World Health Organization

Media centre

Ethical considerations for use of unregistered interventions for Ebola virus disease (EVD)

Summary of the panel discussion

WHO statement
12 August 2014

West Africa is experiencing the largest, most severe and most complex outbreak of Ebola virus disease in history. Ebola outbreaks can be contained using available interventions like early detection and isolation, contact tracing and monitoring, and adherence to rigorous procedures of infection control. However, a specific treatment or vaccine would be a potent asset to counter the virus.

Over the past decade, research efforts have been invested into developing drugs and vaccines for Ebola virus disease. Some of these have shown promising results in the laboratory, but they have not yet been evaluated for safety and efficacy in human beings. The large number of people affected by the 2014 west Africa outbreak, and the high case-fatality rate, have prompted calls to use investigational medical interventions to try to save the lives of patients and to curb the epidemic.

Therefore, on 11 August 2014, WHO convened a consultation to consider and assess the ethical implications for clinical decision-making of the potential use of unregistered interventions.

In the particular circumstances of this outbreak, and provided certain conditions are met, the panel reached consensus that it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention.

Ethical criteria must guide the provision of such interventions. These include transparency about all aspects of care, informed consent, freedom of choice, confidentiality, respect for the person, preservation of dignity and involvement of the community.

In order to understand the safety and efficacy of these interventions, the group advised that, if and when they are used to treat patients, there is a moral obligation to collect and share all data generated, including from

treatments provided for ‘compassionate use’ (access to an unapproved drug outside of a clinical trial).

The group explored how the use of these interventions can be evaluated scientifically to ensure timely and accurate information about the safety and efficacy of these investigational interventions. There was unanimous agreement that there is a moral duty to also evaluate these interventions (for treatment or prevention) in the best possible clinical trials under the circumstances in order to definitively prove their safety and efficacy or provide evidence to stop their utilization. Ongoing evaluation should guide future interventions.

In addition to this advice, the panel identified areas that need more detailed analysis and discussion, such as:

- ethical ways to gather data while striving to provide optimal care under the prevailing circumstances;
- ethical criteria to prioritize the use of unregistered experimental therapies and vaccines;
- ethical criteria for achieving fair distribution in communities and among countries, in the face of a growing number of possible new interventions, none of which is likely to meet demand in the short term.

A report of the meeting proceedings will be available to the public by 17 August 2014.

List of participants

Advisors

1	Prof Michael Selgelid	Director of the Centre for Human Bioethics, Monash University	Australia
2	Dr. Philippe Calain (chair)	Unité de Recherche sur les Enjeux et Pratiques Humanitaires (UREPH), Médecins Sans Frontières	Switzerland
3	Prof. Aisssatoue Toure	Head of Immunology Department, Pasteur Institute, Dakar	Senegal
4	Prof. Ross Upshur	Canada Research Chair in Primary Care Research; Professor, Department of Family and Community Medicine and Dalla Lana School of Public Health, University of Toronto; former Director of the University of Toronto Joint Centre for Bioethics (2006-2011)	Canada
5	Prof. Peter Smith	Professor of Tropical Epidemiology, London School of Tropical Medicine and Hygiene	United Kingdom

Advisors

6	Dr. Helen Byomire Ndagije	Head of the Drug Information Department in the Ugandan National Drug Authority (NDA)	Uganda
7	Prof Jeremy Farrar	Director, Wellcome Trust	United Kingdom
8	Prof Ryuichi Ida	Member of the Expert Panel on Bioethics (National Bioethics Committee)	Japan
9	Ms. Jeanine Thomas	Patient Safety Champion	United States of America
10	Dr. Juan Pablo Beca	Professor, Bioethics Center at Universidad del Desarrollo	Chile
11	Pr. Tariq Madani	Professor of internal medicine and infectious diseases	Saudi Arabia
12	Dr. Marion Danis	Head, Sect. on Ethics & Health Policy (NIH)	United States of America

Resource persons

Dr Stephan Monroe, CDC, US-FDA
Dr Luciana Borio, US-FDA
Dr Frederick Hayden, U Virginia, USA
Dr Daniel Baush, U.S. Naval Medical Research Unit No.6 Lima, Peru

Twelve Declarations of interest for advisors and four for resource persons were reviewed. No conflict of interest was declared by any of the advisors. Dr Fred Hayden, one of the resource persons, declared that “he and his University have received compensation for his time in reviewing one patent case regarding Zanamivir (GSK) and medicolegal cases involving fatal influenza and delayed use of Oseltamivir (Roche).” It was clarified with Dr Hayden that he had conducted the case reviews as a full faculty member and that he had not received any remuneration for them separate from his faculty. It shall be noted that the resource persons contributed their valuable technical expertise only when requested by the chair.

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Related links

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Report of an advisory panel to WHO - August 2014

Background to the panel discussion

WHO's work on Ebola virus disease
Travel advice, FAQs, fact sheet, technical information, information on outbreak in west Africa

Features: Ebola virus disease