

Press Release

European response to outbreak with novel Coronavirus in China

Antwerp, Belgium – 21 January 2020.

On 31 December 2019, the World Health Organisation (WHO) China office was informed of patients infected with pneumonia of unknown aetiology in Wuhan, China¹. Evidence suggested that the initial cluster of cases was related to exposure in a seafood market in Wuhan (closed 1 January 2020). In the three weeks since that notification, numbers have escalated to 222 confirmed cases (218 in China, 2 in Thailand, 1 in Japan, and 1 in South Korea). There have been six deaths related to the outbreak, of which the most recent case was announced on the 21st of January. Of note is that 15 healthcare workers have become infected, one of whom is critically ill. The cause of this outbreak has been identified as a novel Coronavirus (2019-nCoV). The first genetic sequence of the 2019-nCoV was shared on 12 January, aiding the rapid development of diagnostic kits, instrumental for adequate outbreak preparedness and response. Today, WHO confirmed clear evidence of human-to-human transmission of the 2019-nCoV with some suggestion of sustained transmission. The start of Lunar New Year holiday on 25 January will involve significant population movement within China and cross-border, exacerbating potential for spread of the virus. On 22 January, the Director General of the WHO, Dr Tedros Ghebreyesus, will convene and Emergency Committee under the International Health Regulations to ascertain whether the 2019-nCoV outbreak constitutes a Public Health Emergency of International Concern.

Although the exact extend of the outbreak remains to be established, these events have triggered an assessment of the level of preparedness of clinical research networks in Europe for possible deployment in case of further spread. The European Commission has invested in the development of these European clinical networks over many years to ensure preparedness for delivering clinical research in response to new infectious disease outbreaks. These networks include the Platform for European Preparedness Against (Re-) emerging Epidemics (PREPARE), and the IMI-funded projects COMBACTE and VALUE-Dx, and many others, currently collaborating in the European Clinical Research Alliance for Infectious Diseases

¹ WHO Disease outbreak news: 5 January 2020 Pneumonia of unknown cause – China

(<u>ECRAID</u>). With the support of funding provided by the European Commission, Europe is now much better prepared to speed up the processes of clinical research to the extent that findings are generated in real time to inform practice when it is most useful, in the midst of an outbreak, rather than once the threat has passed.

How PREPARE is responding:

PREPARE is checking its readiness to be able to respond in the event that the 2019-nCoV outbreak spreads to Europe. These preparations are proportionate to the current relatively low risk for European citizens. PREPARE is currently operating in outbreak response mode 1 (preparedness), the first of three response modes. Further information on PREPARE's response modes and implications can be found here. Activities are planned and conducted in close collaboration with our partner networks and the European Commission and in alignment with those of WHO and ECDC. The preparations made by PREPARE as part of its Mode 1 response are briefly summarised below.

A paper and electronic case record form (CRF) has been developed by WHO and ISARIC. PREPARE will circulate this CRF among its hospital network, including more than 1,000 hospitals in 42 European countries. This CRF will allow for standardised clinical data collection, even if a small number of travelers would be diagnosed in Europe. Such type of standardised data collection can contribute to our understanding of a new disease. Clinical observational and intervention studies are currently being discussed by WHO. PREPARE will align with these protocols and can rapidly activate its network of hospitals and primary care physicians if required. PREPARE recently conducted studies in patients with acute lower respiratory tract infections in primary care and hospitals in Europe; these protocols can be re-activated very rapidly. For Intensive Care Units, an ongoing global study (REMAP-CAP), initiated by PREPARE, was set up specifically for delivering a clinical research response in case of a pandemic affecting severely ill patients. Currently, the REMAP-CAP investigators are discussing how to escalate the trial (e.g. adding more countries, evaluating existing or novel treatments). As part of our mode 1-preparedness activities, we are assessing the operational readiness for re-activation. PREPARE has access to a network of more than 900 labs in 41 European countries. PREPARE is developing a questionnaire to assess the capacity and capability of these diagnostic labs to detect the new coronavirus. Should PREPARE need to initiate large clinical studies, our first line diagnostic labs should be able to detect the 2019-nCoV. This is done in alignment with a similar initiative at the level of national reference centres, coordinated by the European Centre for Disease Prevention and Control (ECDC), preparing for the ability to detect new coronavirus infections in travelers.

The standing PREPARE Outbreak Mode Committee (Prof. Marion Koopmans of the Erasmus Medical Center in Rotterdam, Prof. Menno de Jong of the University of Amsterdam, Prof. Peter Horby of the University of Oxford, and Prof. Herman Goossens of the University of Antwerp) continue to follow the events closely to ensure PREPARE's clinical research response remains aligned with the risk to health and security of European citizens.

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About PREPARE

PREPARE is funded by the European Commission (2014 – 2021), to establish a European clinical research network covering primary care and hospital care in all EU Member States. Our response to severe outbreaks of infectious diseases is often delayed, isolated, and fragmented. PREPARE implemented large-scale clinical studies to build a European infrastructure for rapid clinical research responses in the face of new infectious disease threats. These clinical studies in interepidemic periods will train PREPARE in mounting a rapid, coordinated deployment of Europe's clinical investigators. PREPARE is coordinated from the University of Antwerp in Belgium.



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