

Ebola treatment trials to be fast-tracked in West Africa

TDR news item
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Investigational Ebola treatments are to be tested in West Africa for the first time as part of an international initiative to fast-track trials of the most promising drugs, for the disease that has already led to over 2 600 deaths.



WHO

A £3.2 million grant from the Wellcome Trust will enable multiple partners around the world, including the International Severe Acute Respiratory

and Emerging Infections Consortium (ISARIC), the University of Oxford, Médecins Sans Frontières (MSF), WHO, TDR, Institute Pasteur, Fondation Merieux and the Global Health Network, to quickly establish clinical trials at existing Ebola treatment centres, as early as November.

The unprecedented outbreak of the virus, one of the most virulent infectious agents known to man, has been declared a threat to international peace and security by the UN Security Council and prompted demands for an urgent response. In August a WHO expert panel unanimously concluded that in such exceptional circumstances it would be ethical to evaluate the use of unregistered investigational treatments that might save lives. Marie-Paule Kieny, Assistant Director-General of WHO's Health Systems and Innovation, said, "This platform provides an excellent opportunity to put this recommendation into action."

Several potential interventions have shown promise in the laboratory and in animal studies on non-human primates, but none has yet been fully and formally tested for efficacy and safety in humans with Ebola. Led by Dr Peter Horby of the Centre for Tropical Medicine and Global Health at the University of Oxford and ISARIC, this initiative will now allow such

treatments to be assessed rapidly in patients so that those proving safe and effective may be adopted for use as soon as possible.

Testing in 6 West African centres

The funding will be used to establish a number of sites where the potential treatments can be formally evaluated in patients with Ebola virus disease in a standardised format. MSF is currently responsible for the treatment of patients with Ebola in six centres in West Africa and will assess the suitability of these centres as sites for the trials, ensuring that activities do not adversely affect the delivery of patient care, staff welfare and safety, and centre operations. The WHO will then facilitate access to the treatments, and rapid ethical review and implementation of the trials in affected countries.

Several candidate treatments are under consideration and a group of independent experts appointed by WHO will recommend which to prioritise based on factors such as which is likely to work best, availability, the ability to safely administer the intervention in treatment centre settings, and the capacity for manufacture to a useful scale. A number of pharmaceutical companies including Mapp Biopharmaceutical, Tekmira, and Sarepta are collaborating in the initiative and are providing key data on efficacy, safety, and production abilities for a number of potential treatments.

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Dr Piero Olliaro, TDR Intervention and Implementation Research

Communities and national agencies involved

While awaiting the WHO recommendation on the products to be tested first, the consortium will begin immediately to work with counterparts in affected countries to assess the suitability of potential sites, and establish the infrastructure, staffing and systems for the clinical trials platform. During this phase investigators will also work with affected communities, local organisations, and national ethical and regulatory agencies to determine the best possible study design that can be conducted under the circumstances of the epidemic.

Piero Olliaro, who leads TDR's implementation and intervention research, is a member of the platform at Oxford. He says, "The data will be openly available, an important step for ongoing investigations and something we are advocating on a broader scale in the scientific community. The Wellcome Trust's financial commitment is an important and valuable contribution to helping us find new treatments for this terrible outbreak."

For more information, please contact

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