WHO R&D Blueprint

novel Coronavirus

Outline of designs for experimental therapeutics

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R&D Blueprint

Powering research to prevent epidemics
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Participants

Members of the R&D Blueprint SAG

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WHO Secretariat

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Agenda items

1. Overview of emerging data on disease epidemiology
2. Identification of research priorities and a collaborative process to offer support -if requested- to the national authorities in China and elsewhere.
3. What is known and what the potential research priorities should be regarding:
   o Diagnostics – individual, population sero-surveys and sequence
   o Therapeutic candidates
   o Vaccine candidates
   o Data, Sharing, Information Flow
4. Next steps including considerations of potential spread scenarios vis a vis research priorities

Overview of the epidemiological situation and measures implemented to date

1. A total of 198 nCoV cases were reported in China, including 139 additional nCoV cases were reported over the weekend (136 in Wuhan, 2 in Beijing, 1 in Guangdong). Not all identified cases have a link with the Wuhan Seafood Market. Date of symptoms onset ranges from 8 Dec 2019 to 12 Jan 2020. 2 additional cases detected in Shanghai were reported during the call.
2. Of the 198 cases reported, 43 were reported as severely ill, 9 were reported as being in critical condition, while the remaining patients are in stable condition. 3 deaths have been reported.
3. All reported cases are adults (youngest being 25, oldest being 89). No children were reported to be infected so far.
4. There is evidence of human to human transmission reported in family clusters. 163 close contacts are being closely monitored. However, no healthcare workers and no nosocomial transmission have been reported to be infected so far.
Epidemiological studies, like household transmission study or occupational-based transmission study, would be needed to better assess the extent of human to human transmission and would require validated serological assays. The possibility of a foodborne event is also being considered.

5. 1 exported case has been reported in Japan. 2 exported cases – unrelated – have been reported in Thailand. 1 exported case has been reported in South Korea. None of them have reported contacts with the Wuhan Seafood Market.

6. WHO published preliminary guidance (e.g. early detection, clinical case management) and has activated various networks of experts (e.g. modelling, lab, risk communications).

7. WHO continues to monitor the situation closely and, together with its partners, is ready to provide technical support to China to investigate and respond to this outbreak. WHO does not recommend any specific measures for travelers, although participants noted that several countries have adopted exit and entry screening procedures.

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**Summary of the Deliberations**

• SAG members encouraged that pre-publication of results of public health importance should be the norm and that authors should be encourage to share information with WHO as appropriate. This norm was built in the ICJME policy

**Case Investigation**

• Regarding optimized clinical care, the network of clinicians has held teleconferences and agreed that the SPRING SARI tools can be offered to China and neighboring countries to promote a standardized approach for clinical data collection and analysis. Through that process, a nCoV case report form has been finalized, has been used in China, and will be advertised through the WHO website. The guidances are being translated to Chinese and the group of experts remains ready to provide trainings as requested. Through that process, a protocol for optimized supportive care is being developed, associated with an essential list of medicines and supply, to harmonize treatment guidelines and to planning for clinical trials.

• WHO has made available some preliminary guidance on the web. The coronavirus website is live ([here](https://www.who.int/)

**Diagnostics**

• While initial diagnosis was based on genome sequencing, now several PCR assays have been developed by multiple groups (e.g. EVAg, Univ. of Hong Kong, China CDC, Shanghai CDC). WHO has published testing protocols and preliminary guidance for testing to ensure coherence among the various testing approaches,
and is working with partners to evaluate the quality of existing assays and to make sure reference materials for testing is made available for at-risk countries.

- General approach to declare a confirmed case is to have 2 different samples of a same patient being positive for at least 2 gene targets.
- 11 separate sequences have now been released by the Chinese authorities. Sequences from the exported cases are also available. All sequences are available through GISAID. WHO will be facilitating any request on physical sample sharing from countries building on existing mechanisms.
- Chinese authorities have intensified their surveillance and are also actively looking at cases outside of Wuhan. Investigations are also underway to better assess the source and extent of the outbreak.

**Experimental Therapeutics and Vaccines**

- SAG members noted that a randomized controlled trial was initiated in Wuhan to assess the effect of lopinavir/ritonavir with IFN-β1b, and that trial material from the MIRACLE trial – that aimed to assess the same treatment for MERS-CoV in Saudi Arabia - was shared to support the initiation of the trial.
- WHO, with support from CEPI and US HHS, has shared with SAG members a draft pipeline of investigational therapeutics and vaccines against coronaviruses that could be granted access to under research protocol, as well as guidance on clinical trials to evaluate vaccine and treatments adjusted from the preliminary guidance on MERS-CoV.
- WHO will now discuss with the WG preliminary steps required to move forward investigational vaccines and treatments for clinical trials. The WHO regulatory team has also initiated interactions with the relevant NRAs to discuss those preliminary steps.
- WHO is establishing 2 separate working group to adjust existing evidence-based framework to transparently select therapeutics and vaccines to move forward to evaluation and to provide a prioritization list of candidates to evaluate therapeutics and vaccines that could be relevant to this novel coronavirus.
- WHO is establishing another working group to move forward the development of study protocols to evaluate investigational treatments.

**Next steps and recommendations**

The SAG welcomed efforts to use standardized approaches for case investigation and clinical characterization.

The WHO R&D Blueprint to convene its working group experts groups and proceed with the implementation of the actions proposed above

WHO will update the SAG members when relevant and SAG members were invited to provide information to the WHO Secretariat when relevant.