



Advisory Group of Independent Experts to review the smallpox research programme (AGIES)

Report to the World Health Organization

Geneva, Switzerland

November 2013

PANDEMIC AND
EPIDEMIC DISEASES



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Organization**

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Acronyms and abbreviations

ACVVR	WHO Advisory Committee on Variola Virus Research
AGIES	Advisory Group of Independent Experts to review the smallpox research programme
CDC	Centers for Disease Control and Prevention, United States of America
DNA	Deoxyribonucleic acid
HIV	Human immunodeficiency virus
PCR	Polymerase chain reaction
SAGE	Strategic Advisory Group of Experts on Immunization
SRC VB VECTOR	The Russian Federation State Research Centre of virology and Biotechnology
USFDA	United States Food and Drug Administration
USA	United States of America
WHO	World Health Organization

Introduction

Background

In May 2007, the World Health Assembly in resolution WHA60.1 requested the Director-General of the World Health Organization (WHO) to undertake a major review, in 2010, of the state of the smallpox research and additional related research needed for global public health purposes. This review was undertaken to enable the Sixty-fourth World Health Assembly, in 2011, to reach consensus on the timing of the destruction of existing variola virus stocks.

In May 2011, the World Health Assembly in resolution WHA64.1 decided, however, to defer discussion of the destruction of the existing stocks of variola virus until the Sixty-seventh World Health Assembly in 2014.

Since 2011, the WHO smallpox secretariat has continued its work supported by the Advisory Committee on Variola Virus Research (ACVVR), which oversees all essential work with live variola virus for public health benefit (resolution WHA52.10). ACVVR held its 15th meeting in September 2013 in preparation for the discussions at the Sixty-seventh World Health Assembly. On 19 and 20 September 2013, an expert consultation was convened to review the evidence on smallpox vaccines and propose recommendations for the size and composition of the WHO smallpox vaccine stockpile to the Strategic Advisory Group of Experts (SAGE) on Immunization. The recommendations from the expert consultation will be considered during the SAGE meeting (Geneva, 5-7 November 2013). Other major activities have included the biennial inspections of the two repositories of variola virus (the Centers for Disease Control and Prevention in Atlanta, Georgia, USA, and the Russian Federation State Research Centre of Virology and Biotechnology (SRC VB VECTOR), Koltsovo, Novosibirsk Region, Russian Federation). The reports of the latest inspections, in 2012, are being posted on the WHO website.

The Advisory Group of Independent Experts to review the smallpox research programme (AGIES) was established by the Director-General of WHO in order to provide advice on matters of strategy and evaluation of the smallpox research programme, and to assess whether additional research with live variola virus is necessary from the public health perspective. Both the approach and the process of the AGIES have been welcomed by Member States, and would thus appear to be well suited for preparation for a historic discussion at the World Health Assembly. The recommendations made by AGIES would represent the Groups' scientific judgement.

Both the report of ACVVR's 15th meeting and the present report of AGIES, together with a report from the WHO Secretariat, will be submitted to the Executive Board of WHO for consideration at its 134th session in January 2014 and then to the Sixty-seventh World Health Assembly in May 2014.

Method of work of AGIES

The WHO Secretariat prepared a series of documents and scientific papers (see below for more details) that were made available to members of AGIES prior to its meeting, which was held on 5 and 6 November 2013 at WHO Headquarters in Geneva.

AGIES' members were asked to read, review and assess these documents and other publications found through searches of the scientific literature.

All members of AGIES discussed and reviewed the smallpox research programme at a meeting organized at WHO Headquarters on 5 and 6 November 2013. Discussions were held under five subheadings: diagnostics, genetics, vaccines, antiviral drugs and other therapeutics.

The members of AGIES prepared and reviewed the current report; it summarizes discussions on the value of smallpox research achievements to date and whether additional research work with live variola virus would be needed to ensure a sufficiently high standard of global public health security from a potential re-emergence of smallpox.

Documents reviewed by AGIES

The following documents were reviewed by members of AGIES:

- WHO Advisory Committee on Variola Virus Research, report of the twelfth meeting, 2010, Geneva, WHO.
- WHO Advisory Committee on Variola Virus Research, report of the thirteenth meeting, 2011, Geneva, WHO.
- WHO Advisory Committee on Variola Virus Research, report of the fourteenth meeting, 2012, Geneva, WHO.
- WHO Advisory Committee on Variola Virus Research, report of the fifteenth meeting, 2013, Geneva, WHO.
- Scientific Review of Variola Virus Research 1999-2010, December 2010, Geneva, WHO.
- Advisory Group of Independent Experts to review the smallpox research programme (AGIES), comments on the Scientific Review of Variola Virus Research 1999-2010,

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