

Trials of novel Ebola drugs to be fast-tracked in West Africa

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Potential new treatments for Ebola 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 against the disease that has already led to over 2,600 deaths.

The new initiative will allow candidate Ebola treatments to be assessed rapidly in patients, so that those proving safe and effective may be adopted for use as soon as possible.

A £3.2 million grant from the Wellcome Trust will enable multiple

partners around the world to quickly establish [clinical trials](#) at existing Ebola treatment centres.

The collaboration is led by Dr Peter Horby of the Centre for Tropical Medicine and Global Health at the University of Oxford and ISARIC, the International Severe Acute Respiratory and Emerging Infection Consortium.

'The Ebola situation in West Africa is an ongoing tragedy of immense proportions and we urgently need to know whether any of these investigational treatments can save lives,' says Dr Horby of the University of Oxford. 'In essence we need straightforward clinical trials, as for any drug for any disease, but new ways of working will be needed to provide rapid and reliable answers in perhaps the most challenging outbreak we have ever encountered.'

'Effective drugs will not only help individual patients but will also increase community confidence in the value of Ebola treatment centres, thereby improving our chances of controlling the outbreak through isolation and treatment of infectious patients.'

The funding will be used to establish a clinical trials platform involving the partners in the consortium and a number of sites in West Africa where treatments can be formally evaluated in patients with Ebola.

Together with partner health authorities in affected countries, the consortium will assess which sites are suited 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.

Partners in the consortium include the University of Oxford, ISARIC,

Médecins Sans Frontières (MSF), the World Health Organisation (WHO), Institut Pasteur, Institut Pasteur de Dakar, Fondation Mérieux and the Global Health Network.

The unprecedented outbreak of the Ebola virus 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 unregistered investigational treatments in people with Ebola virus disease.

Several potential interventions have shown promise in the laboratory, in animal studies on non-human primates, and in a small number of cases of compassionate intervention – but none has yet been tested for efficacy and safety in humans with Ebola. Any new drug needs to be evaluated within the rigorous settings of a clinical trial to assess whether it is doing more harm or good.

The precise details of how the trials will be carried out are being discussed with all stakeholders, and, most importantly, the local communities that would be involved. It is possible that trials will involve both randomised and non-randomised arms.

Several candidate treatments for Ebola are under consideration. A group of independent experts appointed by WHO will recommend which to prioritise based on factors such as which is likely to work best, the availability of the intervention, 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, Sarepta, and Tekmira are collaborating in the initiative and are providing key data on efficacy, safety, and production

abilities for a number of potential treatments.

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 of 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 for the trials that can be achieved under the circumstances of the epidemic.

This latest announcement is part of a series of rapid responses to tackle the public health emergency in West Africa, involving unparalleled international collaboration across the public, private and not-for-profit sectors. This includes a UK safety trial of a candidate Ebola vaccine which began at Oxford University last week.

Dr Jeremy Farrar, Director of the Wellcome Trust, said: 'It is a huge challenge to carry out clinical trials under such difficult conditions, but ultimately this is the only way we will ever find out whether any new Ebola treatments actually work. What's more, rapid trials, followed by large-scale manufacturing and distribution of any effective treatments, might produce medicines that could be used in this epidemic. The Wellcome Trust funding will allow these trials to happen quickly, and in an ethically and scientifically robust setting.'

Dr Marie-Paule Kieny, Assistant Director-General of WHO's Health Systems and Innovation, said: 'In order to benefit the broader community, WHO confirmed that it is ethical to offer unregistered therapeutic interventions to Ebola patients in the context of the current outbreak, while ensuring that as much information on their safety and efficacy is collected as possible. This platform provides an excellent

opportunity to put this recommendation into action.'

Dr Piero Olliaro, Senior Research Manager at TDR, the Special Programme for Research and Training in Tropical Diseases at WHO, said: 'This clinical trials platform will make it possible to rapidly test potential treatments in the affected West African countries. The data will be openly available, an important step for ongoing scientific investigations. The Wellcome Trust's financial commitment is an important and valuable contribution to helping us find new treatments for this terrible outbreak.'

Provided by Oxford University

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