14.3 Smallpox eradication: destruction of variola virus stocks

Contents

In focus

The Assembly will consider A69/23 which

- summarizes the conclusions of the Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox, which met in Geneva at the end of June 2015;
- reports on the WHO's biosafety inspections of the two variola virus repositories in 2014–2015;
- summarizes the work being carried out on the operational framework for access to WHO's smallpox vaccine stockpile; and
- reports on the conclusions of the WHO Advisory Committee on Variola Virus Research (Geneva, 12 and 13 January 2016).

The Advisory Group concluded "that the risk of the re-emergence of smallpox has changed and that there is a need to update preparedness efforts and to adapt research frameworks". This will be quite controversial as there is a widely held view, including among many experts, that the remaining stocks should be destroyed.

The record of EB discussion of this item is at PSR7.

Background

The proposed destruction of remaining variola virus stocks is a recurring item on the WHA agenda. For a summary of this history see PHM comment prepared for WHA67 here.

This item was considered at EB134, informed by EB134/34 (Jan 2014) and again at WHA67 (May 2014), informed by A67/37 (a revision of EB134/34 following the debate within the Board). The focus of discussion was again whether to set a timetable for the destruction of remaining variola stocks. A67/37 provides a summary of previous discussions and decisions regarding the variola stockpile.

There was some concern expressed at the Board in Jan 2014 (EB134) regarding modern biosynthetic technologies and the possibility of synthesising the virus from the known

genome sequence and the DG indicated that she proposed to convene an expert group to advise on this possibility. See official record of discussion at WHA67: WHA67/2014/REC/3.

The Independent Advisory Group met in June 2015; their deliberations were informed by the findings of a Scientific Working Group, convened by the Secretariat in April 2015. The key conclusions and observations of the IAG include:

1. the risk of smallpox re-emergence has increased with the low cost and widespread availability of technology to synthesize genomes;
2. the WHO recommendations concerning synthesis and use of variola virus DNA fragments should be revised urgently (see page 12 for more detail);
3. MS should amend national public health laws so as to provide legal backing for WHO's recommendations concerning the distribution, handling and synthesis of variola virus DNA;
4. if the last stocks of the variola virus had been destroyed in 1996 as originally mandated the risk of synthesis would not arise because the virus had not been sequenced at that time;
5. if there is a refusal to destroy the variola virus, it is unlikely that any dangerous pathogens would be destroyed following eradication in the future;
6. in the event of an outbreak in a remote location "it would be beneficial to have a reference standard against which to measure a circulating virus" to reduce the risk associated with a delay in diagnosis; (see discussion page 9); and
7. consideration should be given to expanding the number of research sites and developing further expertise at the global level (no consensus on these two issues).

A69/23 advises that WHO biosafety inspection teams visited and inspected the containment facilities at the two WHO collaborating centres (Koltsovo, Novosibirsk Region, Russian Federation) and the Centers for Disease Control and Prevention (Atlanta, Georgia, United States of America), in December 2014 and May 2015 respectively. The reports of these biosafety inspections are under preparation, currently pending the submission of self-assessment reports and supplementary information by the repositories to WHO. Once finalized, they will be made available on the WHO website (but NYP).

PHM comment

The reports of the SWG and the IAG are useful.

It is apparent that the risk of smallpox re-emergence has increased with the low cost and widespread availability of technology to synthesize genomes. (It is ironic that if the last stocks of the variola virus had been destroyed in 1996 as originally mandated the risk of synthesis would not arise because the virus had not been sequenced at that time.)

The recommendations regarding the revision of the guidelines under the IHRs appear sensible as does the enforcement of these guidelines through national public health laws.

It appears that there was a view in the IAG to the effect that destruction of remaining stocks could lead to a delay in diagnosis in the event of an outbreak in a remote area. One corollary of this view was that the number of research sites (with variola stocks) should be expanded

so that reference materials for confirmation of the diagnosis could be made available more rapidly. This position appears to argue for increasing the risk (more sites) in order to decrease the risk (more rapid diagnosis).

PHM's position has been that WHO should proceed to the final destruction of the remaining stocks of variola virus. The only argument for not proceeding turns on the need for reference material for more rapid diagnosis. This argument needs to be tested more robustly in both technical and policy terms.

Notes of discussion at WHA69