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August 17, 2023

Via email

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of April 10, 2023, assigned #23-00984-FOIA, for: A copy of the title page and table of contents for each Smallpox response plan at CDC.

We located 14 pages of responsive records (14 pages released in full or part). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) 3 and 5. The foreseeable harm standard was considered when applying these redactions. Please note that we are releasing all 10 pages of an executive summary as a courtesy since it did not contain a cover sheet nor a table of contents.

EXEMPTION 3

Exemption 3 allows for the withholding of information prohibited from disclosure by another federal statute provided that one of two disjunctive requirements are met: the statute either (A)(i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (A)(ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld. Information withheld under this exemption was protected pursuant to 5 U.S.C. 552(b)(3) of the Act and 42 U.S.C. § 247d-6(b)(d) Strategic National Stockpile and security countermeasure procurements.

EXEMPTION 5

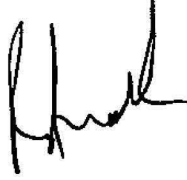
Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both pre-decisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both pre-decisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include titles from a table of content.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

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If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at <https://requests.publiclink.hhs.gov/App/Index.aspx>. Your appeal must be electronically transmitted by November 15, 2023.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roger Andoh', with a stylized, cursive script.

Roger Andoh
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Enclosures

23-00984-FOIA

I. Executive Summary

In response to the potential use of biological agents against civilians, the federal government is upgrading plans for preparedness, readiness, and national defenses against bioterrorist weapons. The Centers for Disease Control and Prevention (CDC) has been designated as the lead agency for the national public health response to biological terrorism. Although smallpox was declared globally eradicated in 1980, there is concern that smallpox virus may exist outside the two WHO-designated repository laboratories, i.e. with groups that might use it as a bioweapon. A single case of smallpox is likely to represent a bioterrorism release and will require an immediate and coordinated public health, medical, and law enforcement response to control the outbreak and to protect the public from any additional release.

This updated *Smallpox Response Plan and Guidelines* incorporates, and extends, many of the concepts and approaches that were successfully employed 30 to 40 years ago to control smallpox outbreaks. These overall concepts for outbreak containment contributed greatly to the eventual global eradication of smallpox. Thus, while this document is an updated plan, many of the elements in the plan have been extensively and successfully utilized in prior decades. This document outlines the public health strategies that would guide the public health response to a smallpox emergency and many of the federal, state, and local public health activities that must be undertaken in a smallpox outbreak. This plan will continue to be updated to reflect changes in capacities and resources for responding to a smallpox emergency.

Smallpox

Variola virus, an orthopoxvirus, is the etiological agent of smallpox. The only known reservoir for the virus is humans; there are no known animal or insect reservoirs or vectors. The most frequent mode of transmission is person-to-person spread via direct deposit of infective droplets onto the nasal, oral, or pharyngeal mucosal membranes or in the alveoli of the lungs from close, face-to-face contact with an infectious individual. Indirect spread (not requiring face-to-face contact with an infectious individual) via fine-particle aerosols or fomites has been reported but is less common. Fine-particle aerosol spread appears to occur more in cases where a significant cough (which can generate fine-particle aerosols) is present in the first week of illness (when oropharyngeal viral shedding is typically highest).

Symptoms usually begin within 12 to 14 days (range 7 to 17) following the exposure of a susceptible person to the virus. The initial symptoms usually consist of high fever, malaise, and prostration with severe headache and backache. This prodromal stage of the disease is followed by the appearance of a maculopapular rash (eruptive stage) that progresses to papules (1 to 2 days after appearance of rash), vesicles (~ 4th to 5th day), pustules (by ~ 7th day), and finally scab lesions (~ 14th day). The rash generally appears first on the oral mucosa, face, and forearms and then spreads to the trunk and legs. Lesions are also seen on the palms of the hands and soles of the feet. The skin lesions of smallpox are deeply embedded in the dermis and

feel like firm, round objects under the skin. As the skin lesions heal and the scabs separate, pitted scarring develops. Smallpox patients are most infectious during the first week of the rash when the oral mucosa lesions ulcerate and release the large amounts of virus into the saliva and are less infectious once the lesions have scabbed over. A patient is no longer infectious once all the scabs have separated from the skin (usually 3 to 4 weeks after the onset of the rash). Historically, the overall mortality rate associated with smallpox was approximately 30%. Other less common but more severe forms of smallpox include: 1) flat-type smallpox with a mortality rate >96%, characterized by severe toxemia and flat, velvety, confluent lesions that do not progress to the pustular stage and 2) hemorrhagic-type smallpox with a mortality rate >98%, characterized by severe prodromal symptoms, toxemia, and a hemorrhagic rash. (See Annex 1 – Overview of Smallpox and Medical Care of Smallpox Patients for a more complete discussion of smallpox.)

Smallpox Vaccine

Smallpox vaccine, a live-virus vaccine made from vaccinia virus, is highly effective at inducing immunity against smallpox prior to exposure. If administered within 3 days after exposure to smallpox virus, it may prevent disease, or decrease the severity of disease and risk of death. Smallpox vaccine production ceased in the early 1980s and current supplies of smallpox vaccine are limited. However, recent studies have demonstrated that vaccines stored in the 1960s and 70s still have excellent potency, even when diluted (1:5). New cell-culture-grown smallpox vaccines will become available for use within the next 1 to 2 years. The US stockpile contains enough vaccine to vaccinate the entire US population.

Although smallpox vaccine is considered a safe vaccine, postvaccination adverse events can occur. These adverse events and their rates as determined in a 1968 10-state survey include: 1) inadvertent inoculation (529.2/million primary vaccinations), 2) generalized vaccinia (241.5/million primary vaccinations), 3) eczema vaccinatum (38.5/million vaccinations), 4) progressive vaccinia (1.5/million primary vaccinations), and 5) postvaccinal encephalitis (12.3/million primary vaccinations). Death also occurred in about one per million primary vaccinations, usually as a result of progressive vaccinia, postvaccinal encephalitis, or severe eczema vaccinatum.

Several groups have been identified as having a higher risk for developing postvaccination complications. These persons are advised not to receive smallpox vaccination unless they have been exposed or are at high risk of exposure to smallpox virus. These include 1) persons with atopic dermatitis or eczema (including a history of atopic dermatitis or eczema), 2) persons with acute, active, or exfoliative skin conditions, 3) persons with altered immune states (e.g., HIV, AIDS, leukemia, lymphoma, immunosuppressive drugs, etc.), 4) pregnant and breast-feeding women, 5) children younger than age 1 year, 6) persons who have a serious allergy to any component of the vaccine. During an outbreak, additional public health guidance will be circulated on priority groups for vaccination.

Vaccinia Immune Globulin (VIG) is used to treat certain vaccine adverse reactions and is available through the CDC. Supplies of VIG may be limited in a post event setting.

CDC Smallpox Response Plan and Guidelines

This Smallpox Response Plan is a working document that is updated regularly. Because state and local health officials are at the heart of an effective response to a smallpox emergency, their input will be continually sought as additional revisions are made. The plan is, however, operational and would be implemented should a smallpox emergency occur. Federal officials may implement all or portions of the CDC Smallpox Response Plan under the “Criteria for Implementation” that are found in the next section.

This document is organized into multiple sections. These sections outline criteria for smallpox response plan implementation, notification procedures for suspected cases, CDC and state and local responsibilities and activities (including some that should take place prior to a smallpox emergency), and CDC vaccine and personnel mobilization. This plan also provides guidelines and annexes to assist federal, state, and local health officials in implementing the specific activities that are essential for the management of a smallpox emergency. The general response strategy and priority activities are outlined below.

General Strategy and Priority Activities for Smallpox Outbreak Containment

As this plan states, the first and foremost public health priority during a smallpox outbreak is control of the epidemic. The following activities would be essential to accomplishing this goal.

Surveillance and Containment

The key to any strategy to control a smallpox outbreak is to:

- 1) Identify and isolate smallpox cases to prevent further disease spread,**
- 2) Identify, vaccinate, and monitor contacts of cases and household contacts of contacts, to prevent secondary cases.**

This surveillance and containment strategy may be supplemented with large-scale vaccination in both affected and unaffected communities.

Vaccinating and monitoring contacts of cases and family contacts of contacts (Surveillance and Containment) will help to protect those at the greatest risk for contracting the disease as well as form a buffer of immune individuals to prevent the spread of disease. The surveillance containment strategy also efficiently uses public health resources to control an outbreak. When the number of potential

contacts of cases is too great to efficiently trace and monitor, large-scale vaccination in potentially exposed communities may become more efficient, although cases will still have to be identified and isolated. Large-scale vaccination might also be used in unaffected communities to protect against further spread of smallpox and additional releases, and to build the public's confidence in its protection and ability to return to normal activities.

Identification of Priority Groups

The following are considered high risk groups and should be prioritized for vaccination in a smallpox outbreak:

1. Face-to-face close contacts (≤ 6.5 feet or 2 meters) or household contacts to smallpox patients after the onset of the smallpox patient's fever.[¶]
2. Persons exposed to the initial release of the virus (if the release was discovered during the first generation of cases and vaccination may still provide benefit).
3. Household members (without contraindications to vaccination) of contacts to smallpox patients[†] (to protect household contacts should smallpox case contacts develop disease while under fever surveillance at home).
4. Persons involved in the direct medical care, public health evaluation,^{*} or transportation of confirmed or suspected smallpox patients.
5. Laboratory personnel involved in the collection and/or processing of clinical specimens from suspected or confirmed smallpox patients.
6. Other persons who have a high likelihood of exposure to infectious materials (e.g., personnel responsible for hospital laundry, waste disposal, and disinfection).
7. Personnel involved in contact tracing and vaccination, or quarantine/isolation or enforcement, or law-enforcement interviews of suspected smallpox patients.^{*}
8. Persons permitted to enter any facilities designated for the evaluation, treatment, or isolation of confirmed or suspected smallpox patients[†] (only essential personnel should be allowed to enter such facilities).
9. Persons present in a facility or conveyance with a smallpox case if fine-particle aerosol transmission was likely during the time the case was present (e.g. hemorrhagic smallpox case and/or case with active coughing).[§]

[¶] Although individuals with smallpox are not infectious until the onset of rash, vaccinating contacts from the time of the onset of fever helps provide a buffer and assures that contacts who may have been exposed at the early onset of rash, when the rash may have been faint and unrecognized, have been vaccinated.

^{*} Includes personnel whose public health activities involve direct patient contact such as case interviewing

[†] Household members of contacts who have contraindications to vaccination should be housed separately from the other vaccinated household members until the vaccination site scab has

separated (~ 2 weeks) to prevent inadvertent transmission of vaccinia virus. They should be housed separately from the contact until the incubation period for smallpox has passed and the contact is released from surveillance.

‡ Only personnel without contraindications to vaccination should be chosen for activities that would require vaccination for their protection. Personnel with contraindications should not perform duties that would place them at risk for smallpox exposure and should otherwise only be vaccinated if an exposure has already occurred.

§ Evaluation of the potential risk for aerosol transmission and initiation of vaccination for non-direct contacts will be done by CDC, state, and local public health personnel. The decision to offer vaccination to non-direct contacts of smallpox cases will be made jointly by federal and state health officials.

Additional Groups to Consider for Vaccination to Expand Response Capacities and Maintain Critical Community Services during an Outbreak

Once a smallpox outbreak is confirmed it is important to expand the number of vaccinated personnel to ensure sufficient staff to rapidly and safely control the outbreak. In addition, persons whose jobs place them at increased risk of being exposed to smallpox cases should also be offered vaccine. These persons would include healthcare workers, public health personnel, first responders, and law enforcement personnel as well as others indicated by the local situation.

Overview: Activities and Guidelines

This *Smallpox Response Plan and Guidelines* document outlines, and in some cases describes in detail, many of the pre- and postevent activities that need to be or would be undertaken in response to a smallpox emergency. These include:

Surveillance and Epidemiological Investigations:

- Pre-event rash surveillance
- Smallpox clinical presentations and differential diagnosis guidelines
- Smallpox case definitions
- Notification procedures for suspected smallpox cases
- Case and outbreak investigations

General Vaccination activities:

- CDC vaccine deployment
- Clinic vaccination procedures and adverse event reporting
- Rapid identification and vaccination of all priority groups (non-contact and contact)
- Evaluation of vaccine responses (takes) with revaccination when needed
- Recognition and treatment of vaccine adverse events
- Decontamination guidelines
- Monitoring of vaccine utilization and supplies

Quarantine/Isolation related activities:

- Fever/rash surveillance and education of contacts (vaccinated and unvaccinated)
- Isolation and care of smallpox patients during the infectious period
- Quarantine guidelines and considerations

Surveillance activities:

- Identification and reporting of suspected smallpox cases through active surveillance at the local, state, national, and international levels
- Surveillance of vaccine adverse events

Epidemiology:

- Epidemiological investigation of the outbreak to determine at-risk populations (contacts), source of outbreak, and risk factors for illness
- Specimen collection and transportation guidelines

Public/Media Communications:

- Communications principles and guidelines
- Pre-event communication education and information
- Smallpox emergency communication operations and activities

These interrelated, multifaceted activities are discussed in the guides and annexes that follow. In addition, this plan identifies and provides examples of many of the specific activities, forms, and procedures that should be followed in preparation for and in response to a smallpox emergency.

The CDC *Smallpox Response Plan and Guidelines* is a draft document that will be updated as needed to reflect changes in capacities and resources for responding to a smallpox emergency. Public health authorities will be notified when updated drafts are available.

II. Criteria for Release of Smallpox Vaccine and Implementation of the CDC Smallpox Response Plan

Federal officials may authorize the release* of all or portions of the smallpox vaccine stockpile and implement all or portions of the CDC Smallpox Response Plan if one or more of the following occur:

1. Confirmation of the presence of smallpox virus, antigen, or nucleic material in clinical specimens by CDC or another laboratory qualified to evaluate specimens for the presence of smallpox virus.

2. Credible reports of clinically compatible cases with pending laboratory confirmation, once an outbreak of smallpox has been previously identified.
3. A large outbreak of a clinically compatible illness as determined by CDC with pending etiological confirmation.
4. Confirmation of viable smallpox virus in an environmental sample, package, distribution device, or other device associated with potential human exposure.

In addition, federal officials may authorize release of a portion of the smallpox vaccine stockpile and implementation of all or portions of the CDC Smallpox Response Plan if a threat of a smallpox virus release has been received, evaluated, and deemed highly credible by federal law enforcement or intelligence authorities.

*Federal officials will notify other federal agencies (HHS, FBI, NSC, etc.) prior to the release of smallpox vaccine.

III. Notification Procedures for Suspected Smallpox Cases

State and local public health authorities should notify the **CDC Emergency Operations Center (770-488-7100)** for any of the following:

1. A suspected case of smallpox with request for clinical specimen testing;
2. An outbreak of illness that is clinically compatible with smallpox;
3. A request to test an environmental sample, package, distribution device, or other device associated with potential human exposure for smallpox virus.

***Medical personnel should notify their state and local public health authorities about suspected cases of smallpox.**

IV. CDC and State/Local Responsibilities and Actions in the Event of a Smallpox Outbreak

Any response to an outbreak of smallpox will involve state and local public health personnel. Therefore, local and state health and emergency authorities must be prepared to mobilize resources to initiate and sustain the necessary outbreak control measures. Federal resources will be available to assist local and state authorities in the implementation of these measures.

CDC Responsibilities and Actions

In the event of a confirmed or suspected smallpox outbreak or of a highly credible threat of a smallpox release as determined by federal law enforcement or intelligence agencies, CDC will immediately mobilize for the following activities/responsibilities:

1. Delivery or standby readiness for delivery of smallpox vaccine and vaccination components
2. Initial laboratory confirmation of smallpox infection and establishment of laboratory protocols for confirmation in surge-capacity laboratories.
3. Coordination with state/local health officials to establish communications and implement federal-state response plans
4. Immediate mobilization and deployment of CDC personnel to assist local and state public health officials with epidemiologic investigations, surveillance, implementation of case isolation protocols, contact identification, vaccine administration, adverse events monitoring, and vaccine inventory monitoring
5. Development of vaccination strategies and prioritization
6. Distribution of guidelines for surveillance, contact identification and tracing, vaccination, isolation strategies, specimen collection and transport, public/media communications, decontamination, and smallpox patient medical care guidelines
7. Provision of technical assistance to the national authority responsible for coordinating the overall federal efforts for managing the event
8. Coordination with federal law enforcement agencies conducting the criminal investigation
9. Provide recommendations on quarantine needs that supercede the capabilities of local/state authorities/statutes
10. Coordination with state/local authorities for public and media communications
11. Tracking and reporting of national surveillance information regarding outbreak
12. Coordination among states for contact tracing and monitoring

State/Local Public Health Responsibilities and Actions

1. Activation of local/state emergency response plans for bioterrorism and/or smallpox outbreaks
2. Designation of state/local leads to coordinate local case surveillance and isolation, contact tracing and monitoring, epidemiologic investigation, and vaccine administration
3. Mobilization of local and state public health resources to conduct epidemiological investigations, surveillance, implementation of case isolation protocols, contact identification, vaccine administration, and adverse events monitoring
4. Designation and activation of sites/clinics for vaccine administration
5. Designation and activation of sites for patient isolation
6. Designation and activation of sites for contact isolation if initiated

7. Utilization of local/state public health statutes and resources for implementation and enforcement of isolation and quarantine within the local/state jurisdiction
8. Coordination with local/state/federal law enforcement agencies conducting the criminal investigation
9. Coordination with federal authorities for public and media communications

V. Vaccine Mobilization and Deployment

Deployment of Vaccine

Initial deployment of smallpox vaccine and vaccine components will occur once approval for release has been obtained from Federal officials.

Vaccine delivery will be prioritized for areas/states with confirmed cases of smallpox and/or confirmed contacts to smallpox cases. States with probable cases will have priority over states with no cases.

The initial amount of vaccine delivered to an area/state will be determined by Federal officials and will be based upon an assessment of:

1. Known or estimated of number of confirmed or suspected smallpox cases
2. Known or estimated of number of contacts
3. Known or estimated number of areas/states potentially effected
4. Number of public health, medical, and response personnel requiring vaccination
5. Vaccination strategy implemented

Supplemental vaccine deployments to an area/state will be based on:

1. Federal assessment of continued vaccine needs to support federally approved vaccination campaigns initiated in an area/state
2. Vaccine availability

VI. CDC Personnel Mobilization and Deployment

Once an outbreak of smallpox has been identified, Federal officials will initiate mobilization of personnel for the following functions:

1. Laboratory:
 - a. Perform initial laboratory confirmation of disease to confirm smallpox outbreak
 - b. Enact protocol for receiving and processing large numbers of specimens at CDC

- c. Initiate protocols in “surge-capacity” state labs for smallpox diagnostics once initial outbreak has been confirmed at CDC
 - d. Provide reagents and consultation as needed to surge-capacity state labs
- 2. Vaccination:
 - a. Deliver vaccine and vaccine components to public health officials in areas with confirmed smallpox outbreaks
 - b. Work with state and local health officials to refine and initiate strategies for vaccine administration based upon initial and ongoing analysis of the outbreak
 - c. Assist in establishing vaccination sites
 - d. Provide instruction on vaccination techniques
 - e. Assist with monitoring of vaccine utilization, take rates, and adverse events
- 3. Isolation and Quarantine:
 - a. Assist with the development and implementation of protocols for isolation of smallpox cases
 - b. Assist with public health decisions regarding implementation of local quarantine and travel restrictions as needed
 - c. Enact federal statutes for quarantine as needed
- 4. Surveillance:
 - a. Assist in the development of case definitions and active surveillance for additional cases
 - b. Assist in surveillance for smallpox cases in states/areas where cases have not yet been identified
 - c. Coordinate and track national surveillance activities
- 5. Contact identification and tracing:
 - a. Assist in the development and implementation of protocols for contact identification and tracing
 - b. Assist in the development and implementation of protocols for contact vaccination and monitoring
 - c. Assist in the development and implementation of protocols for isolation of symptomatic contacts
- 6. Epidemiology
 - a. Assist with the epidemiological investigation of cases to determine the source of infection and to characterize the outbreak
 - b. Coordinate national epidemiological activities
- 7. Coordination:
 - a. Coordinate CDC mobilization and response efforts with state and local health authorities
 - b. Serve as liaisons with other federal agencies (FBI, HHS, OHS, etc.) involved in the response
- 8. Provide technical expertise and assistance to state and local public health authorities and the national authority responsible for coordinating the overall federal emergency response.

U.S. Department of Health and Human Services (HHS)
Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

**NATIONAL VACCINE RESPONSE STRATEGY
FOR A SMALLPOX EMERGENCY
INFORMATION FOR LEADERSHIP**



June 14, 2016

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Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Morbidity and Mortality Weekly Report (MMWR)

Clinical Guidance for Smallpox Vaccine Use in a Postevent Vaccination Program

Recommendations and Reports

February 20, 2015 / 64(RR02);1-26

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