Title: Discovery of Smallpox in U.S. Lab

Activities: Determine policy for long-term sample storage; Long-term storage of samples

Stakeholders: National and subnational health authorities; World Health Organization; National and subnational law enforcement;

Phases: Surveillance and preparedness; Detection; Intervention; Post-intervention & recovery

Years: 2014

Countries: United States

Agent: Smallpox (variola virus)

Case study prepared by: Hannah Todd, July 4, 2020

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Smallpox, also known as variola, was responsible for around 300 million deaths in the 20th century.[1] This serious disease was eradicated in 1980 after a worldwide vaccination campaign. Today, small quantities of the virus are still stored in two official World Health Organization (WHO)-designated research laboratories: Centers for Disease Control and Prevention (CDC) in Atlanta, GA and the State Research Center of Virology and Biotechnology in Novosibirsk, Russia.[2] In July 2014, vials containing the virus were found in an old cold storage room of a Food and Drug Administration (FDA) laboratory, raising significant concern in the public health community.

On July 1, 2014, federal scientists were conducting clean-up and inventory of the FDA's laboratories on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland prior to its move to the White Oak campus in Silver Spring, MD.[3,4] In an old cold storage room, the scientists found six freeze-dried vials labeled as containing variola, along with 10 other vials with unclear labeling information.[5] In total, there were 12 boxes and 327 vials containing an

[1] WHO. Chapter 1: Smallpox: eradicating an ancient scourge in: Bugs, Drugs, & Smoke. Geneva, Switzerland: World Health Organization. 2011. https://www.who.int/about/bugs_drugs_smoke_chapter_1_smallpox.pdf?ua=1.
[2] NIAID. Smallpox. Updated 11 Dec 2014. https://www.niaid.nih.gov/diseases-conditions/smallpox.
[3] Kaiser J. Six vials of smallpox discovered in U.S. lab. Science. 8 Jul 2014. https://www.sciencemag.org/news/2014/07/six-vials-smallpox-discovered-us-lab.
[4] FDA. Report to the Commissioner: FDA Review of the 2014 Discovery of Vials Labeled 'Variola' and Other Vials Discovered in a FDA-Occupied Building on the NIH Campus. 13 Dec 2016. https://www.fda.gov/media/101811/download.
[5] Lupkin S. Vials of Smallpox Virus Found in Unapproved Maryland Lab. ABC News. 8 Jul 2014. https://abcnews.go.com/Health/vials-smallpox-virus-found-unapproved-maryland-lab/story?id=24468024.

array of pathogens associated with diseases like dengue and spotted fever.[6] The vials were thought to date back to the period of time between 1946 and 1964.[7] On the same day, the Associate Director of Research at the FDA and the NIH Select Agent Program Responsible Official transferred the vials to a biosafety level 2 laboratory. The NIH official then notified the director of CDC's Division of Select Agents and Toxins (DSAT). DSAT and the Federal Bureau of Investigation (FBI) commenced a joint investigation.

About a week later, a three-person CDC team flew the samples via government plane to Atlanta, Georgia for transfer to the CDC's biosafety level 4 lab. Overnight PCR testing by CDC confirmed the presence of variola virus DNA in the samples.[8] Moreover, signs of growth in tissue cultures suggested that the samples were viable. On February 24, 2015, the variola-containing vials, in addition to one containing Russian spring-summer encephalitis virus and nine with unidentified contents, were destroyed at the CDC under the supervision of WHO officials.[9]

The FDA further investigated this situation and noted several key findings and important corrective actions to prevent this from occurring again. Specifically, the security and inventory control of orphaned biological materials was inadequate and inappropriate. Policies and procedures must ensure that, in the event of an owner departing from the laboratory in question, the material is not forgotten. Second, the contents and use of the cold storage area were not being monitored, calling for clear designation of these responsibilities. As well, the FDA had failed to conduct a full inventory of its laboratories and associated spaces for smallpox-related biological agents upon smallpox eradication in 1980. Furthermore, they did not conduct a complete inventory in 2003 when the Federal Select Agent Program was enacted. A full inventory and periodic updates are critical to keeping a current inventory list. Other issues included the failure by the FDA to follow the CDC Select Agent Guidelines when transferring the sample to a high-containment facility, a delay between the discovery of the vials and notification of appropriate officials, and improper cold room storage practices. In general, this situation underscored the fact that individuals should be aware of and held accountable to standards for dealing with certain agents and/or toxins.

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[6] Dennis B & Sun LH. FDA found more than smallpox vials in storage room. Washington Post. 16 Jul 2014. https://www.washingtonpost.com/national/health-science/fda-found-more-than-smallpox-vials-in-storage-room/2014/07/16/850d4b12-0d22-11e4-8341-b8072b1e7348_story.html.

[7] CDC. Media Statement on Newly Discovered Smallpox Specimens. 8 Jul 2014. https://www.cdc.gov/media/releases/2014/s0708-NIH.html.

[8] Kaiser J. Six vials of smallpox discovered in U.S. lab. Science. 8 Jul 2014. https://www.sciencemag.org/news/2014/07/six-vials-smallpox-discovered-us-lab.

[9] FDA. Report to the Commissioner: FDA Review of the 2014 Discovery of Vials Labeled 'Variola' and Other Vials Discovered in a FDA-Occupied Building on the NIH Campus. 13 Dec 2016. https://www.fda.gov/media/101811/download.

In July 2014, federal scientists found vials containing the virus known to cause smallpox in an old cold storage room of a Food and Drug Administration laboratory on the Bethesda campus of the National Institutes of Health. The researchers discovered these samples while conducting clean-up and inventory in the lab, highlighting critical issues with inventory and storage of dangerous agents. The threat of these samples was significant due to the agreement of the United States and Russia under the purview of the World Health Organization to only store the virus at two sites and the desire to ensure that smallpox remained eradicated.