

## Ethical issues in the management of patients with Ebola virus disease

Questões éticas no manejo de pacientes com doença pelo vírus Ebola

Cuestiones éticas en el manejo de los pacientes con la enfermedad del virus Ebola

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On October 10, 2014, the Evandro Chagas National Institute of Infectious Diseases of the Oswaldo Cruz Foundation (INI/Fiocruz) in Rio de Janeiro received the first suspected case of Ebola virus disease in Brazil. Twenty-four hours after admission, the result of the patient's first polymerase chain reaction (PCR) test came back negative. Following the prevailing protocol<sup>1</sup>, a second blood sample was drawn 48 hours later, on October 13, and when this second PCR tested negative for Ebola, the case was ruled out and the biosafety measures were suspended. The isolation of a suspected Ebola case allowed some conclusions on the Institute's preparedness and procedures during the patient's hospitalization. The experience also raised some doubts, involving not only technical and scientific issues, but also the way society views the response to challenges posed by a disease with Ebola's characteristics. Some of these doubts are addressed here.

### Individual rights versus collective risk

Isolation of Ebola patients during their symptomatic period is essential to contain virus transmission<sup>2</sup>, and together with contact monitoring constitute the basis for the Ebola management and control strategy. Adequate physical infrastructure and personal protective equipment

(PPE) for effective isolation have been discussed extensively, but all the recommendations are premised on the patient's collaboration<sup>3</sup>. What procedure should be adopted if a patient refuses to remain in isolation? The conceptual, legal, and operational dimensions of mandatory isolation have to be discussed within a consistent communication strategy.<sup>4</sup> Any decision for mandatory isolation requires defining which containment mechanisms can be used, besides the legal grounds for their enforcement. Importantly, the characteristics of Ebola virus transmission make any measure risky when it involves physical contact, and most hospitals lack the physical infrastructure or trained personnel to coercively move Ebola patients. If a patient refuses to remain hospitalized, should the medical team call the police? Should the police wear PPE to contain the patient? Will the patient be placed under surveillance in the referral hospital itself?

Contact quarantine follows the same logic of mandatory isolation. For example, what is the legal basis for limiting travel by Ebola contacts that are under quarantine? In this case, epidemiological surveillance, responsible for monitoring contacts, should be instructed on how to proceed. In my view, quarantine of health care workers is even more complex, due to the possible consequences. The recommendation by the Brazilian Ministry of Health prudently

makes a distinction between health care workers with known exposure to the patient's secretions (or who have treated a patient without using the recommended PPE) and those who have cared for patients with all the adequate biosafety measures and PPE, without known direct exposure<sup>5</sup>. These two groups of health care workers are classified as high and low risk, respectively. They must all have their temperature and other signs and symptoms associated with Ebola virus disease monitored for 21 days, but only high-risk workers are subject to limitations on their movement, for example, they cannot use public transportation. In the United States, some states have already adopted mandatory quarantine for incoming persons from countries with transmission areas, even including health care workers without a history of unprotected exposure to Ebola patients<sup>6</sup>. In addition to the high risk of infection for such health care workers, their freedom to come and go is curtailed, even if they have performed patient care correctly and without breaching biosafety barriers. This could potentially discourage medical staffers from volunteering to work in epidemic areas, besides jeopardizing the appropriate care for possible cases imported into the country.

### Containment of the disease versus intensive care

Considering the high secondary attack rate and high case-fatality rate from Ebola virus disease, from the public health point of view, averting transmission has a greater impact than the outcome of the index case. Thus, until the beginning of the epidemic in West Africa, the health team's contact with patients was limited to a minimum, which precluded even basic supportive therapy<sup>7</sup>. Even the literature that has recently suggested greater emphasis on patient care recommends only the use of parenteral hydration and medication, identifying and correcting fluid and electrolyte disorders and providing nutritional support, still far short of what is now considered advanced support for critically ill patients<sup>8,9</sup>.

Normally, the decision to perform (or refrain from performing) invasive procedures is based on a risk-benefit analysis for the patient. In the case of Ebola, the analysis also includes the risk to health personnel involved in the patient's care. The analysis poses a major challenge for several reasons. First, since clinical recording of Ebola cases is hampered by the recommended biosafety measures, there is very little scientific evidence on the clinical evolution of critical cases, with on-

ly a few reported cases with access to advanced life support, all without impact on the prognosis and thus with no documentation on the benefit of such measures<sup>10</sup>. Second, although the risk to staffers involved in patient care is well-documented<sup>11</sup>, quantification of the risk specifically associated with invasive procedures has not been well-established.

The first detailed report of a critically ill case of Ebola virus disease with a good response to support with intensive care was recently published<sup>12</sup>. However, the patient was hospitalized in a biosafety level-four unit, far higher than the level normally recommended for admission of patients in referral hospitals; even so, although there was an indication for tracheal intubation, the choice was made to use non-invasive ventilation, a procedure with the less risk for the attending health care team<sup>12</sup>. The key to this question appears to lie in the need to increase the level of protection for staffers in order to allow safer intensive care. Nevertheless, society and medical ethics committees need to define how far to invest in critically ill patients within the biosafety conditions available in each unit. This answer has to be ready before a critically ill Ebola patient exists in the unit, and this decision falls exclusively to the attending medical team.

### Experimental treatments

Access to experimental treatments for Ebola virus disease has drawn great attention from the media and society. Motivated by the repercussions of the first use of monoclonal antibodies in the United States, the World Health Organization (WHO) convened an expert panel to discuss ethical issues in the use of treatments lacking proven safety or efficacy in human beings. Considering the severity of the disease and the absence of other treatment options, the panel recommended the use of experimental treatments when available<sup>13</sup>. This issue now calls for a discussion involving the regulatory bodies, which in Brazil's case are the National Health Surveillance Agency (ANVISA) and the National Commission on Research Ethics (CONEP), to determine in advance whether to authorize the importation and use of such drugs for Ebola patients. The decision should be made ahead of time, and all the procedures to provide the drug must be ready in order to ensure timely supply.

Other issues still need to be addressed, such as the responsibility for (and disposition of) bodies of deceased Ebola patients, or the transfer of infected patients from areas with transmission.

Discussion of these issues is certain to result in a mature and socially responsible learning process, to be applied not only in the current epidemic but in other epidemics that may challenge our society in the future.

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