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ETHICS RESOLUTION PROCESS: ETHICAL AND CLINICAL CASE STUDY

PROCESSO DE DELIBERAÇÃO ÉTICA: ESTUDO DE CASO ÉTICO-CLÍNICO

PROCESO DE DELIBERACIÓN ÉTICA: ESTUDIO DE CASO ÉTICO-CLÍNICO

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ABSTRACT

Objective: to describe the ethical resolution process/clinicians using a fictional case study. **Method:** it is a case study, with a current bibliographic references and base legislation on the subject. **Results:** stages analyzed 1) Resolution on the values: list of ethical problems, moral problem to be analyzed, and identification of conflicting values; 2) Resolution on the duties: identification of extreme courses of action, identification of intermediate courses of action (possible alternatives) and identification of the optimal course of action; and 3) Consistency tests: where the aspects of temporality were analyzed, advertising, legality. **Conclusion:** the resolution is a fundamental procedure of ethics, occurring every time the values, individual or collective are in conflict. It is necessary to decide to make the decisions that are concrete considering the act of context and its predictable consequences. **Descriptors:** Bioethics; Decision-making; Ebolavirus.

RESUMO

Objetivo: descrever os processos de deliberação éticos/clínicos usando um estudo de caso fictício. **Método:** estudo de caso, tendo como base referencial bibliográfico atual e legislação sobre a temática. **Resultados:** etapas analisadas: 1) Deliberação sobre os valores: lista de problemas éticos, problema moral a ser analisado e identificação dos valores em conflito; 2) Deliberação sobre os deveres: identificação dos cursos extremos de ação, identificação dos cursos intermediários de ação (alternativas possíveis) e identificação do curso ótimo de ação; e 3) Provas de consistência: onde foram analisados os aspectos da temporalidade, da publicidade e da legalidade. **Conclusão:** a deliberação é um procedimento fundamental da ética, ocorrendo toda vez que os valores, individuais ou coletivos, encontrarem-se em conflito. É necessário deliberar para tomar as decisões, que são concretas levando em consideração o contexto do ato e suas consequências previsíveis. **Descritores:** Bioética; Tomada de Decisões; Ebolavirus.

RESUMEN

Objetivo: describir los procesos de deliberación éticos/clínicos usando un estudio de caso ficticio. **Método:** estudio de caso, teniendo como base referencial bibliográfica actual y legislación sobre el tema. **Resultados:** etapas analizadas 1) Deliberación sobre los valores: lista de problemas éticos, problema moral a ser analizado, e identificación de los valores en conflicto; 2) Deliberación sobre los deberes: identificación de los cursos extremos de acción, identificación de los cursos intermediarios de acción (alternativas posibles) e identificación del curso óptimo de acción; and 3) Pruebas de consistencia: donde fueron analizados los aspectos de la temporalidad, de la publicidad, de la legalidad. **Conclusión:** la deliberación es un procedimiento fundamental de la ética, ocurriendo toda vez que los valores, individuales o colectivos, se encuentran en conflicto. Es necesario deliberar para tomar las decisiones, que son concretas teniendo en consideración el contexto del acto y sus consecuencias previsibles. **Descriptores:** Bioética; Tomada de Decisiones; Ebolavirus.

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INTRODUCTION

The Ebola virus was first identified in Zaire (today is the Democratic Republic of Congo, near the Ebola River) in 1976, and since that time, it has caused outbreaks in Africa Continent. The initial transmission of the virus in human beings occurred to those who had contact with blood, organs or bodily fluids of infected animals, such as chimpanzees, gorillas, giant bats, antelope, and porcupines. The incubation period in human beings may vary from two to 21 days. There are five species of Ebola virus (Zaire ebolavirus, Sudan ebolavirus, Bundibugyoebolavirus, Reston ebolavirus and Tai Forest ebolavirus), being Zaire ebolavirus which has the highest mortality rate, usually above 60% of diagnosed cases.¹

Ebola virus disease (DVE) is caused by virus Filoviridae family, Ebolavirus gender, and the bat is the most likely reservoir. When the infection occurs, symptoms usually begin abruptly, causing fever (over 38°C), headache, weakness, diarrhea, vomiting, abdominal pain, loss of appetite and hemorrhagic manifestations. The World Health Organization (WHO) has drawn its attention to the persistence of an outbreak in western African countries, affecting Liberia, Guinea, and Sierra Leone. This is the most extensive and enduring outbreak of Ebola virus already identified in the world, with a mortality rate of 68%.²

The transmission only occurs after the beginning of symptoms and occurs through contact with blood, body tissues or fluids of infected individuals (including corpses), or contact with contaminated surfaces and objects. There is no transmission during the incubation period. Ebola is an immediately reportable disease. It is considered suspect if individuals come in the last 21 days, from the country with current transmission of Ebola (Liberia, Guinea, and Sierra Leone) presenting signs and symptoms.¹

The disease is confirmed when laboratory results for Polymerase Chain Reaction (PCR) are positive. The case will be discarded when two PCR results are negative for Ebola, held in a Reference Laboratory of the Ministry of Health, with a minimum interval of 48 hours between the two blood collections.²

Personal protective equipment (PPE) to be used by professionals are a surgical mask, eye or face protector, procedure or

surgical gloves, coat/apron, hat, protective footwear (shoe covers). There is no specific treatment yet for the disease, being limited to life support measures with supportive therapy, consisting in hydrating the patients, maintaining their oxygen levels and blood pressure in the normal range and treating infections that may appear.³⁻⁴

Tests for the development of a vaccine and serum of infected patients by the virus are being experienced. Researchers have investigated different combinations of antibodies as a therapy against Ebola. Some combinations have had some success in animal studies. The ZMapp is the latest cocktail containing three antibodies. A doctor Liberian and a Spanish priest died of Ebola, even treated with ZMapp. On the other hand, two American doctors have recovered using this cocktail. According to the researchers, ZMapp appears to be effective in human beings if ingested until the 9th or 11th day of infection.⁵

For a better understanding of the ethical issues inherent in assistance offered to a patient with suspected infection and the route of the ethical decision process, a fictitious clinical case and adapted from real events are discussed. According to the ethical and clinical case proposed, it was considered deliberative ethics for analysis of problems and conflicts, making balance between principles and values, in order to identify the best possible alternatives to provide decent and proper treatment.⁶

OBJECTIVE

To describe how the ethical resolution/clinicians processes are structured using a fictional case study.

METHOD

It is a descriptive study, with a qualitative approach of a case study, structured to ethical/clinical case study model. This article was produced from the discussions held in the discipline of Ethics, Bioethics and Work at the Health Area offered by the Graduate Program in Nursing at the University of Brasilia - UNB (PPGEnf/UNB).

To achieve the proposed objective, a fictitious clinical case was first built. Questions about the ethical aspects of decision-making have been raised and, finally, the steps of a resolution opinion were demonstrated, with the current

bibliographic references and base legislation on the subject. The structure of case studies is important because they show innovative solutions to particular problems.

ETHICAL-CLINICAL CASE

Teresa Ramos, 44, married, nursing assistant, mother of two children, one 10 and another 6 years old, lives with her husband, her children, and her mother. The health worker was part of the team that attended the missionary Manuel García, who died of hemorrhagic fever caused by the Ebola virus on September 26, 2014, at the Municipal Hospital of Foz do Iguaçu.

◆ Hospitalization reason:

She was admitted to the Hospital Ministro Costa Cavalcanti, in Foz do Iguaçu, on October 6, 2014, with a high fever and vomiting. She said she had taken care of a patient with a confirmed diagnosis of Ebola virus for 11 days. As a result, the hospital uses the Brazilian protocol for the care of possible cases of Ebola and she was isolated urgently. This employee works more than 15 years in the Municipal Hospital. After undergoing tests, two analyzes in the patient were positive for the Ebola virus.

◆ Evolution

Admitted with high fever, diarrhea, frequent vomiting and cough, her health worsened after spending one "more complicated" night. Tereza was evaluated by a multidisciplinary team that realizing that the disease was in an evolution criticism, they decided to just treat her with saline solution for hydration, basic life support and let the disease evolved by its natural course. The mortality rate is nearly 70% for this type of infection. Experts believe that Teresa Ramos entered within the decisive 48 hours after 14 days since the first symptoms were revealed and if she can survive to this period, it will be an important step in overcoming the virus.

Tereza's family was informed about the team's decision about the proposed treatment and they disagreed with the decision adopted by the team. In their opinion, only the maintenance of hydration dramatically decreases the chance of survival. Disagreeing with the decision, the family sought the assessment of a renowned infectious disease expert and even he suggested that Tereza could receive an experimental treatment, available in Brazil: ZMapp cocktail and serum donated

by another patient who was cured of Ebola virus.

Tereza's husband told quickly to the health team the possibility of using this experimental treatment, but the professionals did not hear and said she already was in advanced stage of the disease. They mentioned also that there was limited number of doses of the experimental drug, with little chance of obtaining successful treatment. Therefore, it should be used rationally.

During this period, a doctor has also been admitted to the hospital with suspect of having been infected with Ebola virus. However, his symptoms were still soft, with fever, weakness, sore throat and myalgia. The doctor was isolated as well as Teresa and his examinations were positive for Ebola. Due to his stable picture, the health team decided to offer him the experimental treatment.

Tereza's Family does not agree with the decision of the team and was informed that the other patient would receive the treatment. The family argued that it was not correct by the staff to give priority treatment to the doctor, since according to the infectious disease consultation, Tereza would healing chances if receiving treatment, and it is the right of every patient to receive the best treatment available.

Faced with the difficult conflict between the team's decision and the views of family members, it was asked to Clinical Bioethics Committee of the hospital, the resolution on how to best conduct the case.

CASE DISCUSSION

The fictitious clinical report represented was built from two confirmed cases of the disease Ebola Virus (DVE), consisting of suspected cases with laboratory results for Polymerase Chain Reaction (PCR) conclusive for Ebola, held in a reference laboratory.

The technical report and the guidelines for surveillance and reference health services provided by the Ministry of Health in August 2014 say the suspect/confirmed patient should be admitted to a private room with bathroom, in isolation, with conditions of life support. If the clinical picture is unstable or there is a need for blood transfusion, it should be performed blood typing test for later transfusion, indicating oral or intravenous hydration as

clinical evaluation, besides being started antibiotic therapy with a third-generation cephalosporin. The orientation of the patient and his family is essential on the procedures to be adopted.²

Because there is no specific treatment for curing of DVE, the patient confirmed that generally has a dehydration and bleeding picture, needs intensive support through oral or intravenous hydration with solutions containing electrolytes and blood transfusion. However, some experimental treatments have been developed and tested in a limited way, not available for general use.²

One of the experimental treatment being tested is the ZMapp cocktail, which is in the early development phase and that, until recently, there was no data on its efficacy in human beings. Until then, the cocktail has not gone through all phases of clinical trials to prove the effectiveness in human beings, however, two American doctors recovered after receiving treatment, though a physician Liberian and a Spanish priest had died even with the treatment.⁵

In monkeys infected with Ebola virus, ZMapp showed 100% effectiveness through the survival of the 18 monkeys who received the drug until the fifth day after infection, three days before it becomes fatal in animals. However, the development of the disease is slower in human beings than in monkeys. Because of this, it is believed that the treatment is effective in human beings until the 9th or 11th day after infection.⁵

The Charter of Rights of the Health Users (2011), launched by the Ministry of Health and the National Health Council, is composed of six basic principles that ensure, either in the public or private sector of health care, universal and equal access of promotion, prevention, protection, recovery and rehabilitation.⁷

The six principles of the charter are: every citizen has the right to access orderly and organized health systems; every citizen has the right to appropriate and effective treatment for their problem; every citizen has the right to humane care, warm and free from discrimination; every citizen has the right to care that respects their person, their values, and their rights; every citizen has responsibilities for its treatment happen properly; every citizen is entitled to the commitment of the managers so that the above principles are met.⁷

Ordinance 1,820, of August 13, 2009, is about the rights and duties of healthcare users. Article 2, paragraph 2 refers to the user right of access to health services to ensure their treatment, recovery and rehabilitation of their health in cases of urgency/emergency, and any health facility has the duty of receiving and taking care of the person and send it, if necessary, to another service.⁸

Article 3, sole paragraph of the said ordinance, discusses the appropriate treatment guarantee the user in a timely manner, as well as continuity of care. For this, the service must be agile, conducted by multidisciplinary team, with the tool appropriate technologies to meet also with the right to information about their state of health in an objective, respectful and clear as the justification, risk and length of their treatment.⁸

Article 4 states that every citizen has the right to warm and humane care, provided by trained professionals, being free from any kind of discrimination, restriction or denial because of race, color, ethnicity, gender, age, religious belief, identity gender, economic and social conditions, health status, disorder or condition, to ensure the physical and emotional well-being of the user and their family.⁸

Also in Article 4, it is granted to the user information about other therapeutic possibilities, according to their clinical status, provided there is scientific and positive evidence cost-effectiveness of alternative treatment, the choice of alternative treatment, if any, and the refusal to the proposed treatment.⁸

Later, in Article 5, the freedom of the user is ensured at any stage of treatment, to seek a second opinion on their health status, or on recommended procedures. Finally, Article 8 describes the ways in which managers will carry out progressive measures for compliance with the principles of the letter, and every person the right to demand cited by managers and thus monitoring and ensuring the quality of their health.⁸

In this sense, we can understand that caring is very important to watch both the patient out of the healing possibilities as his family. However, for this to be incorporated into professional practice, professionals need to be able to provide a ruled assistance on the principles of bioethics.

The bioethical reflection based on the principles of beneficence, non-maleficence, autonomy and justice act in order to dissolve the conflicts and ethical dilemmas involving terminal life, but also to guide decision making by health professionals.⁹

◆ Resolution on the values

◆ Ethical problems list

- Does the patient have an understanding of the severity of his clinical picture?
- What is the treatment available for the disease?
- What does the patient think about the experimental treatment?
- Was the patient duly informed of the proposed treatment?
- Did the family consult with patients about their opinion regarding the dilemma of treatment?
- How does the family understand the situation of the experimental treatment?
- How is the follow-up of the family by the team as the psychological support?
- Does the consulted infectious disease have access to the medical record of the patient?
- Based on the infectious disease, could it say that Tereza could receive the experimental treatment?
- At what level of the patient clinical picture is suitable for receiving the experimental treatment?
- How could the health care team reconsider the case of Tereza?
- How did the team see the view of infectious disease?
- What would it be to use the experimental treatment in a rational way?
- What is the best treatment available in the case of Tereza?
- What is the best treatment available for the doctor?
- What is the prognosis of the patient?
- How is the access to experimental treatment available?
- Does the proposed therapeutic follow any established protocol?
- Is there any factor that affect the evaluation of the patient?
- Is there any approach by health professionals in influencing decision-

making and implementation of treatment?

- What are the legal implications on the therapeutic measures adopted by the health team?

◆ Moral problem to be analyzed.

Before the dose limiting of the experimental treatment, this would be the best treatment for the clinical picture of Tereza?

◆ Identification of values in conflict

- Efforts to maintaining life;
- Prioritize the life of one over the other;
- Rational use of the experimental treatment at the expense of life;

◆ Resolution about the duties

◆ Identification of extreme courses of action

- a) Do not offer the experimental treatment due to the critical situation of Tereza, with a reduced chance of cure.

Objective: to save the limited resources of an experimental treatment for patients with better prognosis.

- a) Provide the experimental treatment without restrictions related to the clinical picture of Tereza.

Objective: Try to cure the patient, even with a critical situation, since there is no proven evidence of the effectiveness of the treatment in human beings.

◆ Identification of Intermediate Courses of action (possible alternatives)

- To continue offering the treatment of life support;
- To explore what the family knows about Tereza's picture;
- To explain how the experimental treatment works to the family and no cure guarantee;
- To gather the health team, the infectious disease doctor and the family consulted for clarification of the case;
- To gather the health team and the infectious disease to explore the applicability of the experimental treatment;
- To establish criteria for the use of the experimental treatment;
- To provide emotional support to the family of the patient;
- Try to decide with the family the best treatment for Tereza;

- To keep the family informed in a clear and objective way, about Tereza's picture;

♦ Identification of the great course of action

The health team and the infectious disease doctor could further explore the clinical picture of Tereza depending on applicability and possibility of cure with the experimental treatment since it has no evidence to support the best time for this therapy. Monitoring and ensuring clear information to the family about the status and Tereza prognosis, trying consensus.

♦ Consistency tests

Temporality: A decision will be made after a thorough analysis of the case and it will allow the model of ethical deliberation process is applied in possible future cases.

Advertisement: Transparency on the clinical picture of Tereza and the explanation on the appropriate treatment after multidisciplinary meeting allows the decision to be public visibility, as will prerogative for other cases.

Legality: Decisions are confirmed in the current legal picture. Once it ensures the proper treatment to the patient, it also protects the professional regarding the possible negligence.

CONCLUSION

There are several challenges in health care about the Ebola virus, such as lack of scientific knowledge and material resources, human and technological resources for proper monitoring of cases. However, prevention is focused on obedience to behavioral precautions (equipment use personal protection and disinfection).

As for the ethical aspect, there is primarily the factor legality, since all people (Brazilian or foreign) who are under the mantle of the Constitution may use the services offered by SUS. However, to occur the involvement of professionals in care, they should be supplied in technical and scientific expertise and safe working conditions for themselves and the community.

The resolution is a fundamental procedure of ethics, occurring every time the values, individual or collective, find themselves in conflict. It is necessary to decide to make the decisions that are concrete considering the act of context and its predictable consequences. In addition to

having skills and knowledge, adopting attitudes of mutual respect, recognizing the limitations, favoring listening and analyzing critically and publicly their own opinions.

The Ebola virus is a complex and sensitive issue in health practice. For understanding and addressing the conflicts found in attention to people who have contact with the virus. The resolution bioethics is revealed as a system for the controversial confrontation between conflicting values, allowing reflect and study on the subject in order to provide the best care and treatment for patients and the best resources for professionals meet quality to Ebola victims.

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