

Destruction of Smallpox Virus Stocks

An Update for the Sixtieth World Health Assembly

May 2007

Introduction

This short update on destruction of smallpox virus stocks is prepared for the 60th World Health Assembly, beginning on 14 May 2007. Destruction of Smallpox Virus Stocks is Agenda Item 12.2 in Committee A. The Report by the Secretariat (Document A60/9) and a draft resolution (Document EB120.R8) will be considered. This update provides commentary and suggestions concerning the draft resolution (EB129.R8). It builds upon our prior publications, including our update of January 2007, available online at <http://www.smallpoxbiosafety.org/2007poxupdate1.pdf>.

Background: How the Draft Resolution Emerged

The draft before the 60th WHA was first discussed last year at the 59th WHA. Consensus could not be reached in 2006, leading to further consideration at the 120th Meeting of the Executive Board in January 2007. A text with fewer brackets emerged from that meeting, although compromises that have ramifications for smallpox biosafety were made.

60th WHA: Ensuring a Strong Resolution and a Prompt Destruction Date

Although the Executive Board meeting resulted in a diluted draft resolution, it still contains important elements that, if adopted, will contribute to prompt destruction of virus stocks and more effective oversight of research with those stocks in the interim before destruction. Also, some prejudicial resolution language has been inserted that should be deleted as it calls into question previous consensuses. Retaining this language could both delay destruction of the stocks and lead to unacceptable kinds of research with the live virus.

Thus, the task for the 60th WHA is defend the advances contained in the draft resolution while preventing new and inappropriate language from being approved that could have the result of weakening WHO control over smallpox virus research.

The Scope of Research

A general observation should be made that WHO Member States should pay very careful attention to any resolution language concerning the scope of permissible research involving smallpox virus stocks. The kinds of research that may be permitted by WHO, including by the Advisory Committee on Variola Virus Research, is defined by Resolution 52.10 diagnostics, antiviral drugs, and sequencing. Despite this strict limitation, the US has begun to defend its research by stating, "*scientists have yet to exhaust the research potential of live smallpox virus*". This statement misrepresents the scope of permissible research. WHA has never authorized, nor should it ever authorize, research until the smallpox virus has been "exhausted" of all possible studies. No organism is ever beyond the possibility of another study, thus, permitting research until the organism is "exhausted" would be the same thing as never actually destroying the virus. This would negate the goal of all WHO members, repeated in numerous resolutions, to destroy the live virus stocks. Thus, it is critical that any such misrepresentation of the scope of permissible research is rejected, and for all resolution language to clearly indicate that under no circumstances will research outside the bounds of Resolution 52.10 be permitted. The aim of the carefully crafted resolution was to ensure

that only research essential to public health purposes is allowed, given the risks involved in retaining and studying the deadly virus.

Commentary and Suggestions for the Resolution

A) Cleaning Up the Preambular Text

An “Irrevocable Event”

A preambular paragraph on page two describes the destruction of virus stocks as an “irrevocable event” and states that the decision must be made with great care. This paragraph should be deleted because its scientific assertion is technically doubtful and it calls into question prior WHA decisions.

On the issue of fact, it does not appear that destruction of the virus would be an irrevocable event. Synthetic biologists are increasingly able to assemble viable viruses from sequences in databases. For example, viable poliovirus, influenza, and SARS have been created from sequence data. The entire genome of many smallpox strains has been sequenced.

While Variola is a larger virus than those synthesized to date, it may be anticipated that the technical capability to synthesize Variola will soon exist. While it may be hoped that Variola will never be synthesized, it is a virtual certainty that it will be technically possible within a few years, making the statement asserted in the paragraph highly dubious.

The paragraph also calls into question prior WHA consensus decisions to fix dates to destroy the stocks (dates that Russia and US did not honor) by stating that the decision should be made with “great care”. This implies that the WHA has not acted with care in the past when it decided to destroy the virus (WHA 49.10 and WHA52.10). In fact, the WHA has repeatedly visited this issue with care and has repeatedly concluded that the stocks must be destroyed. Accordingly, the language calling WHA’s decisions into question should be deleted.

Reference to WHA55.16

The subsequent preambular paragraph makes reference to WHA Resolution 55.16 in response to deliberate or accidental release of biological (or chemical) agents. But no specific reason for this paragraph, or any specific linkage between the resolutions is articulated. Thus it cannot be discerned what meaning, if any, the mention of 55.16 has. The preambular paragraph should be deleted. If proponents of the paragraph insist upon its inclusion, they should articulate more specific links and reasons for its appearance, and those reasons should be carefully scrutinized.

The Question of Alleged Illicit Stocks: Should be Addressed in a Security Forum

The next preambular paragraph concerns the alleged existence of illicit stocks of smallpox virus outside the WHO repositories in Russia and the US. The US consistently mentions this issue as a reason for its retention of smallpox virus stocks.

In the first instance, it should be noted that the United States has never produced any verifiable evidence that any illicit stock of smallpox virus exists outside of the US and Russia. Thus, the allegations concerning illicit stocks are completely without documentation. It should also be noted that the most senior US officials have recently accused other countries of illicit biological activities and those accusations have turned out to be completely wrong.

At its core, in this preambular paragraph and in other places, the US is advancing a national security argument for its retention of smallpox virus stocks. For reasons we have explained in previous papers, the existence of illicit stocks, even if actually true, does not provide reason to retain stocks in the WHO repositories. Most pertinent is that the WHA is a health, and not a security, intergovernmental body. Curiously, the United States insists upon the security argument at the

WHA yet it has not advanced allegations of illicit smallpox stocks in the most pertinent intergovernmental security forum, the Biological and Toxin Weapons Convention (BWC).

WHA is the proper venue for consideration of public health aspects of smallpox virus stocks and it should formulate its decisions on that basis. National security arguments should be considered in their proper venue, the BWC (or another security venue). Accordingly, the entire issue of illicit stocks should go to another body and not be entertained by WHA and, accordingly, the preambular paragraph should be deleted.

Variola Virus and Efficacy Testing of Antivirals and the Animal Model

A subsequent preambular paragraph states categorically that live Variola virus will be needed to test antivirals and that it may also be needed for further studies to infect monkeys with the virus (the “animal model”). We have previously argued that due to many factors, including safety and the risks and length of time involved in drug development, that research with the live virus for antiviral drugs cannot now be considered essential research and, accordingly, should not be permitted and should not stand in the way of destruction of the stocks. This argument remains valid.

The preambular paragraph, however, omits important information and should be either clarified or deleted. The specific reason for the need for live smallpox virus in antiviral testing is not stated. It is, according to the US, for its domestic regulatory reasons. Because the research itself is dangerous and smallpox has been eradicated, however, the US “two animal rule” arguably should not apply to the unique situation of smallpox antivirals, if any actually approach licensure. Thus, the paragraph overstates the need for live virus by failing to explain the complexity of circumstances and that the need is driven by a Member State’s safety regulation. Also, the paragraph mentions a possible continued need for Variola virus in monkey studies; but is not balanced with the suggestion, made by WHO’s own experts, that monkey studies could utilize the much less dangerous monkeypox virus, rather than smallpox. Thus, the paragraph again overstates the case for retention of the stocks.

WHO Inspections and Security

As is customary, a following preambular paragraph makes reference to the important role that the WHO biosafety program plays in inspecting the repositories in the US and Russia. It should be noted, however, that WHO’s laboratory biosafety program is very small and has limited capabilities. In particular, it is unclear if WHO has the necessary experience and expertise to affirm the security of the smallpox virus stocks. Clarification should be sought from the Secretariat about the extent of WHO’s inspections (how many WHO employees, how long, any limitations on access, etc.) and, in particular, its capacity to certify security. The preambular paragraph may then be amended to encourage this important WHO role; but also to more accurately reflect the limitations in WHO’s actual capability to oversee the safety and security of the stocks.

B) Improving and Defending the Operational Paragraphs

Destruction Date: Setting the Stage for a Renewed Effort

Among the compromises made at the 120th Executive Board meeting was to delete language that would immediately set a destruction date for the virus stocks. This was because the US refused to accept one. Instead, the resolution calls for a “major review” of the smallpox stocks to be performed in 2009 or 2010. This major review should happen as soon as possible, certainly by 2009 if not next year, in 2008. A new destruction date can then be fixed in the resolution adopted upon the WHA’s major review and future efforts prior to the “major review” can focus on achieving that outcome.

Operational Paragraph 1

States that prior WHA resolutions concluded that the virus “should” be destroyed. In fact, prior WHA resolution went further, and fixed a destruction date (which the US and Russia refused to implement). Thus, this paragraph should use the stronger term “shall” in place of “should”.

Operational Subparagraph 2 (2)

Subparagraph (2(2)) mentions WHA Resolution 55.15 and its mandate for open and transparent research. 55.15 also set the limits of what types of essential research are to be permitted. When recalling 55.15 in the operational paragraphs, the limitations on the scope of permissible research should also be recalled.

Operational Paragraphs 3 and 4(1)

Paragraph 3 offers an option between the 63rd and 64th WHA for the major review. The sooner date is better, and even the 62nd WHA would be a better opportunity for the major review, given the seriousness of the situation. Similarly, 4(1) should read 2009 (or 2008 if it is possible to hold the major review at the 62nd WHA).

Operational Subparagraph 4 (5)

This is linked to the preambular paragraph on inspections. This operational subparagraph may need amendment in accordance with WHO's actual capabilities to ensure safety and security.

Operational Subparagraph 4(8)

This prohibition on genetic engineering is very important to help reduce the risks associated with retention of the stocks. This prohibition includes the genetic engineering of the smallpox virus itself, and of other viruses with smallpox genes. This subparagraph should appear in the final resolution. If it is changed at all, it should only be to strengthen it by also explicitly prohibiting the insertion of smallpox genes into other poxviruses and prohibiting the use of synthetic smallpox virus genes in genetic engineering experiments.¹

Operational Subparagraph 4(9)

The language of subparagraph 4 (9) concerning distribution of smallpox DNA could lead to confusion and serious problems that would allow unwelcome expansion of smallpox virus research. Current WHO rules require all transfers of DNA to be from the US or Russian repositories and only with the approval by WHO. (Russia does not report ever transferring DNA, while the US does.)

As currently written 4 (9) may be interpreted as radically altering those rules, because it refers to institutions other than the repositories holding and transferring smallpox DNA for non-diagnostic purposes, and to the recommendations of the Advisory Committee as determining their disposition. This is problematic because third party institutions should not be exchanging smallpox DNA and, while the Advisory Committee has a role, it cannot change the WHA-approved rules.

The confusing language could lead to the resolution being interpreted as permitting third parties to hold smallpox DNA collections, transfer them, and even to manufacture it from sequences, as has happened – without WHO approval - in the US in the Sandia National Laboratory experiments described in the reference in footnote one.

Accordingly, it is very important that 4 (9) be amended to ensure consistency with existing rules and to prevent loss of WHO control over smallpox through the presence and the exchange of smallpox DNA outside of the repository framework.

Operational Subparagraph 4(10)

A major problem in the past has been a lack of information about WHO's oversight of smallpox virus research. This subparagraph mandates an important new report on the research program. This subparagraph should remain and, if possible, be strengthened by adding language such as "each research project" to ensure that the research program is reported in detail and not generalities.

¹ See "Nuclear Weapons Lab Starts Research with Smallpox Genes" in our January 2007 newsletter, URL: <http://www.smallpoxbiosafety.org/news220107.html>