

WHO Advisory Committee on Variola Virus Research

Report of the Thirteenth Meeting

Geneva, Switzerland
31 October–1 November 2011



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Executive summary

The work done under supervision of the variola virus research programme was summarized and presented to the WHO Advisory Committee on Variola Virus Research. It may be summarized as follows.

The Committee recalled the provisions for research approved by the World Health Assembly in resolution WHA60.1 that "*authorization was granted to permit essential research for global public-health purposes, including further international research into antiviral agents and improved and safer vaccines*".

The Committee received reports from the two authorized repositories of variola virus (VECTOR, in the Russian Federation, and the Centers for Disease Control and Prevention, in the United States of America) on the virus collection that they hold.

All WHO's archives of the Smallpox Eradication Programme have been digitized and uploaded into a dedicated database. Plans are in place to make them available on the Internet.

The Committee noted that two excellent drug candidates (ST-246[®] and CMX001) were in advanced stages of development and that two live attenuated smallpox vaccines showed good safety profiles in human beings and protected against disease induced by several orthopoxviruses in animal models. PCR-based diagnostic tests developed by researchers in the variola virus repositories in the Russian Federation and the United States of America were accurate and sensitive; they could detect variola virus DNA and distinguish it from DNA from other orthopoxviruses.

The Committee agreed to develop the smallpox laboratory network further in collaboration and coordination with the Emerging and Dangerous Pathogens Laboratory Network recently launched by WHO.

Remaining objectives of the research programme were to improve the reproducibility of the non-human primate model for variola virus infection so that additional data on the effectiveness of antiviral agents and vaccines could be generated. Such data would help regulatory agencies to have greater confidence in the effectiveness of these drugs and vaccines against variola virus and therefore help their progress to licensure. The Committee recommended continuation of this work.

Planning for the WHO biosafety inspection visits to the containment facilities in the Russian Federation and the United States of America in mid-2012 is under way. The European Committee for Standardization's Laboratory biorisk management standard, CWA 15793:2008, provides the framework for the forthcoming inspection.

The Committee recommended that the Ad Hoc Committee on Orthopoxviruses should be reconvened to discuss an emergency response to a possible future outbreak of smallpox.

The Committee was informed that the membership of the scientific subcommittee had been renewed.

1. Report from the WHO Secretariat

- 1.1. The WHO Advisory Committee on Variola Virus Research met on 31 October and 1 November 2011 with Professor G.L. Smith as Chairman and Mr D. Bramley as Rapporteur.
- 1.2. Dr K. Fukuda, Assistant Director-General for Health Security and Environment, welcomed participants on behalf of WHO. He recalled the appreciation of the work of the Committee and its regular reports expressed at the Sixty-fourth World Health Assembly in May 2011. The Health Assembly had welcomed progress with the archive project and noted the developments in vaccine stockpiling. Dr Fukuda stressed the importance of developing standard operating procedures for the use of smallpox vaccines in recipient countries. During the influenza A (H1N1) pandemic, because of logistical and legal issues, there were notable challenges in moving stocks of vaccines rapidly to the places they were needed.
- 1.3. Dr Fukuda also recalled the World Health Assembly's appreciation of the development of the network of smallpox diagnostic laboratories in the context of surveillance. In decision WHA64(11), the Health Assembly strongly reaffirmed previous decisions that the variola virus stocks should be destroyed, and agreed that a new date for the destruction should be fixed, and decided to include a substantive item on smallpox eradication: destruction of variola virus stocks on the provisional agenda of the Sixty-seventh World Health Assembly.
- 1.4. The work of the Committee and of the Advisory Group of Independent Experts (AGIES) had been recognized as crucial. Continuing work would be needed on developing the research agenda, stockpiling, and furthering the network of diagnostic laboratories.
- 1.5. Dr P. Formenty presented the report of the Secretariat. The report of the 12th meeting of the Committee had been considered by the Sixty-fourth World Health Assembly. He further summarized progress in developing the smallpox diagnostic laboratory network. An inspection of the two repositories, in the USA and in the Russian

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