Human Rights in Global Health: Team-Based Learning Education Resource for Medical Students, Residents, and Fellows

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Acknowledgments

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Introduction

Team Based Learning (TBL) is a learner-centered active learning strategy for small groups (5-7 students) that can be implemented in large and small classes (1). This type of activity promotes learning in groups/teams and fosters collaboration. Students are assigned readings and are expected to come to class prepared. Roughly, TBL consists of 3 separate sections:

1. Individual Readiness Assessment Test (iRAT) that consists of 5-15 Multiple Choice Questions (MCQs) and is used to assess students’ preparedness for the class. Results are revealed by immediate feedback via an Audience Response System (ARS) or via the Immediate Feedback Assessment Technique (IF-AT) “scratch-off” sheet (2), (3)

2. Team/Group Readiness Assessment Test (gRAT/iRAT) that consists of the same set of questions that students are now answering as a group

3. Application Exercises that consist of a set of problems that require applying the acquired knowledge in order to solve them. Students do the Application Exercises in groups/teams. All groups receive the same problem at the same time and report their answers as a group.

There are some basic rules that need to be observed when conducting a TBL session. Those are:

- The facilitators of this activity should be content experts.
- Students are assigned in their groups for the duration of the year. Groups/Teams are designed in such a way to be heterogeneous.
- Students are required to provide peer-assessment of other students in their group.
- The TBL session always begins with iRAT.

This resource is intended for teaching medical students, residents, and fellows. Ten iRAT/gRAT questions are provided with the correct answers and the appropriate rationale. Two application exercises, followed by discussion questions and MCQs, answers, and the rationale for them are also provided. The resource consists of a Session Plan, required and recommended readings, a Faculty Guide, a Student Guide, iRAT/iRAT questions with answers, and Application Exercises with answers.

Session Plan

Materials needed: Audience Response System or the Immediate Feedback Assessment Technique (IF-AT) “scratch-off” sheet (2), (3)

Duration: 2-3 hours

Course Support: WHO defined “Health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (1946). Regardless of race, ethnicity, social, economic, political or cultural factors, people should have the right to receive the same healthcare. The right to health includes access to timely, acceptable, and affordable health care of appropriate quality. The right to health means that governments must generate conditions in which everyone can be as healthy as possible. Such conditions range from ensuring availability of health services, healthy and safe working conditions, adequate housing, and nutritious food.

About 150 million people globally suffer financial catastrophe annually, and 100 million are pushed below the poverty line as a result of health care expenditures.

The General Comment on the Right to Health and how health is defined under international agreements such as the United Nation’s Universal Declaration of Human Rights or the Declaration of Alma-Ata will be introduced in this session.

Session learning objectives:

By the end of this session students will be able to:

- Demonstrate a basic understanding of the relationship between health and human rights
- Discuss the right to health and how this right is defined under international agreements such as the United Nations’ Universal Declaration of Human Rights or the Declaration of Alma-Ata
• Discuss how social, economic, political or cultural factors may affect an individual's or community’s right to healthcare (availability, accessibility, affordability, and quality)

• Understand the physician's role as an advocate for human rights, especially for vulnerable populations

• Identify ways in which physicians can participate in providing health care for those who cannot afford to pay for it

• Understand health professionals' roles in helping refugees gain asylum

• Recognize how health professionals may be involved in the documentation and adjudication of cases of human rights abuses

• Recognize that physicians have been used as agents of the state in abusing human rights

• Understand the rights-based approach to promoting reproductive rights for women

• Learn the guidelines for conduct of physician-investigators engaged in "dual-use" research

Students should receive clarification from the instructor on the issues that they have been struggling with as a team. (30 minutes)

3. **Exercise:** Case scenarios reflecting different aspects of human rights to healthcare access are introduced to each team. Students will discuss the cases and answer the provided related questions as a group. The same cases are given to all groups. Group/Teams work in class, on the same problem and provide their answers at the same time. (40 minutes)

4. **Debriefing:** Students will provide and defend their answers. (20 minutes)

5. **Peer Assessment and Session Evaluation** (15 minutes)

6. **Appeal:** Students have the right to request that the instructor consider an alternative answer to the question. This occurs after and out of class. Students need to provide a written re-worded question if they believe that the question was poorly worded or a written rationale including references to demonstrate that the alternative answer is as correct, if not more than, the one chosen by the faculty. Only the team providing the written feedback and only if they are successful, can receive credit for that question.

**Session Timeline**

1. **Individual Readiness Assessment Test (iRAT):** participate in the iRAT part of TBL session. Ten MCQs based on the required reading materials are prepared for this exercise. Students receive feedback immediately through the Audience Response System or through using the Immediate Feedback Assessment Technique (IF-AT) “scratch-off” sheet. (15 minutes)

2. **Group/Team Readiness Assessment Test (gRAT/TrAT):** As soon as they finish with iRAT students will be taking the exact same test as a group/team. Within their teams they should discuss the answer options and reach a consensus as to how to answer each question. Each group/team provides a single answer to each MCQ. When answers are different between teams each team should provide a rationale as to why they thought that was the correct answer.
Faculty Guide

Forming the teams for TBL: There are several rules that are helpful in forming the teams for TBL sessions. To start with, teams should be permanent and should never be self-selected by students. Teams should be diverse with various students contributing to the team in different ways. Determine the contributing factors ahead of time. Those could be: previous experience and education, background (local as opposed to international student), gender, previous performance, etc. Make the criteria known to the students and the whole selection process transparent. Ensure that all teams have similar or equal distribution of the important contributing factors. Once teams are formed they are permanent. Students should be allowed to switch teams only in exceptional circumstances, on a permanent basis, and with prior approval of the faculty.

Assigned readings:


Recommended readings:

Virtual Mentor.

August 2011, Volume 13, Number 8: 521-585


March 2010, Volume 12, Number 3: 143-252.

October 2007, Volume 9, Number 10: 661-734.

Prior to session:

- Review the literature on TBL (see references)
- Review the assigned and the recommended readings
- Prepare Audience Response System for 20 students and distribute at the beginning of the session
- Assign the students in groups of 5-7 as described in Forming the teams for TBL
- Prepare and distribute the ARS devices or IFAT “scratch-off” sheets (can be purchased from http://www.epstineeducation.com)

During session:

- iRAT: Implement the iRAT question session.
- gRAT/tRAT: Implement the gRAT/tRAT question session in the pre-determined teams.
- Application exercise: Students will be working in groups to discuss the cases and answer the case-related questions.
- Debriefing: Each group will discuss and provide justification for their answers.
- Peer Assessment and Session Evaluation of the session.

After session:

- Review any Appeal requests
- Incorporate the appropriate change requests in the session
Individual/Group Readiness Assurance Test Questions and Answers

1. The Universal Declaration of Human Rights was adopted at the United Nations General Assembly on:
   a. February 1, 1689
   b. April 1, 1933
   c. September 25, 1789
   d. December 10, 1948

Correct answer is d.

The United Nations was established in 1945 when World War II was ending. With the atrocities of World War II still fresh in people's minds, an 18 member Commission on Human Rights was established and was chaired by Eleanor Roosevelt. The Commission was given the task of creating a universal bill of human rights. The Commission worked during 1947 and 1948 and produced the declaration that was adopted on December 10, 1948. Eight countries abstained from voting yes. The six countries of the Soviet bloc abstained because they felt that the Declaration was not going far enough and was not explicitly condemning Nazism and fascism. Saudi Arabia abstained because of the wording in Article 16 on equal marriage rights and because Article 18 stated that everyone has the right to change their religion and beliefs. South Africa abstained because it knew that the Declaration would be used to condemn apartheid and racial discrimination.

2. Article 25 of the Universal Declaration of Human Rights speaks about:
   a. Equal right to education
   b. Equal rights to medical care
   c. Equal rights in marriage
   d. Equal right to own property

   Correct answer is b.

Article 25 of the Universal Declaration of Human Rights says: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”

Article 26 speaks about equal rights to education.

Equal rights for men and women in marriage are described in Article 16 that says: “Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution. Marriage shall be entered into only with the free and full consent of the intending spouses.”

Article 17 says that everyone has the right to own property alone as well as in association with others. No one shall be arbitrarily deprived of his property.

3. You are a physician and you are called to a detention facility to be present during interrogation of the prisoner. You notice that the prisoner is being forcibly deprived of sleep for more than two days. You are not asked to participate in any interrogation methods but to merely make sure that the prisoner survives the interrogation. According to AMA Code of Medical Ethics you should:
   a. Refuse to be present and to verify the health status of the prisoner
   b. It is fine to monitor the prisoner and to administer any necessary medications
   c. It is fine to monitor the prisoner as long as you are not administering any medications
   d. Refuse to be present, refuse to verify the health status, and request that the torture is stopped
Correct answer is d.

Opinion 2.067 of AMA Code of Medical Ethics says: Torture refers to the deliberate, systematic, or wanton administration of cruel, inhumane, and degrading treatments or punishments during imprisonment or detention. Physicians must oppose and must not participate in torture for any reason. Participation in torture includes, but is not limited to, providing or withholding any services, substances, or knowledge to facilitate the practice of torture. Physicians must not be present when torture is used or threatened. Physicians may treat prisoners or detainees if doing so is in their best interest, but physicians should not treat individuals to verify their health so that torture can begin or continue. Physicians who treat torture victims should not be persecuted. Physicians should help provide support for victims of torture and, whenever possible, strive to change situations in which torture is practiced or the potential for torture is great.

4. Regarding the role of physicians in capital punishment, the AMA position on this issue is:

   a. If requested by law, physicians should administer lethal injections

   b. Physicians should not directly cause death but can be present and can monitor vital signs

   c. Physicians can give technical advice about the execution or prescribe the necessary medications but should not be present at the execution

   d. Physicians should not in any way be participants in legally authorized execution

Correct answer is d.

According to AMA Opinion 2.06 on Capital punishment: An individual’s opinion on capital punishment is the personal moral decision of the individual. A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution.

Physician participation in execution is defined generally as actions that would fall into one or more of the following categories:

1) an action which would directly cause the death of the condemned;

2) an action which would assist, supervise, or contribute to the ability of another individual to directly cause the death of the condemned;

3) an action which could automatically cause an execution to be carried out on a condemned prisoner.

Physician participation in an execution includes, but is not limited to, the following actions: prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure; monitoring vital signs on site or remotely (including monitoring electrocardiograms); attending or observing an execution as a physician; and rendering of technical advice regarding execution. In the case where the method of execution is lethal injection, the following actions by the physician would also constitute physician participation in execution:

   selecting injection sites; starting intravenous lines as a port for a lethal injection device; prescribing, preparing, administering, or supervising injection drugs or their doses or types; inspecting, testing, or maintaining lethal injection devices; and consulting with or supervising lethal injection personnel.

The following actions do not constitute physician participation in execution:

1) testifying as to medical history and diagnoses or mental state as they relate to competence to stand trial, testifying as to relevant medical evidence during trial, testifying as to medical aspects of aggravating or mitigating circumstances during the penalty phase of a capital case, or testifying as to medical diagnoses as they relate to the legal assessment of competence for execution;

2) certifying death, provided that the condemned has been declared dead by another person;

3) witnessing an execution in a totally nonprofessional capacity;
(4) witnessing an execution at the specific voluntary request of the condemned person, provided that the physician observes the execution in a nonprofessional capacity; and

(5) relieving the acute suffering of a condemned person while awaiting execution, including providing tranquillizers at the specific voluntary request of the condemned person to help relieve pain or anxiety in anticipation of the execution.

5. You are approached by a major pharmaceutical company that is asking you to be a Primary Investigator for a clinical trial testing a new treatment of end stage renal carcinoma. In designing your clinical protocol and in order to better assess the efficacy of the treatment you need to include a control group. You should design it as follows:

   a. Half of your participants should be treated with a placebo consisting of saline injection
   b. Half of your participants should be treated with a placebo consisting of injections of pain medications
   c. Half of your participants should be treated with conventional chemotherapy
   d. Half of your participants should receive half of the dose of the new treatment

Correct answer is c.

Although it is necessary to have a control group in order to assess the efficacy of the new treatment, using saline instead of therapy may have dire consequences (including death) for those in the control group. Likewise, the option of using pain medications as a placebo in the control group might lessen the pain in the participants but it does not offer hope to prolong survival. Treating the control group with a half dose might not give you a sufficient difference to assess the treatment’s efficacy nor does it truly offer hope for treatment because the dose is suboptimal. The only ethically sound choice is to treat your control group with conventional chemotherapy.

The AMA position on this issue can be found in Opinion 2.075 of the AMA Code of Medical Ethics and it is as follows:

Protocols that involve conditions causing death or irreversible damage cannot ethically employ a placebo control if alternative treatment would prevent or slow the illness progression. When studying illnesses characterized by severe or painful symptoms, investigators should thoroughly explore alternatives to the use of placebo controls. In general, the more severe the consequences and symptoms of the illness under study, the more difficult it will be to justify the use of a placebo control when alternative therapy exists.

Consequently, there will almost certainly be conditions for which placebo controls cannot be justified. Similarly, the use of a placebo control will more easily be justified as the severity and number of negative side effects of standard therapy increase.

6. AMA will take action in physician persecution:

   a. Every time a physician who is USA citizen is facing persecution
   b. When a physician is facing persecution due to refusing to act contrary to professional ethics
   c. Every time a physician who is USA citizen is facing persecution if he/she has a valid USA license to practice
   d. Evert time a physician who is USA citizen is facing persecution in another country

Correct answer is b.

The AMA can take action on a case only when existing AMA policy supports such action.

(1) A physician is facing persecution due to refusing to act contrary to professional ethics

(2) A physician is facing persecution as a direct result of providing care that meets ethical and professional medical standards (such as for providing necessary care to patients who are enemies of the state)
(3) A physician is facing persecution as a result of speaking out against policies or actions that are clearly contrary to internationally accepted ethical norms.

(4) A physician is facing persecution due to the physician’s racial or ethnic background or other factors unrelated to competence or character.

(5) If a physician is not a US citizen, when that physician has a connection to the US, such as through training, work history, family ties, etc. (physicians with or without such ties may also be referred for action to the World Medical Association).

(6) When the existing system of justice where a physician faces persecution is not functioning effectively to protect the physician’s rights.

(7) When a physician faces a risk of abuse or torture while in detention.

(8) The degree to which the facts of the case are clear.

(9) The degree to which information about the case is made available for AMA deliberation (specifically, action may be taken in the absence of clear information if the reason for this lack of clarity is that the alleged persecuting authority is withholding information).

AMA Physician Persecution Advisory Group reviews every case and determines if it is appropriate to recommend AMA action.

7. Related to care for the poor, the AMA position is:

   a. Healthcare for the poor is governed by the policies of the country and has nothing to do with physicians.
   
   b. Physicians can provide care to the poor if they wish to do so.
   
   c. It is an obligation for physicians to provide care to the poor.
   
   d. Physicians can provide care for the poor only if they are in the USA legally.

Correct answer is c.

As outlined in the opinion 9.065 of the AMA Code of Medical Ethics, each physician has an obligation to share in providing care to the indigent. The measure of what constitutes an appropriate contribution may vary with circumstances such as community characteristics, geographic location, the nature of the physician’s practice and specialty, and other conditions. All physicians should work to ensure that the needs of the poor in their communities are met. Caring for the poor should be a regular part of the physician’s practice schedule.

In the poorest communities, it may not be possible to meet the needs of the indigent for physicians’ services by relying solely on local physicians. The local physicians should be able to turn for assistance to their colleagues in prosperous communities, particularly those in close proximity.

Physicians are meeting their obligation, and are encouraged to continue to do so, in a number of ways such as seeing indigent patients in their offices at no cost or at reduced cost, serving at freestanding or hospital clinics that treat the poor, and participating in government programs that provide health care to the poor. Physicians can also volunteer their services at weekend clinics for the poor and at shelters for battered women or the homeless.

In addition to meeting their obligation to care for the indigent, physicians can devote their energy, knowledge, and prestige to designing and lobbying at all levels for better programs to provide care for the poor.

8. You are a physician volunteering your services to nearby farms and catering to the needs of the farmer’s migrant workers. One day you receive a call from the farmer asking you urgently to come and see a migrant worker who arrived last night with a fever, a severe headache, vomiting and diarrhea. You go and examine him. Upon discussion via translator it becomes clear that he is an illegal immigrant who comes originally from Sierra Leone. He left his country ten days ago. You notice multiple cuts and bruises all over his body. You suspect Ebola and recommend to him that he needs to be quarantined.
All of the other farmer's migrant workers who came in contact with him should be quarantined as well. Your proposal generates fierce opposition by the patient, by other migrant workers, and even more by the farmer who says that this will completely ruin him financially.

a. It is only your duty as a physician to warn the patient and the contacts of what might happen

b. You should notify the authorities despite the farmer's objections and facilitate mandatory quarantine and isolation

c. You should take the patient to Infectious Diseases where he will be tested and treated and postpone the decision until the results are known

d. The farmer is an old friend of yours so you accept his objections about other migrant workers but you insist on quarantining the patient only

Correct answer is b.

The AMA position on quarantine is described in Opinion 2.25 of the Code of Medical Ethics: Physicians should encourage patients to adhere voluntarily to scientifically grounded quarantine and isolation measures by educating them about the nature of the threat to public health, the potential harm that it poses to the patient and others, and the personal and public benefits to be derived from quarantine or isolation. If the patient fails to comply voluntarily with such measures, the physician should support mandatory quarantine and isolation for the non-compliant patient. Physicians should also comply with mandatory reporting requirements and inform patients of such reports.

9. The Nuremberg Code is an important document governing:

   a. Treatment of prisoners of war

   b. Ethics of medical research

   c. Patient-physician relationships

   d. Health resources allocation in war zones

Correct answer is b.

The Code was formulated in August 1947, in Nuremberg, Germany, by American judges sitting in judgment of Nazi doctors accused of conducting murderous and torturous human experiments in the concentration camps. It served as a blueprint for today's principles that ensure the rights of subjects in medical research. It reads as follows:

(i) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility that may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

10. You are a 3rd year medical student serving as a volunteer in the surgical ward of a hospital in Bangladesh. You are supervised by local physicians. One day the attending asks you to perform a pelvic exam on a woman who is under anesthesia. He explains that this is part of the required activities for you and that doing it on an anesthetized patient will minimize her pain and discomfort. The patient consented to be examined by a foreign medical student but the details of the exam were not explained to her. You should:

a. Refuse to perform the pelvic exam explaining that you feel uncomfortable that the patient was not given the details of the exam

b. Do the exam since the patient already consented to being examined by a medical student

c. Ask to see the written consent and then do the exam

d. Call your supervisor in the USA and ask for permission

Correct answer is a.

There are three ethical issues in this request. The first issue is that you as a medical student were asked to do an exam for which you are not sufficiently trained yet. The second and more important issue is that the patient was not fully informed of what kind of exam will be performed. The third issue is that the patient is unconscious. For this kind of request to be ethical, the patient consent should contain all the details such as that it will be pelvic exam, that a medical student not yet fully trained in the technique will do it and that it will be done under anesthesia.
Group Application Exercises with Correct Answers to the Cases

Case 1.

You are serving with Doctors Without Borders on invitation of the government of a developing country that is under a strict military regime when massive anti-government protests break out. You have witnessed numerous human rights violations while in the country and have made many friends. Your local friends are inviting you to join them in the protest. You believe that their fight is just. What should you do?

a. Follow your heart and join the protests
b. Discuss the issues first with your colleagues at work, then decide
c. The government invited you into their country so you should back them up
d. Abstain from comments and try to remain neutral

Correct answer is d.

Even if it feels right to join the protests you are not visiting the country in a private capacity but as a member of an organization that was invited by the current government. All of your actions while in the country will reflect on the organization that you are representing as well as on your country, the USA. This is why you should try to abstain from comments and to remain neutral.

If the student answered a:

You followed your heart and joined the protest. The protest became violent and police got involved. You are arrested and put in jail. The next day during the interrogation, you and your organization are questioned as instigators of the unrest. Doctors Without Borders is kicked out of the country as ‘troublemakers’ and an official note is delivered to the government of the USA protesting the involvement of US organizations in the ‘internal affairs’ of the country. You know now that you will never be allowed to join and serve in any organization operating outside of USA borders.

If the student answered b.

You decided that the best way to proceed is to discuss the situation with the local colleagues that you are working with. You are very much surprised by their reluctance to discuss these issues. The next day the official government note of protest is issued to your superiors stating that you acted as a ‘provocateur’ trying to stir up the people.

If the student answered c.

You feel that the fact that Doctors Without Borders is in the country on invitation by the current government obligates you in some way and although you personally disagree with many things that you see, you say something along the lines that you are grateful for being invited and do not want to go against those who welcomed you. The next day, a government official in a military uniform comes and visits you. He publicly expresses his satisfaction with your loyalty in the presence of other doctors from Doctors Without Borders and your other colleagues. Some of your colleagues look at you with hate. This does not feel right and it is not what you wanted.

Case 2.

You are a physician who is employed as a Medical Officer for a major pharmaceutical company. As such you are in charge of supervising global clinical trials. One of the trials is testing a pediatric vaccine in children 0-12 months old in Sub-Saharan Africa. It is a Phase 2 trial and the children who are to be enrolled must be healthy and reasonably well nourished. As an enrollment incentive the company offers milk, flour, vitamins, and other nutritional items to the families who enroll their children. Malnutrition and death by starvation is rampant in many of your clinical sites but is especially prevalent at one. The site also has a very high illiteracy rate. You notice that this site is enrolling particularly well. During your site visit, you notice a long line of mothers with children waiting to be enrolled into the trial. Parents are given a consent form to sign as described in the clinical protocol. Most of the parents whom you observed consented by a fingerprint. The room is very crowded and the medical staff is extremely busy and has no time to talk to the families but they organized the procedure in such a way that they obtain a consent form for each patient. Children are not weighed during the exam prior to immunization and when asked, the PI explains that the scale that they had is now broken. Body temperature is also not measured.
What irregularities do you detect during the consent and exam process?

Correct answer:

1. Most of the parents consent by fingerprint, thus they are illiterate. They are unable to understand the possible side effects, as the medical staff is not providing explanation. Therefore, the parental consent in this case is not valid.

2. Although criteria for enrollment specify that the child must be healthy, the medical staff is not measuring body temperature.

3. Although criteria for enrollment specify that the child must be well nourished this is impossible to determine, as the medical staff is not weighing the children.

What could be the consequences?

1. If anything goes wrong, in addition to the parent being able to sue the company, these kinds of violations of the consent procedure could cause serious damage not only for this company but also for any other trying to do business in Africa.

2. Enrolling children who may be potentially ill in the clinical trial and vaccinating them could potentially cause additional serious side effects and this could endanger the children’s’ lives and will also render the trial invalid.

3. One of the greatest consequences of malnourishment is the secondary immunodeficiency that goes with it. Malnourished children launch delayed and much weaker immune responses to immunization (about 1/3 of that of a healthy child). So, any assessment of the efficacy of the vaccine would be greatly incorrect if done on malnourished children.

The parents should be well aware of the potential side effects of the vaccine. The consent is not valid unless they fully understand what is going on. The next day you come to the clinical trial site with a translator. You initiate a conversation with one of the mothers who came with a child who appears to be very thin, with a swollen belly and who is tired. The woman explains that she has another six children at home; the youngest one is one month old. They have no source of income and it has been difficult to obtain food for them. She hopes that enrolling this child into the trial might provide enough nutrition for the others and save them from certain death. Looking at the infant you have an impression that the child is below the required weight/height to be enrolled in the trial. Your request for the child to be weighed has been met with anger by the medical staff that is trying to persuade you that the scale is not working.

What will you do?

a. Enroll the child in the trial and vaccinate

b. Refuse to enroll the child on the grounds that he is malnourished and does not fulfill the enrollment criteria

c. Explain to the mother through the translator what are the possible complications if the child is vaccinated and leave it to her to decide

b. Do not enroll the child but provide the food and vitamins to the mother anyway

Correct answer is b.

Choice a is incorrect because enrolling the child in the trial will compromise its results. Malnourishment causes immunodeficiency that severely affects the immune responses to immunization.

Choice c is incorrect because you cannot leave the decision to the mother. In addition to the reasons outlined above, the mother already has several children at home who are severely malnourished and might be facing death from starvation. If you leave the choice to her you are basically asking her to choose between this child and her other children, which is a highly unethical thing to do.

Choice d is incorrect because, although your intentions are good and noble, the next day you will have a whole group of mothers asking for food for their children. Perhaps this could be done if you contact your company, explain the situation, and ask for food donations for the region; if you find a way to apply for some kind of grant to help them out; if you contact a nonprofit organization or UNICEF and ask for help etc.
Student Guide

Assigned readings:


Prior to session:

- Please review the required readings before class and come prepared

- You will be grouped into teams of five to seven. The teams are permanent and will be the same for any other TBL activity

During session:

- iRAT: Answer the iRAT questions by yourself using the Audience Response System or the Immediate Feedback Assessment Technique (IF-AT) “scratch-off” sheet

- gRAT/TrAT: Within your team discuss the same questions and answer them as a team. The responses should be derived by consensus of all of the members of the team.

- Application exercise: Within your assigned teams, discuss the cases and answer the case-related questions. Be prepared to give the rationale for each answer if asked. The facilitator will pick the student to provide the rationale randomly.

- Debriefing: Each group will discuss and provide justifications for their answers.

- Peer Assessment: You will be asked to provide an assessment of your peers who work in your team. You will need to assess their preparedness for the session, participation level and collaboration.

- Student’s evaluation of the session.

- Appeal: You have the right to request that the instructor considers an alternative answer to the question. This occurs after and out of class. Your team will need to provide a written re-worded question if you believe that the question was poorly worded or a written rationale including references to demonstrate that the alternative answer is as correct if not more than the one chosen by the faculty. Only the team providing the written feedback and only if they are successful can get a credit for that question.
Bibliography