dean of clinical research, is the co-director of the Meta-Research Innovation Center at Stanford University, which aims to improve the reproducibility of scientific research.

Designing an ethically acceptable trial to test new Ebola treatments is challenging. It sounds inhumane to give sick and dying people placebos when testing experimental treatments, but it is tragic on a different scale to conduct a study that doesn't tell us clearly whether, or how well, a new treatment works. When high-dose chemotherapy was developed for

advanced breast cancer, desperate patients were diverted from trials by treatment advocates whose hope in a cure overrode the lack of scientific evidence of its efficacy – all in the name of ethics. As a result, thousands of women endured highly toxic, ineffective therapy until controlled trials were conducted.

Adaptive approaches allow researchers to modify their study, in almost real time, as they learn more about a drug.

Ethics is not just figuring out which side poses better arguments; often it's best to find a third way. Given the breadth and deadly nature of the current Ebola outbreak, and unknowns about treatments, an "adaptive approach" seems most appropriate. Adaptive approaches allow researchers to plan a sequence of studies, or modify a single study in almost real time, as they learn more about a drug. In West Africa, for example, the first 40 Ebola patients in a trial could all get an experimental treatment, and nobody would take a placebo. If nearly all patients survived, in settings where most others were dying with the same supportive care, then it is possible that placebo testing could be avoided, and subsequent trials could randomize to different doses or treatments.

But if the results of the first trial, without placebos, revealed anything less than an almost certain cure, a design with proper controls would have to be initiated, and explained to those participating in the trial. Patients must be told that the drug is not a guaranteed life-saver, so they can see the point of the control group. (And given the multiple beliefs about Ebola among West Africans, creative approaches to promoting understanding and consent are important as well.) These placebo-controlled trials could themselves be adaptive in design, randomizing more patients to whichever therapy appears most effective, until the verdict is clear. If we are to design trials to minimize suffering and death in a whole population, we must temper our compassion with humility about what we think we know.

Don't Ignore Established Research Ethics When Treating Ebola

Lina Moses is an epidemiologist and the director of Community and Ecology Based Research at Tulane University's Lassa Fever Program.

The blinded randomized control trial is the most robust study design for testing the efficacy of a treatment, and its application is imperative in West Africa. Because of randomization, this design controls for effects (known and unknown) that may affect the results of other study designs. It also requires a relatively smaller study population than other designs so it can be done quickly.

The blinded randomized control trial is the most robust study design for testing the efficacy of a treatment.

When it comes to treating Ebola in West Africa, some have proposed a retrospective control: the method would be to treat every sick person and then compare outcomes to a group of cases that came through an Ebola treatment unit when an experimental treatment was not available. But having worked in West Africa since 2005 and on the ground for most of this year in Sierra Leone, I've seen firsthand how much patient outcomes fluctuate in treatment units based on the number of health care workers, the quality of care, the willingness of communities to identify and report cases early, availability of supplies and resources, and the distance that patients have to travel to receive care. Retrospective controls do not submit to the same conditions and it is dangerous to compare them.

The execution of any Ebola trial in West Africa is difficult because of the lack of resources, the educational level of the participant population and the unavailability of skilled research coordinators that can monitor data quality. The randomized control trial is challenging to implement for another reason: the patients or their families must be informed that they could receive a placebo.

But my experience with the Sierra Leonean population is that, when you take the time to carefully explain a study, the reasons for the placebo and listen to people's concerns and address them, patients are remarkably willing to participate, much more so than my American research subjects. It takes time and patience but it is the least we can do to alleviate the stress, confusion and pain that comes with the devastation of Ebola. And all participating patients, regardless of whether they receive the experimental medication or the placebo, receive elevated care and observance by virtue of participating in the trial.

In the United States, science has been routinely ignored over politics and this has outraged many. We should also be outraged over the idea of caving to public opinion and politics and ignoring established research ethics when implementing therapeutics trials on West Africans. In my opinion, it is unethical to subject research participants to a weaker study design when a better one is feasible. We have a limited amount of time to get this right, and we don't want to do this again. We owe it to the people whose lives have been lost and to those who are at risk now.

Nonrandomized Trials Could Minimize Deaths of Ebola in West Africa

Peter Horby the director of the Epidemic Diseases Research Group at the University of Oxford, has conducted research on emerging and epidemic infections for more than a decade.

When it comes to infectious disease epidemics, the clinical research community has failed time and again to move beyond business as usual, instead following a well-worn path to impeccable but obsolete clinical trial protocols that enroll, at best, a handful of patients. Where are the clinical trials that have informed the treatment of SARS, avian

influenza, pandemic influenza and Middle East Respiratory Syndrome coronavirus? We still don't know which drugs work in patients with these infections.

This time it needs to be different. Obtaining evidence of the effectiveness of experimental drugs in the midst of an epidemic is not high science, it is "the art of the possible." In West Africa the risk of death from Ebola is roughly 50 percent. We don't know if families, communities and health care workers will accept the randomizing of patient care with so much at stake, particularly when evacuated patients have received multiple experimental treatments and survived.

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An alternative, multistage approach to evaluating experimental drugs that begins with a nonrandomized trial, in which all eligible patients who want the medication can have it, could provide early indications of drug safety and efficacy. This tactic could minimize in-study deaths and, if ineffective, clear the path for more rapid investigation of other interventions. Nonrandomized trials have weaknesses but they do not shortcut normal scientific and ethical research practice. This trial design is routinely used to provide early indications of drug safety and efficacy, particularly in conditions with high case fatality and no existing effective treatments. The recent accelerated approval by the F.D.A. of Keytruda for use in patients with advanced melanoma based on data from a nonrandomized trial is a case in point.

Ultimately, an insistence on randomized, controlled trials as the only way to gather useful information risks a repetition of previous failures.

In Africa, Broader Ethical Considerations Are Common

Monique Wasunna is the Africa regional office director of the Drugs for Neglected Diseases Initiative and assistant director of research at the Kenya Medical Research Institute.

For many diseases in Africa, ethical dilemmas are far too common. Ethical considerations vary greatly depending on the disease and sometimes experimental treatments and approaches are the only tools that health care professionals have at their disposal.

In some cases, for example, doctors must decide whether to use existing drugs "off-label," meaning that they apply a drug that has been approved for one disease to treat another, because there is reason to believe the drug could be effective. The choice to use a drug off-label is not taken lightly but we have seen their use numerous times, from the worst years of the H.I.V. epidemic in the U.S. to today's Ebola outbreak in West Africa.

In some cases, doctors must decide whether to use existing drugs "off-label" or treat with medications that have toxic side effects.

In the 1990s, during an outbreak of leishmaniasis, a deadly parasitic disease, in East Africa, Doctors Without Borders began using off-label drugs because of the lack of safe and effective treatment options. When some treatments showed promise, our organization, the Drugs for Neglected Diseases initiative, worked with them to successfully test combinations of these drugs in randomized clinical trials.

It would have been unethical to use placebos in those trials because there was already a treatment available for leishmaniasis, even though that drug was old and had toxic side effects. But the ethical considerations are different if there is no proven treatment or the disease is not as viral or deadly.

This does not change the fact that even in the most poor, remote, unstable settings, trials must be held to the highest international ethical standards. Health care professionals must do everything they can to strengthen the health infrastructure and ensure that the safety and well-being of patients and needs of local staff are at the heart of clinical research activities, even when cures for diseases are not yet clear.

Controls Are Needed to Test Vaccines, Not All Ebola Drugs

Peter J. Hotez a professor of pediatrics and molecular virology and microbiology, is the dean of the National School of Tropical Medicine at Baylor College of Medicine, and the fellow in disease and poverty at Rice University's Baker Institute.

Ebola has killed half the people it has infected in West Africa, where the medical care, even provisions for fluids and nursing, are extremely poor.

To test medications that would treat infected people, there is a strong case for pursuing innovative trial designs, without standard placebo controls, that could rapidly compare drugs to each other among small cohorts of patients.

Controlled trials would be the fastest and most accurate tests and the only proven path to determine vaccine safety and efficacy.

Evaluating preventative vaccines would be different and would require immunizing larger groups of health care workers or other healthy populations.

At least a half dozen possible Ebola vaccines that have protected nonhuman primates are entering early clinical trials for safety. What's the fastest way to determine which one is most effective?

Perhaps the closest we've come to facing this sort of dilemma was in the fight against smallpox. By the time the smallpox vaccine was widely deployed in the 1960s and 70s, though, there had been so much clinical experience with it that a randomized trial was not required.

But when we're testing a vaccine against a disease that causes more than 50 percent mortality, do the normal procedures apply? Yes, because a randomized controlled trial in a highly affected area would be the fastest and possibly only accurate way to test the Ebola vaccines. A randomized trial is also the most ethical way because it's the only proven path to determine vaccine safety and efficacy.

Health care workers might resist getting a possible placebo. If the United States were in the midst of an epidemic that killed half of those infected, Americans might not tolerate randomization with a placebo.

An alternative trial could be proposed, but it would risk delaying an answer on which vaccine is the safest and best, or possibly never coming up with an answer and having to start all over again.

Creative and Time-Efficient Approaches to Curbing Ebola Are Necessary

Jason Schwartz is the Harold T. Shapiro fellow in bioethics at Princeton University's Center for Human Values.

Ebola has receded from the headlines in America, and public health officials are now optimistic that the most dire projections for the scale of the outbreak in West Africa may not come to fruition. However, the situation remains out of control in parts of the region, particularly in Sierra Leone.

The foremost challenge for the global public health community will be to maintain momentum for the efforts underway.

As the world's attention drifts elsewhere, the foremost challenge for the global public health community will be to maintain momentum for the efforts underway to end the current outbreak and to develop new tools to prevent and treat Ebola now and in the future. Last week's news that a small, early-stage clinical trial of one Ebola vaccine candidate was successfully completed at the National Institutes of Health was a very encouraging development toward this end. President Obama is expected to promote this progress to make the case for continued funding to fight the disease.

As testing of this and other products accelerate and move into Ebola-affected regions, it is imperative that the international community design and conduct trials that fit the context of a continuing public health emergency and humanitarian crisis. That does not mean that researchers must sacrifice methodological rigor, nor abandon ethical standards. But creative approaches are required to ensure that scientifically sound research is conducted as safely as possible without unnecessarily delaying, or limiting access to, potentially effective treatments and vaccines.

Thanks to the heroic efforts of the international community fighting Ebola in West Africa with existing tools and public health methods, it is possible that new drugs or vaccines may not arrive in time to contribute to the response to the current outbreak. Still, products emerging from ongoing research will be invaluable for future outbreaks and the strategies shown to be effective for the Ebola response could be applied to other emerging global health threats. But the international health community must act quickly to highlight the continued need for intensive efforts to curb this epidemic -- or lose the international attention that brings badly needed funding.

People Infected With Ebola Would Fear a Placebo

Aissatou Toure is head of the Unit of Immunology at the Pasteur Institute in Dakar, Senegal.

When dealing with a disease as fatal as Ebola, ethical, social and pragmatic considerations require that we abandon methodological rigidity and take other paths that have been followed in previous catastrophic outbreaks.

If you were infected by the Ebola virus and knew of a possible treatment with low toxicity, would you be willing to take your chance with that treatment even though the outcome might be uncertain? A desire to stay alive would win out, even if side effects had yet to be determined. This option would be even stronger if you had suffered the loss of several of your loved ones taken by the disease.

If there was the slightest hope that a treatment would work, no one would want to be part of a control group that could give them a placebo.

If randomized controlled trials were used a situation as deadly as the Ebola epidemic, sick people would have only 50 percent of chance of benefitting from a potential treatment.

Such trials can quickly obtain information about a treatment?s effectiveness. But they would be very difficult to implement in such a dramatic context.

When people sick with Ebola can get nothing more than supportive care, and saw that despite these supportive care the mortality rate can reach as high than 70%t and if there was even the slightest hope that a treatment would work, is it unreasonable to predict that no one would agree to be part of the control group and lose what they would consider as

50% of chance of better situation.

Would you?

Heading Off a Bigger Ebola Catastrophe

The Wall Street Journal, Scott Gottlieb and Tevi Troy Sept. 1, 2014 6:05 p.m. ET

The Ebola virus, which has already killed more than 1,500 people since the epidemic began earlier this year, is wreaking havoc in West Africa, leaving death, economic hardship, social stigma and civil unrest in its wake.

In response, the Obama administration has stressed that the disease is highly unlikely to spread inside America. Given international travel, we will certainly see cases diagnosed here, and perhaps even experience some isolated clusters of disease. For now, though, the administration's assurances are generally correct: Healthcare workers in the U.S. and other advanced Western nations maintain infection controls that can curtail the spread of nonairborne diseases like Ebola.

Yet our ability to prevent an epidemic here doesn't reduce our obligations abroad. Even if the epidemic remains only in West Africa, the continued spread of Ebola infections could eventually rank as one of the cruelest natural catastrophes of recent times—if not in human death and suffering, then certainly in the economic and social devastation caused by declining commerce, restricted travel and the strife resulting from mass quarantines. Compared with a storm that delivers its destruction all at once, the swelling nature of a viral epidemic can magnify its impact on economic and civil life.

To address this problem, the U.S. should lead an immediate effort to assist stricken nations in West Africa. This effort should have three main elements.

First, Ebola's basic structure has similarities to other viruses that we have been able to target with drugs and vaccines. So it should be addressable with modern therapeutics—and we should initiate a concerted effort to rapidly, though carefully, advance a number of promising drugs and vaccines that have been tested in animals but not yet in man. In ordinary circumstances, an experimental Ebola drug couldn't be tested on healthy people to see if a medicine can work. But now we have infected people whose only hope of survival may be an experimental medicine.

There is an ethical way to approach this. The Food and Drug Administration, working with the Centers for Disease Control and private sponsors, can create a special program to advance treatments that have already demonstrated some measure of safety, and where there is plausible scientific data showing that they might be active against Ebola in humans. In the mid2000s, the Bush administration worked with industry to plan for accelerated vaccine development in case of flu pandemic. This groundwork bore fruit during the effort to fashion a new vaccine against pandemic swine flu in 2009. We need to undertake a similarly urgent drug effort against Ebola.

Second, President Obama should lead a major charitable effort to raise resources to combat the outbreak and stabilize the affected countries. The World Health Organization estimates that its battle strategy for bringing the outbreak under control will cost $489 million. That figure may increase if we don't act soon. As recently as early August, the WHO estimated that it would need $71 million.

More than half the money will be needed for treatment and isolation centers, laboratory diagnostic capabilities, and surveillance and contact tracing in the countries experiencing the epidemic. The rest will go to managing the relief effort and strengthening capabilities in countries at risk for the virus but so far without major outbreaks.

The first major gifts could be donations from our own inventories and private sources of basic supplies like fieldhospital equipment, gloves and other protective gear for medical staff. If we can't raise sufficient resources through private or charitable sources, Congress should consider leading by example and appropriating money for an international effort to fund these assets.

Third, we need to help countries adjacent to the hardhit West African nations implement effective screening and trackandtrace procedures for people thought to be infected. Too many countries in the region that have avoided outbreaks are simply sealing borders and suspending travel from affected nations and hoping that will be enough.

But border closings and flight bans will exacerbate the economic and social impact on countries currently combating the epidemics. If we help unaffected nations implement better procedures to contain new cases, we could reduce the temptation of understandably scared governments to use draconian measures.

The most optimistic assessments envision slowing the expansion of this epidemic within two months, and stopping all transmission in six to nine months. The WHO said on Aug. 28 that the epidemic was still accelerating and could infect more than 20,000 people before it's brought under control. That is the standard projection, but the numbers could get substantially worse.

Could Ebola mutate and become airborne? It would be highly unlikely for a virus to transform in a way that changes its mode of infection. Yet this disease produces a massive level of the Ebola virus in the blood, called viral load, which can lead to excessive mutations. An Aug. 28 article in the journal Science shows that Ebola is already mutating during the

current outbreak, in ways that could make it harder to diagnose. So the longer the virus spreads unchecked, the greater the chance of other random mutations that could also make it harder to contain, or to target with a new drug.

President Obama has made outreach to Africa a cornerstone of his foreign policy. Ebola is a clear and present danger to that region and a moment for the U.S. to act with forcefulness—and demonstrate our commitments to those nations.

Government cordons may be all some African countries can do with their existing resources, although this is creating panic and stoking civil unrest as army units try to enforce quarantines, sometimes with deadly force. Absent more help from America and other donors, this macabre strategy may leave tens of thousands to die inside hot zones of disease, and it may fail to stop Ebola's merciless spread.

Dr. Gottlieb, a physician and resident fellow at the American Enterprise Institute, was deputy commissioner at the Food and Drug Administration from 200507. He also advises medical products companies. Mr. Troy is a former deputy secretary of Health and Human Services and president of the American Health Policy Institute.

Opting Against Ebola Drug for Ill African Doctor

The New York Times, By ANDREW POLLACK, AUG. 12, 2014

The doctor who had been leading Sierra Leone's battle against the Ebola outbreak was now fighting for his own life, and his international colleagues faced a fateful decision: whether to give him a drug that had never before been tested on people.

Would the drug, known as ZMapp, help the stricken doctor? Or would it perhaps harm or even kill one of the country's most prominent physicians, a man considered a national hero, shattering the already fragile public trust in international efforts to contain the world's worst Ebola outbreak?

The treatment team, from Doctors Without Borders and the World Health Organization, agonized through the night and ultimately decided not to try the drug. The doctor, Sheik Umar Khan, died a few days later, on July 29.

The doses of the drug that were not used were eventually sent to Liberia, where other doctors made the opposite decision — and two American aid workers became the first people in the world to receive ZMapp. Both of them survived and are now being treated at Emory University Hospital in Atlanta.

"It's a little political; that's what it looks like to me," Alhajie Khan, Dr. Khan's brother, said of the decision. "Why would you not give it to him? The guy who helped all of these people."

The provision of ZMapp, which is in extremely limited supply, to foreign aid workers has raised broad ethical questions about the disparities in treatment between white outsiders and the Africans who form the overwhelming majority of victims in the epidemic.

Those concerns were heightened further after Spanish officials confirmed that they had obtained a supply of ZMapp for a third patient, a 75-year-old Spanish priest who died Tuesday after having been evacuated to Madrid from Liberia.

The previously untold story of Dr. Khan, recounted by two doctors involved in discussions about whether to use ZMapp, offered an unusual glimpse into the wrenching ethical dilemma of when and how experimental drugs should be used to combat the Ebola epidemic in West Africa. Had the treatment team decided differently in his case, the first person treated with the drug would have been African.

On Tuesday, the World Health Organization endorsed the use of untested drugs to combat the outbreak, which has already killed more than 1,000 people and continues to spread. But ZMapp and other potential treatments are in such short supply that another politically charged question remains: Who should get them?

Marie-Paule Kieny, assistant director general of the World Health Organization, said at a news conference in Geneva on Tuesday that several drugs and vaccines had shown some promise in animal testing and might conceivably be used.

But none are "available in unlimited supplies right now," Dr. Kieny said. "I don't think that there could be any fair distribution of something which is available in such a small quantity."

On Tuesday, Liberia's government announced that it would receive ZMapp after its president, Ellen Johnson Sirleaf, requested the drug from the United States. It said the drug would be used to treat two doctors who have Ebola.

That would be the first known use of the drug to treat Africans, but it also might be the last for a while. The manufacturer, Mapp Biopharmaceutical, said that it had complied with a request from a West African nation, but noted in a statement that the available supply of the drug was now exhausted.

In the case of Dr. Khan, who has been called "the arrowhead of the fight" against Ebola in his country, the doctors involved said there was no intention to save the drug for Americans. They said it was not known that the American aid workers were sick at the time of the decision not to treat Dr. Khan, around July 23. Instead, they said, doctors feared stoking the considerable suspicion of Western medical institutions in the country, which was already making it harder to contain the outbreak.

"What they really didn't want to do was kill Dr. Khan with their attempt at therapy," said Dr. Armand Sprecher, a public health specialist at Doctors Without Borders. "If word got out that M.S.F. killed Dr. Khan, that would have implications for outbreak control," he added, using the initials for the French name of the relief group.

Dr. Sprecher, who is involved in the procurement and use of drugs for Doctors Without Borders but was not directly treating Dr. Khan, said another factor was that Dr. Khan's virus levels were so high it was believed the drug would probably not work.

He said the treatment team never discussed the option of using the drug with Dr. Khan himself, deciding it would do so only if it decided to go ahead with the treatment.

"There are an awful lot of people who are very traumatized by the whole event," Dr. Sprecher said in a telephone interview from Brussels on Tuesday.

At the time the decision was made, less was known about ZMapp, which may have helped the two American relief workers, Dr. Kent Brantly and Nancy Writebol, who were initially treated in Liberia and then evacuated.

Dr. Sprecher said the Spanish priest, the Rev. Miguel Pajares, had received the first of three recommended doses of ZMapp. He said the drug sent to Spain had originally been obtained by Doctors Without Borders and the World Health Organization for use in emergencies. It was kept at the University Hospital of Geneva, which had the authority to decide how the drug was used.

Father Pajares worked in a hospital in Liberia and was the first European to return home after being infected with Ebola. The Spanish Health Ministry confirmed that it had obtained ZMapp for him, but hospital officials in Madrid, citing patient confidentiality rules, declined to say whether Father Pajares had ultimately been treated with ZMapp. Officials said he would be cremated in a sealed coffin, with no autopsy, to reduce the risk of any further contagion.

Also on Tuesday, the press in Canada reported that the country's Health Ministry planned to offer hundreds of doses of an experimental vaccine for use in Africa.

Dr. Kieny of the W.H.O. said Tuesday that intensifying public health measures to contain the outbreak was more important than supplying drugs. "It is very important to not give false hope to anybody that Ebola can be treated now," she said.

A string of coincidences led to the decision in Dr. Khan's case, Dr. Sprecher said. A Canadian team setting up a laboratory had taken some of the drug with it to Sierra Leone. It set up shop next to the Doctors Without Borders treatment center in Kailahun, and let the relief organization know the drug was available.

Dr. Khan was in charge of the Lassa fever ward in Kenema, which had become the Ebola ward. But when he became ill he was moved to Kailahun so he would not be treated by his own colleagues. Dr. Khan was going to be airlifted to Switzerland, where he would receive better care, making the drug less necessary, his treatment team reasoned. But after the decision was made, and just before he was to depart, Dr. Khan began vomiting and having diarrhea, and the transportation company refused to take him.

Dr. Daniel G. Bausch, an associate professor of tropical medicine at Tulane University who was involved in the discussions, said that he disagreed with the decision and that if he were sick with a life-threatening disease he would have wanted the drug, even if it had not undergone safety testing.

He also said he thought Dr. Khan should have been asked for his own opinion. "Dr. Khan was the perfect patient, I think, to understand the complexities of that gray area," he said.

Nonetheless, he said that it was a close call and that he respected the decision of the doctors on the ground. "There was considerable difference of opinion even within M.S.F.," he said.

Dr. Bausch, who has been a consultant to the W.H.O., said he had been a close friend of Dr. Khan and had recruited him in 2004 to take over the Lassa fever ward at the hospital in Kenema, a dangerous job given that the previous holder of the position had died from Lassa fever.

Dr. Bausch was in Sierra Leone until July 16. When he and Dr. Khan said goodbye to each other that day, Dr. Khan felt well. But he became sick within hours and tested positive for Ebola virus around July 21 or July 22, setting the stage for the decision.

"We were willing to try anything," said Dr. Khan's sister, Umu Khan. "It was not right; we should have had a say."