PROJECT REPORT

The Use of Untested Drugs to Treat the Ebola Virus Epidemic:
A Learning Activity to Engage Learners

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Abstract

One objective of this activity is to help students understand an Ebola virus outbreak and epidemic, and particularly how this might affect human life and society within and between various human communities, not only in a given country or society, but also on an international scale. A second objective is to actively engage students in a library investigation, conducting literature research, and collaborating in group work, not only to achieve understanding, but also to retain new information and apply what has been learned to different situations. The aim is to provide an opportunity for students to become deep learners by engaging in active learning. The paper is divided into two parts. Part one provides background on the nature, character, and epidemic of Ebola and the impact of the last outbreak not only on the affected regions, but also on the whole world. Part two is a learning activity that is designed as a role-playing exercise to engage students in research to learn about the biology behind Ebola. They also debate the question of whether or not the use of drugs and Ebola vaccines that have not gone through the clinical trial process should be used to control the epidemic before it can no longer be contained. The willingness to bypass government approval of treatments and scientific and clinical practices demonstrates the severity of this outbreak and the desperation it has caused. Yet there are good reasons why clinical trials are essential in obtaining objective evaluations of the effectiveness of treatments. In conducting research on the topic and engaging students in an informative debate about the matter, we hope to promote deep learning and a lasting understanding of viruses in general and Ebola in particular. An Ebola epidemic is a good vehicle to introduce students to the need for civic and community engagement at the local, national, and global level by extending student learning beyond the classroom and into the community.

Key words: Clinical trial, placebo, enveloped and non-enveloped viruses, retrovirus, Ebola epidemic, treatment group and control group, critical experiment, community engagement, social mobilization, service-learning.

Part I — Ebola: Its Nature, Character, and Epidemic

Introduction

The recent Ebola outbreak in West Africa (Figure 1) has placed various governments, non-government organizations, and communities at local, national, and international levels in situations that they have never faced before. According to the World Health Organization (WHO), if left untreated, Ebola virus disease (EVD), formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans, further spread through contact with bodily fluids (WHO 2014, ¶1). Initial EVD outbreaks typically start in rural areas but quickly spread to urban centers with larger populations, further compounding the need for consideration of human needs and proper scientific investigation (Quammen 2015; Wolinksy 2015).

A dilemma that had previously been considered "unthinkable" seemed to call for desperate measures, including "withholding emergency treatment from infected patients" and using drugs that have not yet gone through clinical trials to treat infection. As a result, hospitals all over the world have started to review their policies on the treatment, handling, and screening of patients with the virus. This is due first to the lack of trained health care workers to care for potential patients, and second, to the high risk of transmission to health care workers in contact with Ebola patients (The Week 2014). Finally, it is important to note that there is a widespread assumption that if an Ebola outbreak occurred in a wealthy developed nation, the response would be swifter and more comprehensive than the current response in affected countries of West Africa (Joanne Lin in Marsa 2016). This assumption only further complicates the ethical issues at hand. Adding to the complexity of the situation is the fact that the "urgency of human needs in an outbreak makes scientific investigations difficult" (Quammen 2015, 52).

The development of therapies to combat the virus has been an ongoing process; "there is as yet no licensed treatment proven to neutralize the virus, but a range of blood, immunological and drug therapies are under development. There are currently no licensed Ebola vaccines, but multiple candidates are undergoing evaluation" (WHO 2014, ¶1). For many human advocates and civic engagement activists, the current medical options available are not acceptable. Lack of insight into the drug development process also results in public distress which further compounds the issue. Furthermore, as Joanne Lin, the president of Médecins Sans Frontières International in Geneva, Switzerland, stated:

> Initially, we told people it's a deadly disease and we have no cure, so essentially we're telling them "Come and die in an Ebola Center." We need to change that because if these people come in earlier, they have a better chance to pull through and not infect their loved ones. We know what to do because it's like HIV and AIDS two decades ago – it was a death sentence, and people hid from it. But today it is not a death sentence, and we need to apply what we learned from fighting that epidemic. (Marsa 2016, 17)

The Biology of the Virus

A virus is a non-cellular infectious agent, typically 20 to 30 nanometers in diameter (Ebola being exceptionally large, at 970 nanometers), which typically consists of a genome encased in a protein coat. As an extracellular entity, it is given the term viroid. The viral genome contains either DNA or RNA. Many viruses have additional structural features, for example, an envelope composed of a protein-containing lipid bilayer, whose presence or absence classifies viruses as either enveloped virus or non-enveloped virus (Strohl et al. 2001; Tortora et al. 2015).

As they lack ribosomes or other necessary protein-making machinery, viruses do not have the ability to grow or replicate on their own, but only do so inside the cells of living hosts by subverting their cellular machinery. They are thus considered obligatory intracellular parasites (Strohl et al. 2001; Tortora et al. 2015). The host cell would be unable to carry out normal function, reproduce, and would typically die. With the ability to replicate within cells of living hosts, viruses are able to generate great diversity, giving rise to various forms, such as RNA virus, DNA virus, viroid, etc. (Rudin 1997, 385). Today, scientists classify viruses into families based primarily on the type of genome, capsid symmetry, and the presence or

absence of an envelope (Strohl et al. 2001; Tortora et al. 2015). For example, scientists have identified the families seen in Table 1 below.

The Ebola virus belongs to the family Filoviridae; its members are enveloped viruses with RNA genomes. The Filoviridae family has three genera: Cuevavirus, Marburgvirus, and Ebolavirus. Five species of Ebolavirus have been identified thus far: *Zaire*, *Bundibugyo*, *Sudan*, *Reston*, and *Taï Forest*. *Zaire*, *Bundibugyo*, and *Sudan* are the Ebola viruses that have been associated with large outbreaks in Africa, with Zaire currently causing the West African epidemic (WHO 2014, ¶2).

The differences within the species of the Ebola virus are significant. The *Reston* species has never caused illness in humans, and researchers have never found definitive evidence of air-based transmission. Zaire Ebola virus, on the other hand, does cause illness in humans. A non-airborne infection, it spreads by direct contact with body fluids (Science News 2014, 30).

Thus based on Table 1, we can summarize that Ebola is

> A member of the Filoviridae family of viruses (so named because the viruses adopt various filamentous shapes), the Ebola virus consists of a single strand of RNA and associated proteins, wrapped in a fatty membrane. Scientists have so far isolated two members of the family — Ebola and Marburg viruses — and grown them in

TABLE 1. Viruses are classified into families based on the type of genome, capsid symmetry, and presence or absence of an envelope (Strohl et al. 2001; Tortora et al. 2015)

Type of Virus	Families	Genetic Make-up	Enzyme Presence
Enveloped Virus	Papovaviridae	Double-stranded, circular DNA	Virions contain no enzyme
	Adenoviridae	Double-stranded, linear DNA	Some contain DNA-dependent polymerase
	Picornaviridae	+Single-stranded, non-segmented RNA	Virions contain no enzyme
	Caliciviridae	+Single-stranded linear RNA	Virions contain no enzyme
	Poxviridae	Double-stranded linear DNA	Contains RNA polymerase
	Flaviviridae	+Single-stranded, non-segmented RNA	Virions contain no enzyme
Nonenveloped Virus	Parvoviridae	Single-stranded, linear DNA	Virions contain no enzyme
	Hepadnaviridae	Circular DNA, parity single-stranded, parity double-stranded, DNA	Contains DNA polymerase and reverse transcriptase
	Herpesviridae	Linear, double-stranded, DNA, circularizes in host	Virion contains no enzyme
	Togaviridae	+Single-stranded, non-segmented RNA	Virions contain no enzyme
	Coronaviridae	+ Single-stranded linear RNA	Virions contain no enzyme
	Rhabdoviridae	-Single-stranded, non-segmented RNA	Contains DNA -dependent RNA polymerase
	Paramyoxviridae	-Single-stranded non-segmented RNA	Some contain RNA polymerase
	Orthomyxoviridae	-Single-stranded, segmented RNA in eight pieces	Contains RNA polymerase
	Filoviridae	- Single-stranded RNA	RNA-dependent RNA polymerase
	Bunyaviridae	-Single-stranded segmented RNA	Contains RNA polymerase
	Arenaviridae	-Single stranded segmented RNA	Contains RNA polymerase
	Retroviridae	+Single-stranded linear RNA—two copies per virion	Transcriptase

http://www.life.umd.edu/classroom/bsci424/BSCI223WebSiteFiles/DNAvsRNAVirusBiosynthesis.htm

TABLE 2. A Typical Example of Viral Life Cycle

A Typical Example of Viral Life Cycle (Garrett and Penn 2009, 197)		
1	Attachment	A specific attraction between a molecule on a virus and a receptor molecule on a host cell
2	Penetration	All or some of the virus enters the host cell.
3	Uncoating	Protein coat is removed if entire virus enters host cell.
4	Biosynthesis	Viral nucleic acid and proteins are biosynthesized by the metabolic machinery of the host cell.
5	Assembly	Viral nucleic acid and the structural proteins assemble together to form new viruses.
6	Release	Virus bursts out of host cell or "buds" out within an envelope of the host membrane.
7	Re-infecting other cells	New viruses infect new host cells

culture. Genes from a third member – Lloviu virus – have been sequenced, but the virus has not yet been fully characterized in a laboratory. Of the five known strains of Ebola, Reston is the only one that apparently does not cause disease in infected people. (Branswell 2015, 52)

The Life Cycle of a Virus

Most viruses exhibit similar behaviors during their lifespan. As shown in Table 2, at each stage the virus tries to accomplish a specific set of tasks. Some viruses undergo a more dormant lysogenic cycle, in which the infection still controls the systems of the cell and often inhibits its function, but does not kill the host cell. In many cases, a cell's death results when the virus takes up the lytic cycle, either after a lysogenic phase or immediately. The steps to replication are described in Table 3.

Like most other untreated viruses, Ebola virus successfully completes replication and generates more copies of itself in four general steps.

1. Using surface proteins Ebola virus recognizes and attaches to cells in the host organism. It fuses with cells lining respiratory tract, eyes, or body cavities, then penetrates the membrane of the host cells and sheds its protein coat.
2. The virus's genetic content (viral nucleic acid [RNA]) is released into the cell and enters the host cell nucleus.
3. The viral genetic material takes over the cell machinery to replicate new viral nucleic acid, which then goes from the nucleus into the cytoplasm and combines with structural proteins to form new viruses. In other words, they become physically and functionally incorporated into host cell (Adams 2014; Hart et. al. 2012).
4. The newly produced copies of the virus are broken off and expelled from the host cell into the system to infect more cells and hijack their metabolic machinery systems to manufacture instead more of the viral components needed to form more of the new viruses.

As the immune and circulatory systems are compromised, the pathogen is free to proliferate and furthermore given new opportunities to affect more people as blood is lost (Branswell 2015, 52). The World Health Organization has strongly argued that the most critical keys to the treatment of the Ebola epidemic include, but are not limited to, the following: civic and community engagement, proper case management, surveillance and contact tracing, good laboratory service, safe burials, and social awareness and mobilization.

TABLE 3. Symptoms of Ebola's Infection

"Ebola virus enters through eyes, mucus membranes, or tiny cuts or scrapes. Symptoms typically appear four to 10 days later" (Lydersen 2015, 9).		
Early Symptoms	Mid-stage Symptoms	Advanced Symptoms
Flu-like symptoms; fatigue, muscle soreness, sore throat, headache, chills.	Severe diarrhea and vomiting; red eyes, spotty rashes and bruises; chest pain, shortness of breath.	Can include bleeding from eyes, mouth, nose, and anus. Seizure; organs fail; shock; coma.

The Reservoir Host for Ebola Virus

Despite having caused dozens of outbreaks in a forty-year span, the Ebola's reservoir host remains unknown. The fact that the virus does not infect very often has possibly kept its genome stable over the years. It has not had many opportunities to mutate, causing infrequent outbreaks with a low genetic diversity (Quammen 2015). From 1977-1994, no human death as a result of Ebola was reported, and researchers have concluded that the reservoir host for Ebola virus must be non-human because of high fatalities from human infection. Ebola cannot be circulating in the human population latently; it must reside in a non-human host so that when it spills over into another species it causes deadly disease.

In searching for a reservoir host, researchers have ruled out chimpanzees and gorillas, because they have also died from becoming infected with Ebola virus. When there have been Ebola disease outbreaks in humans, carcasses of chimps and gorillas have been found nearby, and some have tested positive for signs of the virus (Quammen 2015). Coming in contact with these carcasses for food has been one way in which populations initially contract the virus. Based on disease outbreak trends and research studies, it was found that the fruit bat from the Pteropodidae family and the Angolan free-tailed bat are a possible reservoir for Ebola (Quammen 2015; WHO 2014). People who use fruit bats as a food source or who come in contact with them do become infected.

In 1976, two outbreaks of Ebola virus disease occurred parallel to each other, in regions about one thousand kilometers apart in central Africa. One outbreak appeared in Nzara, Sudan, and the second in Yambuku, Democratic Republic of Congo. The recent epidemic is the greatest and most complex Ebola outbreak since its discovery, leading to more cases and deaths than all other outbreaks combined. It has spread to other countries, starting in Guinea and spreading across land borders to Sierra Leone and Liberia (Figure 1). It has also spread by air to Nigeria, and by land to Senegal. Guinea, Sierra Leone, and Liberia are the countries that have been most severely affected. Even as the number of cases for the 2015 outbreak decreases, a resurgence of cases has occurred due to survivors continuing to pass on the disease after recovery (Farge and Giahyue 2015). Weak health systems, lack of human and infrastructure resources, and having recently emerged from periods of conflict have further contributed to the devastating impact that the Ebola virus disease has inflicted.

How is Ebola Virus Spread Amongst Humans?

The time it takes the virus to kill an infected individual depends on how it enters the body and how much virus the person has been infected with. Any form of contact with bodily fluids, either directly or through syringes, is the likely mode of the spread of the virus. Once inside the host, Ebola virus primarily targets dendritic cells and macrophages to replicate its RNA. The virus forces these cells to produce and secrete free-floating glycoproteins that resemble its own surface glycoproteins. These secreted glycoproteins become the target of the immune system cells and effectively cause a distraction in which the virus can continue to infect other host cells and proliferate. Macrophages and dendritic cells circulate in the body and phagocytize foreign organisms or damaged cells. When the virus infects these cells, it is able to travel to various points of the body and wreak havoc when it replicates. Researchers believe that the severity of the virus infections in large human populations is due to these mechanisms. For individuals who are immunocompromised or malnourished, the virus can

have an even greater advantage in taking over the already weakened immune system and thus have a greater chance of proliferating.

In short, all the evidence indicates that "Ebola isn't nearly as contagious as measles and many other viruses. … and a person infected with Ebola may not show any symptoms for 21 days" (Adams 2014 9–10). However, as the recent outbreak has shown, Ebola is not a subtle bug. It "…kills many of its human victims in a matter of days, pushing others to the brink of death, before vanishing" (Quammen 2015, 40). Bray et al. (2015) have summarized the symptoms and signs of disease as follows:

> Patients with Ebola virus disease typically present with a nonspecific febrile syndrome that may include headache, muscle aches, and fatigue. Vomiting and diarrhea frequently develop during the first few days of illness, and may lead to significant volume losses. A maculopapular rash is sometimes observed. Despite the traditional name of "Ebola hemorrhagic fever," major bleeding is not found in the majority of patients, and severe hemorrhage tends to be observed only in the late stages of disease. Some patients develop progressive hypotension and shock with multiorgan failure, which typically results in death during the second week of illness. By comparison, patients who survive infection commonly show signs of clinical improvement during the second week of illness. (Bray et al. 2015, ¶2)

Treatment of Ebola is primarily aimed at mitigating the effects of the symptoms that arise as the disease progresses (King 2015). Necessary precautions are followed by the caregivers and healthcare staff to eliminate unnecessary exposure of the patient and prevent harm to self. As resources permit, the overall state of the patient in vital signs, fluid levels, and electrolyte levels is carefully monitored and remediated appropriately, especially in the earliest stages of infection. Some medication may be administered if the patient is strong enough, such as antipyretic agents, analgesics, antiemetic, anti-motility, and anti-epileptic medication. At the height of the onset of the more severe symptoms, more invasive interventions must be given, such as intubation (for respiratory failure), dialysis/renal replacement (for kidney failure), and antimicrobial therapy (for co-infecting diseases, such as malaria) (Bray et al. 2015).

Ebola virus survivors are not safe either; as Kupferschmidt (2015) has recently reported, there is a growing and alarming trend in Ebola survivors displaying health problems after they have fought the disease. Not only do these individuals suffer from emotional and psychological problems, they also suffer from post-Ebola syndrome, such as headaches and memory and vision problems. It is believed that the symptoms may arise from cells and organs that were damaged by the virus before it was brought under control (Kupferschmidt 2015). The side effects could be caused by the immune system trying to fight the virus, or the immune system could have turned against its own tissues with host molecules similar to Ebola.

To learn more about the clinical manifestations and diagnosis of Ebola virus disease, instructors can direct students to the work of Bray and Chertow (2015), which provides an update about this matter.

The Role of Clinical Trials in Determining the Effectiveness of a Drug

In Guinea, a clinical trial is being conducted for an experimental Ebola vaccine that is yielding promising results. More than 7,651 individuals were involved in the study, and over 3,400 received the vaccine. Individuals who were vaccinated were those who came in contact with Ebola infected patients, as well as the contacts of those contacts. Some people were vaccinated immediately and others were vaccinated after 21 days. The individuals who were immediately vaccinated were found to not contract the disease, whereas some who were vaccinated twenty-one days after contact with Ebola infected patients developed the disease. This might have occurred due to the nature of the virus incubation period, which is twenty-one days. Although significant, these results are preliminary; further research and monitoring must be performed to test the efficacy of the vaccines over time. The side effects to the patients were reported to be minimal (Fink 2015; Seppa 2015).

The Public Health Agency of Canada created the vaccine by combining a piece of the virus's covering and

TABLE 4. Summary of Current Ebola Treatments in Development

Drug / Vaccine	Description	Status
ZMapp	"ZMapp™ is composed of three "humanized" monoclonal antibodies manufactured in plants, specifically Nicotiana. It is an optimized cocktail combining the best components of MB- 003 (Mapp) and ZMAb (Defyrus/PHAC). ZMapp™ was first identified as a drug candidate in January 2014 and has not yet been evaluated for safety in humans. As such, very little of the drug is currently available" (Mapp Biopharmaceutical, Inc . n.d.).	Granted fast track status by the FDA
TKM-Ebola-Guinea	"...a modified RNAi therapeutic, based on the Company's original TKM-Ebola investigational therapeutic, to specifically target Ebola-Guinea. The new product, termed TKM-Ebola-Guinea, is designed to match the genomic sequence exactly, with two RNAi triggers" (Arbutus Biopharma 2015).	Discontinued after poor efficacy in trials.
Favipiravir (Avigan)	"The anti-influenza drug Avigan® Tablets was developed by the Fujifilm Group company Toyama Chemical Co., Ltd. Results of mouse experiments showing the antiviral effect of Avigan® Tablets against EVD have been published, and Avigan® Tablets have already been administered as an emergency response to multiple patients infected with EVD. The production of Avigan® Tablet 200mg for the treatment of Ebola Virus Disease" (Fugifilm 2014).	Trials show early promise but are in danger due to lack of patients.
Brincidofovir	"...brincidofovir (CMX001), a clinical-stage nucleotide analog lipid-conjugate, which has demonstrated potent antiviral activity and safety in convenient, orally administered dosing regimens. Chimerix is currently enrolling SUPPRESS, a Phase 3 study of brincidofovir for the prevention of cytomegalovirus (CMV) in adult hematopoietic cell transplant (HCT) recipients. In addition, Chimerix is enrolling the Phase 3 AdVise trial of brincidofovir for treatment of adenovirus (AdV) infection" (Chimerix 2015).	Trials for use in Ebola have been discontinued to due lack of patients.
VSV-EBOV (vaccine)	The experimental vaccine is based on an animal virus called vesicular stomatitis virus (VSV) that is combined with a portion of the protein covering of the Ebola virus. When administered, it induces an immune response against the Ebola virus" (Public Health Agency of Canada 2015).	In Phase III Trials with very promising results.
BCX4430	"...BCX4430, a novel synthetic adenosine analogue, inhibits infection of distinct filoviruses in human cells. Biochemical, reporter-based and primer-extension assays indicate that BCX4430 inhibits viral RNA polymerase function, acting as a non-obligate RNA chain terminator. Post-exposure intramuscular administration of BCX4430 protects against Ebola virus and Marburg virus disease in rodent models" (Warren et al. 2014, 402).	Awarded Advanced Development in 2015 by U.S. Government to support clinical trials.

an animal virus to set off an immune response against Ebola (Fink 2015). The results of this and other clinical studies are expected to be analyzed and scrutinized so that the vaccine can be approved by the Food and Drug administration (FDA). If approved, this vaccine would completely change an Ebola crisis by preventing the development of new Ebola cases in the vaccine's recipients. A summary of current experimental Ebola treatments has been compiled in Table 4 below.

Clinical trials are a critical part of doing science involving people. It is these trials that decisively determine whether a particular treatment is effective by testing the drug in a "treatment" group and in a "placebo control" group. If the tested drug is not effective, we will be able to show empirical evidence that it has failed and reject it with statistical confidence. After all, science, through the scientific method approach, is an efficient and objective pathway by which we can discover and better understand the world around us" (Cherif 1998; Cherif and Roze 2013; Phelan 2013). As defined by the National Cancer Institute (NCI) (2014 a and 2014b) at the National Institutes of Health (NIH), clinical trials are research studies that involve people, test new ways to prevent, detect, diagnose, or treat diseases, and thus contribute to our understanding of the world in which we live. It is an effective approach when research studies involve people because it is empirical, testable, repeatable, and self-correcting. In short, the clinical trial is "a device

for obtaining objective evaluations of the effectiveness of treatments" (Fehan 1979, 32). Because of this, policies and regulations at the national and international level have been developed to protect the rights, safety, and well-being of those who take part in clinical trials. They also ensure that trials are conducted according to strict scientific and ethical principles. Through informed consent people learn about the clinical trial so they can decide whether they wish to participate (NCL 2014a, ¶1).

Furthermore, people who take part in any type of clinical trial have an opportunity to contribute to scientists' knowledge about a given targeted disease and to help in the development of improved treatments for that particular disease (e.g., cancer, HIV) (NCI 2014a,¶2). When it comes to Ebola virus, the stakes are very high, since both the rate of infection and the rate of death from infection are extremely high. Adding to this complex equation of urgency is that fact that to date there is no licensed effective drug on the market for people to use with Ebola epidemic.

The WHO Director-General declared this outbreak a public health emergency of international concern, but the UN's Anthony Banbury predicted that the Ebola outbreak would end in 2015 (NBC News 2015b). The World Health Organization (WHO) declared the end of the Ebola outbreak in Liberia in September 2015, Sierra Leone in November 2015, and in Guinea in December 2015, two years after the epidemic began there. However, this good news has been interrupted by the thought among a number of experts that the problem might still be around. This might be why Alexandre Delamou, Chief of Research at the National Center for Training and Research, Maferinyah, stated:

> Guinea Ebola's lasting legacy may be in maternal and child health: Public health officials worry that deaths during childbirth and from preventable childhood diseases like measles could escalate into the tens of thousands. Delamou talks about why the collateral damage triggered by the epidemic could turn out to be even more lethal than the outbreak itself. (Marsa 2016, 16)

Because of this, the recent Ebola epidemic is an ideal vehicle to introduce students to the need for civic engagement, global awareness, and social mobilization at all levels of involvement. It is also a good topic for extending student learning beyond the classroom and into the community and for helping students develop a sense of caring for others and a desire to meet actual community needs (Belbas et al. 2003). Public awareness, education, civic and social engagement, and global mobilization are urgently needed at all levels as part of both the treatment and prevention of the Ebola epidemic.

Part II Learning Activity

To Use or Not To Use Clinically Untested Drug for Ebola Treatment

One objective of this activity is to help students understand the Ebola virus's effect on societies and communities. The second objective is to actively engage students in a library investigation, conducting literature research, and in collaborating in group work, not only to achieve understanding, but also to retain new information and apply what has been learned to different situations. The aim is to provide an opportunity for students to become deep learners by engaging in active learning and civic engagement (Cherif et al. 2011). As Houghton (2004) has argued, deep learning promotes understanding and application for life and "involves the critical analysis of new ideas, linking them to already known concepts and principles, and leads to understanding and long-term retention of concepts so that they can be used for problem solving in unfamiliar contexts" (Houghton 2004, 5).

In this role-play learning activity, the class is divided into nine groups of three or four students each. The members of each group will engage in focused research, meet several times to formulate their chosen perspective, and revise strategy and plan on how they are going to introduce their own perspective, supported with convincing informative arguments. The task of each group's members is to come up with an agreed-upon perspective that reflects their collective informed opinions about their specific issue and to defend it against other groups' perspectives.

Scientifically, any drug intended to be used with people is tested with two separate groups of patients; one group is given the actual drug, and the other group is given a placebo. The members of both groups do not know whether or not they are taking a placebo drug.

A placebo is "an inactive substance used in controlled experiments to test the effectiveness of another substance; the 'treatment group' receives substance being tested, the 'control group' receives the placebo."(Norris and Warner 2009, vlg-2)

The Scenario—The Problem

Clinical trials are research studies designed to assess the safety or efficacy of a medical product including medicines, procedures, treatment and/or intervention and to determine which one may benefit the targeted patients the most. To successfully ensure obtaining objective outcomes, these types of research studies often involve expert teams from the academic, governmental, and pharmaceutical sectors. As a result of this, clinical and medical trials are often funded by both government agencies such as NIH and industries. Furthermore, the 1993 Revitalization Act requires that *"all federally funded clinical research prioritize the inclusion of women and minorities and that research participant characteristics be disclosed in research documentation"* (Basken 2015; Ehrhardt et al. 2015).

No one can statistically guarantee the drugs will work on humans or predict their effect on humans without evidence from clinical trials. Two opposing views arose from this standard in light of the outbreak. On the one hand, the government and the medical communities were asked to follow the agreed-upon experimental procedures of using "treatment groups" and "control groups" to test the drugs on human subjects regardless of the epidemic's severity and how many people were in real need of any available drug to try. Those who argued this were well aware that the "treatment group" receives the substance being tested, while the "control group" receives the placebo. On the other hand, there are many dissenting opinions arguing that in an epidemic such as this, we cannot afford to wait for a given drug to be tested on humans, since it will take months or potentially years to determine its efficacy and long-term effects. In addition, using the placebo with a group of people infected with the Ebola virus might result in most of them missing an opportunity to get the potential drug and recover.

The question then becomes: should or should we not authorize the administration of the three drugs that are not yet tested through clinical trials on humans? In other words, because of the severity of the epidemic, should we skip the clinical trials and the use of the "treatment group" and the "control group" to first test the effectiveness of the drugs before using them on all Ebola patients? This is a learning activity in which students will engage in active learning to deal with this ethical dilemma, which is faced not only by the countries that are affected by the current Ebola outbreak, but by countries worldwide where similar epidemics are possible.

In this learning activity:

1. Students are asked to conduct research regarding the following:
   a. Learn about the Ebola viruses and how they are different from other viruses.
   b. Learn how Ebola virus infects people, the myths and facts about an Ebola outbreak, and the modes of transmission between people.
   c. The distribution of the Ebola epidemic worldwide, past and present.
   d. The symptoms and the signs of the Ebola infection and how the people infected with virus can be treated.
   e. The types of drugs and treatment therapies that are available for Ebola patients to use.
   f. How effective the treatment of people infected with Ebola virus is in various countries.
   g. The effectiveness of the available treatment therapy for Ebola infection and Ebola virus.
   h. Clinical trial experimental procedures and their critical role in determining the safety and effectiveness of a given drug for a given illness.
2. Based on their research findings, the members of each community (group) formulate their informed and supported perspective on the use of untested drugs for the treatment of patients who are already infected with Ebola virus.
3. When the members of each group have developed their own informed perspective, they engage in a

debate with the members of the other communities (groups).

The Communities

The class is divided into the following nine groups (communities):

- The scientific community
- The legal community
- The pharmaceutical community
- The civic engagement and activist community
- The local community
- The government and political community
- The medical community
- The board debate committee
- The media group

Each community consists of three or four students. The members of each community work together for three weeks to conduct research using the questions that have been presented to all the communities as a starting point. In the fourth week, the members of each community meet together to finalize the outcome of their research and research paper, as well as their own strategy for how they will present their adopted informed perspective that reflects their collective thoughts about the issue at hand. The members of each group will then argue this perspective, in a face-to-face debate with the other communities. The members of each community will write and submit to the instructor a three- to four-page paper on their research, in which they will explain where they stand and why, on the use of drugs that have not yet been tested in clinical trials in general and in the treatment of Ebola in particular.

The instructor of the class reads all the papers, provides feedback, and raises challenging questions, if needed. Then the instructor gives the students one week to work on their paper again, using his/her feedback, and informs them about the day of the debate. The instructor tells the students in each community to prepare

1. A one- or two-minute written statement that will be read at the beginning of the debate.
2. A one-minute closing written statement that will be read at the closing of the debate, to support their own perspective.
3. A few key points that represent the core of their main argument.
4. Any illustrations, diagrams, or figures that might be useful in helping them to convey their own point of view.

Pedagogical Strategies

The activity can be assigned as a group research project, individual term paper, or as a class presentation. Students may be asked to communicate with scholars in related fields, such as pharmacists, virologists, politicians, lawyers, judges, psychologists, sociologists, medical doctors, scientists, and community advocates, and the activity can be conducted in courses teaching such subjects.

Conducting the Learning Activity

Before the Activity

Instructors and teachers might want to use the following questions to help students start their search.

1. Research three different viruses including Ebola and then write one informative page distinguishing between the three of them. Submit your outcomes to your instructor and prepare yourself to talk about it in the class.
2. In scientific research that focuses on drug discovery, use, and effectiveness, such as in cancer, influenza, malaria, Ebola, etc., there are clinical trials that differ according to their primary purpose. Conduct research to find out if there are also types of clinical trials in Ebola treatment research that differ based on their primary purpose. Use the table below to report your findings.
3. Distinguish between airborne transmission and non-airborne transmission of the virus.
4. Provide three examples of airborne pathogens and foodborne pathogens.

TABLE 5. Are There Different Types of Ebola Vaccine Clinical Trials?

Different types of Ebola vaccine clinical trials		
1	Treatment	
2	Prevention	
3	Screening	
4	Diagnostic	
5	Quality of life or supportive care	

TABLE 6. Explaining the Meaning of Selected Terms to Non-science Person

	Selected Terms	Meaning
1	Placebo	
2	Experimental group	
3	Control group	
4	Placebo effect	
5	Blind experimental design	
6	Double-blind experimental design	

5. Explain which of the following terms best define a virus: pathogenic, microorganism, infectious agent, all of these, none of these.
6. Search the meaning of each term in Table 5, and then write one page distinguishing between Placebo, Experimental group, Control group, Placebo effect, Blind experimental design, Double-blind experimental design, Critical experiment. Based on your research, can you think of two more terms that are related and important to include into the list? In your writing, keep in mind that you are writing to someone who doesn't have your knowledge and is from a non-science field.
7. It has been stated that it is more challenging to create a new drug or vaccine for the treatment of a viral infection than for a bacterial infection. Conduct some library research to investigate the validity of this claim.

Procedures

I - Before the Enacting Procedures

1. Divide the class into nine groups. Each group consists of a leader plus a few members based on the nature of the community and the needed number for adequate representation.
2. Present to the students the scenario that the drugs to treat Ebola have not been tested on humans in any rigorous experiments to determine their efficacy and safety—no one can guarantee they will work on humans—as well as what might happen as a result of taking these untested and unapproved drugs. This dilemma naturally results in two camps arguing the case for or against the use of these clinically untested drugs.
3. Inform the students that as active members of their respective communities, they are to present their stance on the use of the drug candidates for treatment. They should identify the significance of making the

right decision and understand how their decision is the best for their community. They should also predict how their respective communities will react to their final choice and decision.

4. Give the groups two to three weeks to prepare for their class presentation. In addition to working outside class time, students should have ten to fifteen minutes of class time each week for the members of each group to join together and discuss their work and preparation. This will ensure continuous progress on the project.
5. Ask the members of each group to meet and divide the roles among themselves by selecting a leader for each category, as well as which areas within that category they would like to represent. In addition, the members of a given group must make their own choice about the type of decision they would like to take, support, and advocate. This type of involvement is very critical in ensuring high level of student involvement in the learning activity.
6. For the presentation, each group must

    a. Have a well-researched presentation and strategy of how to present their respective community's views and reaction to the decision they would like to make.
    b. Explain their respective community's views and reaction to the decision they would like to make.
    c. Explain how the public might react to their respective community's views and reaction to the decision they would like to make.
    d. Prepare a well-researched student hand-out as well as an illustrated poster.
    e. Integrate the use of technology such as PowerPoint, animations, interactive activities, etc. into the presentation. Students should present their plan and strategy, show how it will work, and convince everyone that their decisions support their community's beliefs and understanding.

II - During the Presentation

1. The groups take turns presenting to the whole class the significance of their decision as well as the prediction of how their respective communities would react to it, including why this is a good decision for both the infected and the community.
2. The leader of each group introduces the members of his or her team, and provides a brief introduction. Then the leader of the group can call on the members of his or her group to talk about the significance their decision as well as predict how their respective communities would react to their decision.
3. The members of the other groups can ask up to three questions after a given group finishes their presentation. The members of each group must also take note of all the questions that were asked by all the groups.
4. When all the groups finish their presentations, the media group reports on the events and provides a list of questions that the members of the communities failed to raise, answer, or avoided discussing.

III - After the presentation

1. Following the class meeting, the members of each group (community) bring answers to the questions that are raised and presented to them by the media group.
2. Each group is given three to five minutes to address the class one more time. In this short final remark, the groups must have a written statement that can be read to support their views and understanding. The written statement doesn't have to be shared with the other groups beforehand. This is a very important stage in the activity and is related to the "Creative Domain" of McCormack and Yager's (1989) taxonomy for science education, as we will see in the assessment section and in Table 6 below.
3. After all the groups present their final remarks, the groups are asked to evaluate, in writing, the performance of each group.

Homework Learning Activity

In this learning activity, students are provided a copy of Table 1 and given one week to conduct library research to answer the following questions:

1. Differentiate between viruses, viroids, prions, and bacteria.
2. Why we often include viruses, viroids, prions with microbes, but we don't qualify them as "living" entities.
3. What type of virus would you choose to work with or on? Describe its structure and explain why you selected this particular virus.
4. If you have the means, the know-how, and the will, what would you:
   a. Add to the existing structure of the virus and why?
   b. Take out of the existing structure of the virus and why?
   c. Modify in the existing structure of the virus and why?
5. What is/are the reason(s) why some viral infections, such as AIDS virus, are incurable?
6. Conduct Internet research to investigate the claim that the Junck DNA in our chromosomes may have come from ancient viruses that managed to insert their hereditary blueprint into our ancestors' DNA (Shukman, 2012).
7. What right do we have to go and tell people what type of drug or treatment they must take? What if they choose not to follow our advice when there is a potential community risk involved? Explain.
8. What have you learned from this learning activity?

Assessments

McCormack and Yager's (1989) taxonomy for science education is both formative (conducted during instruction) and summative (conducted at the end to measure what has been learned). It provides a good framework for assessing students' achievement, performance, and understanding, as well as the effectiveness of the activity. Table 6 below summarizes McCormack and Yager's (1989) taxonomy for science education. We have found this to be very effective in enabling both teacher and student to explore how and why each group reached their decision, and whether this whole situation could have been approached in other ways (Joyce and Weil, 1986). Furthermore, Tables 8, 9, and 10 in the appendix section have been used successfully as tools to record information and to monitor the level of cognitive involvement of the members of a given group during role-play learning activities. For example, using Table 7, instructors can record the type of questions being asked by the members of a given group as well as the relevancy of the questions to the subject matter and to the point being addressed. In addition, using table 8, instructors can record the number of questions being addressed to the other groups by the members of a given group. Instructors can use Table 9 to record the type of questions or conditional statements and their value for assessment purposes (Cherif et al. 2009).

Pre- and Post-test Homework Assignments

To reinforce the learning objectives of the activity and to allow for compelling attitudinal change, ask the students to answer the following questions (adapted from Cherif et al. 2015), either individually or in groups.

I. Pre-test Homework Assignment

1. What will you do to make sure that the perspective and the reaction of your chosen community would be the one favored by each student in your class?
2. What will you do to make sure that you are selecting the right categories of representatives within your chosen community?
3. If you decide to adopt a real and well-known person from your community, what will you do to make sure that you are selecting the right category of representatives within your chosen community?
4. What do you think you will learn from the activity at both the academic and personal levels?

II. A Post-test Homework Assignment

1. What have you learned from the activity at both the academic and personal level?
2. If you had to do this all over again, what would you change or do differently and why?

TABLE 7. Summary of McCormack and Yager's (1989) Taxonomy for Science Education as a Framework for Assessment

	Domain	Description	Type of Questions That Can be Looked At
I	Knowledge Domain	Students acquire knowledge of the subject, an understanding of relationships between the bodies of knowledge, and give reasons for their approach to solving the problem.	What concepts did students learn and how well did they understand them? How well did the students integrate knowledge from different subject areas? To what extent did students demonstrate the understanding of multiple relationships of various bodies of knowledge? Were the students able to disprove or verify some of the supporting theories used in the role-playing activity? What kind of explanations did students offer for the relationship they observed and understood?
II	Process Domain	Students learn how to collect, organize, and analyze data; develop strategies for building rational arguments and thoughts; state problems and generate valid conclusions; participate in team-work; interpret meaning from the project.	How did members of a given group compile data and information? Was there cooperation in putting the information together? How efficient was each group in presenting and communicating the collected data and information? Was their delivery of statements and arguments smooth and coherent? How well did the students use knowledge meaningfully? Did all members participate in the activity?
III	Creative Domain	Students apply creative thinking to the project; cultivate the ability to recognize, evaluate, and use data and information provided by the other parts of the role play; learn to modify a given design as needed.	In what new ways did students use objects and ideas generated during the enactment of the role playing to enlarge their understanding? How imaginative were students in identifying relevant problems and solutions, and conceptualizing new ideas?
IV	Attitudinal Domain	Students learn to listen closely and comprehend the other parts of the role playing. They also learn cooperation in a group performance and self-evaluation.	How persuasive were group members in articulating their positions in order to change the attitudes of the others? How effectively did each group function? Did students' sensitivity and respect for others develop during the process? Did members of a given party demonstrate skills and abilities to resolve conflicts with others constructively? How might each group have functioned more effectively?
V	Application and Connection Domain	Students learn to generate alternative approaches, problem-solving strategies, and solutions.	Did they come up with practical and workable solutions? To what extent did the students utilize their personal experiences and collective group understanding in making decisions related to the activity? How well did the students integrate knowledge from different disciplines in problem-solving strategies? How well did the students learn to negotiate constructive solutions to conflicts?

3. Knowing what you already know, how would you argue against the perspective and the predicted reaction of your own community?

4. If you have selected an actual well-known person from your chosen community, how did this help you to convey the perspective of your community?

5. It has been claimed that finding the right drug to treat illnesses that are caused by viruses presents a more difficult problem than treating illnesses caused by bacteria, because of the potential and the rate of damage to the host. Based on your research, explain why and how. Research what scientists have been doing to overcome that type of obstacle and challenge

when searching for the right drug to treat illness caused by viruses.

Final Remark

As teachers and mentors we need to keep in mind that learning activities and teaching approaches should always aim to capture the students' interest and spark motivation for learning and knowledge creation among students. To achieve this, students should be given the opportunity to be involved in the planning, implementation, and assessment of a given learning activity. To make the teaching approach of the given learning activity more productive, teachers should lead students toward greater levels of involvement in the process by including them in planning the five factors that make up a typical role-playing situation: 1) the problem to be solved; 2) the characters to be played; 3) the roles to be followed; 4) essential information to be gathered and; 5) procedures for the play to be adapted (Cherif and Somervill 1994 and 1995). In this activity, the problem to be solved and the characters to be played are given to the students. However, the roles to be followed, the essential information to be gathered, and the procedures for the play to be adapted as part of the learning activity are the students' responsibility.

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Appendix

FIGURE 1. West African Countries

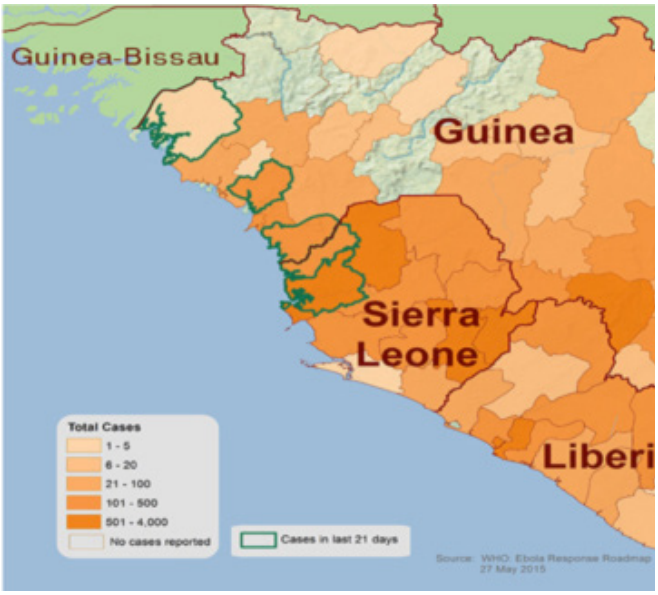

TABLE 8. Individual group questions analysis and account (Cited from Cherif et al. 2009, 350)

	Type of Question or Conditional Statements	Extremely Relevant	Relevant	Less Relevant	Not Relevant	Not Relevant
1.	Why					
2.	How					
3.	What do you think if...?					
4.						
5.	Which					
6.	What					
7.	When					
8.	Where					
	Is/Are					
	Total of questions and or wondering statements					

TABLE 9. Tracking the number of questions asked by each group of other groups

	Scientific community	Legal community	Pharmaceutical community	Politicians & policy makers	Civic engagement	Medical community	Public advocates	Media Group
Scientific community	X							
Legal community		X						
Pharmaceutical community			X					
Politicians and policy makers				X				
Civic engagement					X			
Medical community						X		
Public advocates							X	
Media Group								X
Total of Questions								

TABLE 10. Type of questions or conditional statements and their values for assessment purposes

Type of Question		Why How	What do you think if	Which	What Where When	Is Are	Total
EXTREMELY RELEVANT	# of Questions						
	Value per question	5	4	3	2	1	
	Total Values						
RELEVANT	# of Questions						
	Value per question	4	3	2	1	0.5	
	Total Values						
LESS RELEVANT	# of Questions						
	Value per question	3	2	1	0.5	0	
	Total Values						
NOT RELEVANT	# of Questions						
	Value per question	1	1	0.5	0	0	
	Total Values						
TOTAL							