Information note on sample sharing, biobanking and material transfer agreements

A prompt response to a public health emergency, including the research response, can depend upon being able to access and move relevant samples and data from one place to another. Such transfers can be important for clinical reasons, such as for diagnosis, and for public health purposes, such as for pathogen characterisation studies. They can also be important for the development of countermeasures both in the short and longer term. As a result, access to, and the movement of, these samples and data needs to be as simple and transparent as possible, whilst protecting the interests of their owners.

The EVD PHEIC was unprecedented in scale, and has generated a great number and variety of biological samples. Such samples constitute a precious, non-renewable resource, and afford a unique opportunity to study a range of samples gathered from a large population over a wide geographic area and over a prolonged period of time, including those to be taken in the future from prospective follow-up of cohorts of survivors. To help maximise the public health benefit derived from these samples, WHO is holding a series of informal consultations on biobanking:

- An initial consultation, in May 2015, brought together key international partners to identify needs associated with the storage and use of samples, explored options for short-term arrangements needed to safely and securely store the samples during the PHEIC as well as longer-term arrangements, highlighting the importance of guiding principles, governance, ethics and integration into future research and public health arrangements.
- A second informal consultation, in August 2015, focused on the needs of the countries in West Africa – in particular capacity building in terms of regional cooperation, biobanking in an African context, as well as practical considerations such as requirements for facilities, identifying valuable samples, ethical oversight and arrangements for transferring samples.
- A third round of consultations is planned for the first quarter of 2017 and will translate lessons learned from the EVD and zika PHEIC’s into more generalised lessons to help strengthen preparedness against the next public health emergency. It will distill tools and resources drawn from a range of R&D Blueprint consultations, including guiding principles, governance and ethics oversight, and material transfer agreements (MTAs).

Lessons learned during the EVD PHEIC on the importance of having appropriate MTAs in place quickly were reinforced by the challenges of moving samples during the early stages of the zika-related PHEIC. More generally, increasing awareness as to the potential value of certain samples or data has increased the demand for adequate protections. MTAs can play an important role in enabling transfers and subsequent use by the recipient, whilst protecting the interests of the transferee. There is a clear need for scalable, sustainable approaches to build the necessary capacity, especially for transfers in which WHO is not directly involved. WHO has been an active partner in a series of meetings organised by the Wellcome Trust on these issues. A January 2016 meeting explored in more detail the tools for biobanking discussed during the 2015 WHO informal consultations. A follow up meeting in May 2016 specifically addressed MTAs. In partnership with the Pasteur Institute and in cooperation with the Wellcome Trust, the WHO will hold an informal consultation in Paris in December to explore options and practices in real-world MTAs for addressing key issues in a public health emergency context, such as sample ownership, benefit sharing, and intellectual property. A better understanding of these issues will enable WHO to explore opportunities for strengthening capacity to develop these important agreements.

Taken together these consultations and resources provide a firm foundation on which WHO could consider developing a policy statement on sample sharing in public health emergencies.