Annex 6,
Part 1:

Smallpox Response System Requirements

Introduction

The guidelines in this document describe functional needs and data exchange requirements for systems implemented to manage data collection for a post-event response for smallpox. A post-event response system is used to track cases, vaccinations, and other related data in the circumstance of a known smallpox event.

As states may choose to use their own systems, these guidelines describe the functional requirements and data formats needed to support information exchange between systems, as well as processes created to ensure the security of data.

To describe the high level functional requirements, data exchange format, and underlying support processes, this guideline document has been divided into three sections:

- High-level functions that should be supported by any post-event response program system.
- Data requirements that must be followed to support exchange of collected data.
- Processes that have been designed to support post-event response programs.

All systems should follow the baselines presented in this document to ensure program compliance. These guidelines provide minimum functional requirements and should in no way preclude a system from incorporating additional functionality beyond what is covered.

1. High Level Functions

1.1 Post-Event Response Functions

The following describes the baseline functionality that should be supported by any system implemented to manage post-event response programs:

- Person registry-based system that supports case, primary contact, and secondary contact records
- Ability to match patient records to a patient registry to eliminate duplication of patient data, and
- Smallpox specific functionality, including:
    - Case data recording and management, including:
        - Case tracking,
        - Demographics,
        - Travel/Activity,
        - Specimen,
        - Lab results,
        - Clinical data, and
        - Intervention (vaccination/prophylaxis).
    - Specimen/Result tracking and reporting,
    - Vaccination tracking,
        - Ability to search and retrieve existing patient and vaccination records for case and contact, and
        - Ability to generate a callback list for a vaccine take reading.
    - Case contact data management, including:
        - Contact tracing,
        - Demographics,

- Specimen,
- Result,
- Clinical,
- Intervention (vaccination/prophylaxis),
- Ability to generate detail and aggregate reports in the field and from the central data store,
- Support for remote standalone deployment with backend synchronization to a central data repository, and
- Support for identified data exchange with other authorized organizations.

2.   Requirements for Data Exchange

2.1   General Description

This section describes required data and a data exchange format that should be followed for electronic exchange of information between grantee and CDC data systems.

2.2   Post-Event Response Program Data Exchange

The post-event response system stores case information including travel information and contacts. Separate formats are provided to support data exchange for these three areas with the case identifier linking these formats; the contact information can alternately be linked using another contact identifier.

- The first four elements contain header-level data regarding the source and date of the file. The exchange is then organized by three optional repeating elements:
  - Case,
  - Travel, and
  - Contact.
- Each element has several levels of nesting to convey the normalization of the fields detailed in Appendix A. The structure is organized to repeat data only where necessary. Only data captured since the last data exchange should be included.
- The case element holds data concerning all cases that are under investigation (demographics). Important child elements of the case are the lab tests and results.
- The travel log element is organized by case. The travel log is separate from the case demographics to allow for the identification and description of a case to be forwarded via the exchange first and then, after the information has been gathered, to allow for the related travel log information to be forwarded.
- The contact element provides for the exchange of demographic information on all primary and secondary contacts of a case and/or contacts of primary contacts. This element requires either a related case number or a related contact number, or both.

It is critical that as much of the requested data as possible be included in the data exchange to the CDC data store. The data in this data store not only provides a record of cases and contacts, but will also be used for:

- Outbreak containment,
- Tracking of cases and contacts, and
- Process improvement in the event of another outbreak.

The data format defined for exchange between the grantees and the CDC should also be followed for exchange between the grantees and other authorized organizations.

2.3   Post-Event Response Program Assumptions

1. Each state sends one exchange per day; the exchange is generated and uploaded on each day

there is activity.

2. The exchange will contain identifying information for the cases and contacts (name, SSN [social security number], PPN [passport number], DLN [drivers license number], DOB [date of birth], phone number, fax number, and gender). This data is required for proper outbreak containment.

3. The exchange will be sent in XML format using a schema provided by the CDC.

4. The daily extracts from the state system will contain all data collected on the previous day, (e.g., the extract for 10/15/2002 will contain information on all investigation activity on 10/14/2002).

5. The data type, size, format and valid values of the data elements with indicated data types, size, format, and valid values will match those provided in Appendix A of this document (e.g., gender will only contain the values "male" or "female"; dates will be in format yyyy-mm-dd; and death indicator will have a data type of character, size 1, and value of either "Y" or "N"). These constraints will be validated; any violation may result in the data in the exchange not being loaded into the CDC system.

6. States will generate a unique case ID for each of the cases; the format of this identifier will be the USPS abbreviation for the state + a unique number (integer).

7. States will use and return the Form 2D-supplied unique contact ID for each of the contacts; this identifier will be the text "SCTF" followed by a number (integer) and is unique across all smallpox investigations.

8. States will generate and supply unique case internal identifiers for tracking cases within their own system. These identifiers will be used to provide linkage back to the state systems.

9. States will generate and supply unique contact internal identifiers for tracking contacts within their own system. These identifiers will be used to provide linkage back to the state systems.

10. The states must be able to identify if a contact has become a case by assigning a case identifier to a contact as well as full case information upon identification of a contact as a case.

11. The area code, exchange number, and line numbers are required for all telephone numbers sent in the exchange.

12. The data elements and required formatting for the data is documented in Appendix A. The technical details of the data exchange format are described below.

2.4   Post-Event Response Data Exchange Technology

The state exchange utility will enable state health departments to upload smallpox investigation data to the CDC in a structured format. This utility will leverage the security structure of the CDC's SDN using a Web-application for the user interface. The data exchange format will be well-formed XML conforming to the supplied schema. This schema enforces a valid file structure and data element restrictions. Appendix A outlines the data requirements for each field as well as a rough structure for grouping fields. See http://www.w3c.org/ for additional information on XML and schemas.

When the user logs on to the exchange utility they will first be authenticated through SDN. An upload page will be presented where the user will select the file to be transferred from disk. Upon successful transfer and subsequent validation, the application will respond with confirmation that the data was stored correctly. Data that is not XML formatted or does not adhere to the schema definition will be rejected. The utility will attempt to diagnose the problem and provide meaningful error messages if validation is unsuccessful.

3. Processes

3.1 Post-Event Response System

Smallpox and other virulent contagious diseases are unique in that they must be effectively contained. Containment requires:

- Identifying the source of the exposure,

- Identifying and tracing contacts, and

- Administering vaccination and/or ordering quarantine.

- Tasks:

    o Collect and track case, contact, and vaccination information,

    o Collect and track specimen and result information on initial cases,

    o Insure all contacts for each case are vaccinated,

    o Analyze data on spread and eventual containment, and

    o Provide information to partners and media.

- System requirements:

    o Efficient data exchange among all response teams,

    o Linking of cases and contacts in a central repository to insure all are offered vaccine, and

    o Linking of vaccine records with contacts to insure vaccine coverage for all contacts related to each case.

Due to these containment requirements, a smallpox response system must allow the input of data to define a case's infectious period. More importantly, it must support the input of places, events, and individuals associated with the case as obtained through interviews. These steps are necessary not only to determine the source of exposure of the case, but also to trace contacts of the case. Primary contacts are individuals who may have been exposed to smallpox by coming in contact with the case, thus contributing to the spread of the outbreak.

The processes section describes underlying processes that should be created to secure data and support users in administering the program. These processes should include:

- Data entry of information gathered on smallpox response forms,

- Distribution and use of case ID numbers,

- Distribution and use of Smallpox Contact Tracing Form (SCTF) ID numbers,

- Generation of and distribution of fever, rash, and severe adverse event callback phone numbers,

- Maintenance of data linkages between cases, contacts (primary and secondary) and vaccinations,

- Report generation for efficient response efforts, and

- Authentication and setup for data exchange.

3.1.1   Data Entry of Information Gathered on Smallpox Response Forms

The response system should support the smallpox response forms that will be available from the CDC's Public Health Emergency and Preparedness Web site: www.bt.cdc.gov/agent/smallpox/response-plan/

[Please Note: The forms online are currently being updated to match the form names and number listed below]

These forms are:

Form Title	CDC Form Number	Unique Number/ID	Data in response system?
Smallpox Case Investigation Form	Form 1	State/Case ID	Yes
Smallpox Case Travel/Activity Calendar This is used as a worksheet only	Form 2A	State/Case ID	**No**
Interviewer Contact/Site Summary Worksheet	Form 2B	State/Case ID	Yes
Contact Transportation Worksheet	Form 2C	State/Case ID	Yes
Smallpox Contact Tracing Form (SCTF)	Form 2D	SCTF ID/ Case ID	Yes
Household Surveillance Form	Form 2E	SCTF ID/ Case ID	Yes
Vaccination Referral Ticket	Form 2F	SCTF ID/ Case ID	**No**
Smallpox Source of Exposure Form	Form 3A	State/Case ID	Yes
Vaccination History Form	None	SCTF ID/ Case ID	Yes
Virtual Household Roster/Surveillance (Follow-up)	None	SCTF ID/ Case ID	Yes
Rash Surveillance Form	None	State/Case ID	Yes

3.1.2 Process Flows

Please reference the following link:

Smallpox Response Plan and Guidelines (Version 3.0)

http://www.bt.cdc.gov/agent/smallpox/response-plan/files/complete-workflow.pdf

3.1.3 Distribution and Use of Case ID Numbers

Unique case ID numbers are necessary to keep contact data unique within the state of investigation as well as unique within the nation. The case ID number should be of sufficient size to ensure uniqueness within the state's response system. This number is referenced on most of the smallpox response forms with the state USPS code.

Together the state + case ID (i.e. CA123456789012) will be unique nationally. The case ID number will be used to link the case to their contacts as well as to specimen and lab results.

It is recommended that case IDs follow this format:

> 2-digit State USPS Code + numerical characters =

- State would be: 2-digit state code + 7-numerical characters + 1-alpha character = 10-digits example:

> CA1234567A

The case ID should be entered in the response system implemented by any state. It is requested that the case ID be included with any case data record that is sent to the CDC.

3.1.4 Distribution and Use of Smallpox Contact Tracing Form ID Numbers

Unique Smallpox Contact Tracing Form (SCTF) ID numbers are used to uniquely identify the data about a contact and are linked to the unique case ID of the case to which they are associated. The SCTF ID should be kept unique by using the state USPS code with the number, similar to the state + case ID number format but with the addition of an alpha character at the end to increase the number range.

> It is imperative to keep the SCTF ID number unique from the case ID number.

- Federal generated contact IDs would be:
  - 9-numerical characters + 1-alpha character = 10 digits example: 123456789A
    - This would give 24 billion (23,999,999,976) unique numbers for the national printed forms.
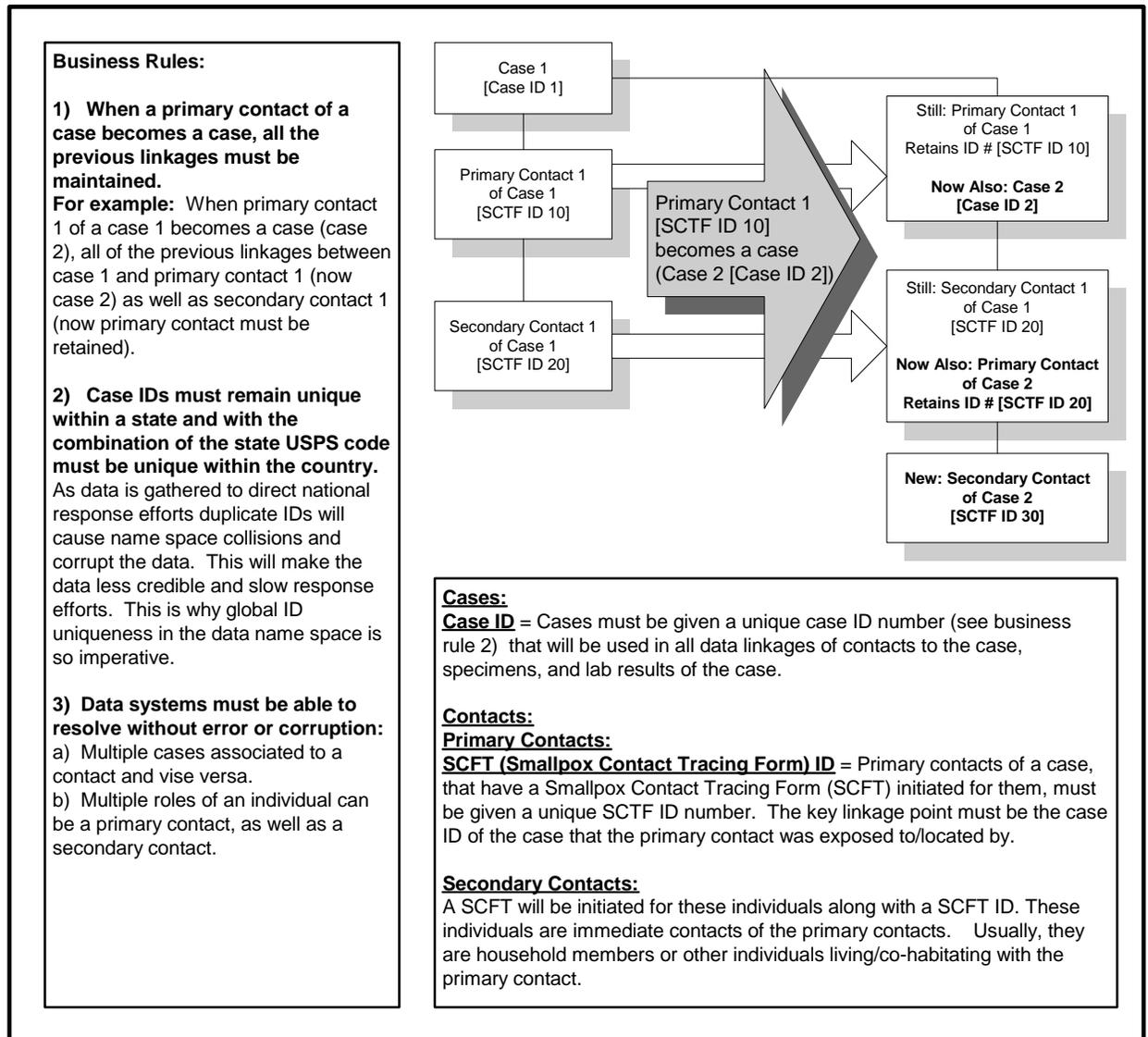
- State generated contact IDs would be:
  - 2-state code + 7-numerical characters + 1-alpha character = 10 digits example:

> CA1234567A

  - This would give 240 million (239,999,976) unique numbers per state.

The SCTF ID should be entered in the response system implemented by any state. It is requested that the SCTF ID be included with any contact data record that is sent to the CDC.

3.1.4.1 This diagram illustrates some, not all, of the data linkage issues to take into account when designing a

smallpox response system.

Business Rules:

1) When a primary contact of a case becomes a case, all the previous linkages must be maintained.
For example: When primary contact 1 of a case 1 becomes a case (case 2), all of the previous linkages between case 1 and primary contact 1 (now case 2) as well as secondary contact 1 (now primary contact must be retained).

2) Case IDs must remain unique within a state and with the combination of the state USPS code must be unique within the country. As data is gathered to direct national response efforts duplicate IDs will cause name space collisions and corrupt the data. This will make the data less credible and slow response efforts. This is why global ID uniqueness in the data name space is so imperative.

3) Data systems must be able to resolve without error or corruption:
a) Multiple cases associated to a contact and vise versa.
b) Multiple roles of an individual can be a primary contact, as well as a secondary contact.

Case 1 [Case ID 1]

Primary Contact 1 of Case 1 [SCTF ID 10]

Secondary Contact 1 of Case 1 [SCTF ID 20]

Primary Contact 1 [SCTF ID 10] becomes a case (Case 2 [Case ID 2])

Still: Primary Contact 1 of Case 1 Retains ID # [SCTF ID 10]
Now Also: Case 2 [Case ID 2]

Still: Secondary Contact 1 of Case 1 [SCTF ID 20]
Now Also: Primary Contact of Case 2 Retains ID # [SCTF ID 20]

New: Secondary Contact of Case 2 [SCTF ID 30]

<u>Cases:</u>
Case ID = Cases must be given a unique case ID number (see business rule 2) that will be used in all data linkages of contacts to the case, specimens, and lab results of the case.

<u>Contacts:</u>
<u>Primary Contacts:</u>
SCFT (Smallpox Contact Tracing Form) ID = Primary contacts of a case, that have a Smallpox Contact Tracing Form (SCFT) initiated for them, must be given a unique SCTF ID number. The key linkage point must be the case ID of the case that the primary contact was exposed to/located by.

<u>Secondary Contacts:</u>
A SCFT will be initiated for these individuals along with a SCFT ID. These individuals are immediate contacts of the primary contacts.   Usually, they are household members or other individuals living/co-habitating with the primary contact.

3.1.5 Generation and Distribution of Fever, Rash and Severe Adverse Event 'Hotline' Phone Numbers

The primary contact on the Household Surveillance Form (Form 2E) references 'hotline' phone number(s). It is recommended that the 'hotline' phone number(s) be generated for each location in a sticker format . The 'hotline' phone number sticker would then be placed on Form 2E, and used to contact the designated local health official in the event a primary contact or household member (secondary contact) develops:

- Smallpox symptom of fever over 101°F (38.3°C) or rash, and/or
- Severe adverse event symptoms due to the vaccination.

3.1.6   Maintenance of Data Linkages Between Cases, Contacts (Primary and Secondary) and Vaccinations

Contacts should be linked to the case(s) to which they are associated. In addition, both cases and contacts should be associated to their vaccination records. Post-event response systems will use these associations for many purposes:

- The linking of cases to contacts within a response system supports the contact tracing process required to track the path of an outbreak.

- The linking of cases and contacts to their vaccination records will support generation of callback lists. The callback lists are used to contact patients to determine if their vaccine take response to the vaccination was positive or if a revaccination should be given.

- The ability to track contacts and vaccinations supports completion of a ring vaccination.

3.1.7   Report Generation for Efficient Response Efforts:

- Source of exposure including person and travel logs for exposure investigation.

- Contact tracing reports:

  - Contact and travel logs,

  - Priority rosters to prioritize contact investigations,

  - Contacts found and not found,

  - Symptoms of contacts; disposition of found contacts, and

  - Status of found contacts.

- Household surveillance reports:

  - Number of contact's household members, and

  - Number of contact's household members' vaccination/referred for vaccination

- Vaccine take callback reports:

  - The system should be able to generate 7-day vaccine take callback lists based on the date of vaccination.

- Data quality reports:

  - Number of case or contact records that are complete versus incomplete.

3.1.8   Logon Authentication

The response system users should have a single level logon that could be specific to a user on a single machine. This must be considered to keep sensitive case and contact personal data secure from un-authorized access.