

**DRAFT**

**Pre-Event Vaccination Administration Support and  
Post-Event Response Systems  
Functional Needs and Data Exchange Requirements  
Overview**

**Version 1.0**

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## 1. Introduction

This document describes functional needs and data exchange requirements for systems implemented to manage Pre-Event Vaccination Administration and Post-Event Response for smallpox.

“Pre-Event Vaccination” is concerned with the support of a vaccination program. Specifically, data and functional needs for the administration of a licensed vaccine in a pre-event campaign. It assumes that the Vaccine Adverse Events Reporting System (VAERS) will be used to collect adverse events, as is the current practice for other licensed vaccines. If the vaccine used were held under an Investigational New Drug (IND) protocol, the data collection and exchange requirements would greatly increase. IND protocol requirements would suggest the use of one system by all vaccination clinics to collect the named patient data, as well as the IND adverse events diary data. This data would be required for the mandated reporting of IND data to the IND holder.

“Post-Event Response” relates to vaccine administration support, but also to tracking cases, possible cases, lab results, contacts and other related data in the circumstance of a known smallpox event.

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

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

- High Level Functions that should be supported by any Pre-Event Vaccination Program and Post-Event Response Program application.
- Data requirements to support exchange of collected data.
- Processes that have been designed to support Pre-Event Vaccination programs and Post-Event Response programs.

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

## 2. High Level Functions

### 2.1 Pre-Event Vaccination Functions

The following describes baseline functionality that should be supported by any system implemented to manage a Pre-Event Smallpox Vaccination program using licensed vaccine:

- Recording of organization data - clinics, state and local health departments, hospitals
- The use of uniquely identified patient administration records including:
  - Demographic data
  - Current vaccination data
  - Vaccination history data
  - Take Response data

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- Adverse Events data
- Re-vaccination data
- Support for identifying a patient vaccination record with the Patient Vaccination Number (PVN) sticker that is provided with the vaccine shipment or an equivalent
- Recording of validated vaccine batch and diluent lot numbers and manufacturers for each vaccination event, including:
  - vaccine lot/manufacturer
  - diluent lot/manufacturer
  - date of reconstitution
  - clinic where the batch was created
- Ability to match patient records to a patient registry to eliminate duplication of patient data
- Ability to search and retrieve existing patient and vaccination records
- Ability to generate detail and aggregate reports
- A central repository for vaccination records
- Support for identified data exchange with other authorized organizations

## 2.2 Post-Event Response Functions

The following describes the baseline functionality that should be supported by any system implemented to manage Post-Event Response programs:

- A person-based system that supports Case, Primary Contact, and Secondary Contact records
- The ability to match patient records to a patient registry to eliminate duplication of patient data
- Smallpox specific functionality, including:
  - Case data recording and management, including:
    - Case tracking
    - Demographics
    - Travel/Activity
    - Specimen
    - Lab result
    - Clinical data
    - Intervention (vaccination/prophylaxis)
  - Specimen/Result tracking and reporting
  - Vaccination tracking
    - Ability to search and retrieve existing patient and vaccination records for Case and Contact
    - Ability to generate a call-back list for Take Response reading
  - Case contact data management, including:
    - Contact tracing
    - Demographics
    - Specimen
    - Result
    - Clinical

### Intervention (vaccination/prophylaxis)

- Ability to generate detail and aggregate reports both in the field and from the central data store.
- Support for remote standalone deployment with backend synchronization to a central data repository.
- Support for identified data exchange with other authorized organizations.

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### 3. Requirements for Data Exchange

#### 3.1 General Description

This section describes required data and a data exchange format that should be followed for electronic exchange of information between State and CDC data systems. Specifications are included for both Pre-Event Vaccination Administration and a Post-Event Response program.

#### 3.2 Pre-Event Vaccination Program Data Exchange

Pre-Event Vaccination Administration support systems store data about the vaccination event, take response, and adverse events. Separate formats are provided to support data exchange in these three areas. The XML schema document follows the structure depicted below:

- The first four elements contain header-level data regarding the source and date of the file. The import is then organized by two optional repeating elements; Clinic, and Take. Each 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 import should be included.
- The Clinic element holds data concerning all vaccinations that occurred at a certain clinic site. Important child elements of the Clinic are the Daily\_Aggregate and Vaccine\_Batch. Patient data is organized below Vaccine\_Batch nested inside the Referring\_Organization element. Patients should thus be grouped by referring organization and then batch.
- The Take element is likewise organized by clinic site. A Patient\_Followup element will then follow for each recorded followup.

It is critical that as much of the requested data as possible be included in the data exchange to the CDC; the data will be used:

- For vaccine take response surveillance
- For vaccine lot tracking (including waste)
- For national preparedness assessment

#### 3.3 Pre-Event Vaccination Program Assumptions

1. Each state sends one exchange per day; the data file is generated and uploaded on each day there is activity.
2. The user has a CDC Secure Data Network certificate and access to the PVS State Import Utility.
3. The data from the state does not contain identifying information for the patient (name, dln, dob, phone number, fax number) but does contain a state generated unique identification number so that a patient can be identified by the state.
4. The state will have to ensure uniqueness of patient records.
5. The extract will be sent in XML format using the schema provided by the CDC as specified in the document pvsStateImport.xsd.
6. The daily extracts from the state system will contain all data collected by the vaccination clinics and take response locations for the previous day, e.g., the extract for 10/15/2002 will contain information on all activity on 10/14/2002.
7. 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 this document (e.g., gender will only contain the values "male" or "female"; dates will be in format yyyy-mm-dd). These constraints will be validated; any violation may result in the data in the import not being loaded into the CDC system.
8. The states will utilize and return the CDC-supplied Patient Vaccination Numbers (PVNs) or

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an equivalent number; PVNs will be supplied to the vaccination clinics in the vaccine kits. PVNs are the single unifying data element for linking the vaccination event (including take response), any adverse events, and vaccine surveillance.

9. Only information for patients who have received the vaccination will be included in the data exchange file.
10. States generate a unique Patient identifier; this identifier will be a number (integer) and is unique within the state.
11. States generate a unique identifier for each of the organizations (Clinics, Take Response Locations, and Referring Organizations); this identifier will be a number (integer) and is unique within the state.
12. The area code, exchange number, and line numbers are required for all telephone numbers sent in the import.

The data elements and required formatting for the data is documented in Appendix A. The technical details of the State Import Utility designed to accept the data exchange format are described below.

### 3.4 Pre-Event Vaccination Technical Details of the State Import Utility

The State Import Utility will enable state health departments to upload aggregate vaccination data to the CDC in a fixed format. This utility will leverage the security structure of Secure Data Network (SDN) using a web-application for the user interface. The data transfer file format will be well-formed XML conforming to the attached 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. Additional documentation can be requested that describes the details of the XML validation schema and the State Import Utility. For additional information on XML please refer to <http://www.w3.org/>.

When the user logs on to the upload 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 not successful.

The XML schema and example file are provided with this package in the documents:

*Example File:* PVS\_State\_Import.xml  
*Validation Schema:* PVS\_State\_Import.xsd

### 3.5 Post-Event Response Program Data Exchange

The Post-Event Response system stores additional information including Case information, 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 has several levels of nesting to convey the normalization of the fields detailed in Appendix B. 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.

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- 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
- For tracking of cases and contacts
- For process improvement in the event of another outbreak

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

### 3.6 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, phone number, fax number, 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 B 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 B. The technical details of the data exchange format are described below.

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### 3.7 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 B outlines the data requirements for each field as well as a rough structure for grouping fields. See <http://www.w3.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.

## 4. Processes –

### 4.1 Pre-Event Vaccination

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

- Distribution and use of Patient Vaccination Number stickers (PVNs) or equivalents
- Authentication and setup for data exchange

#### 4.1.1 Patient Vaccination Numbers

Patient Vaccination Numbers (PVNs), or equivalents, are used to uniquely identify a vaccination event for a patient. The PVN is an important component of the system and is used to tie together patient vaccination information potentially stored in multiple systems. PVN stickers will be provided to the state along with the vaccine 'kit'. PVN stickers will be printed in sets of 6 stickers with 'PVN\_' prefixed to a 10 digit numeric value in both a text format and a bar coded format (Code 128). Clinics will be asked to use the PVN on the:

- Consent Form (2 stickers, one for each signature sheet)
- Adverse Events Diary Card (if distributed)
- History Form
- Vaccination Card

The PVN, or an equivalent, should also be entered in the electronic system regardless of whether it is the CDC provided Pre-Event Vaccination System or a different system implemented by the state. The CDC's Pre-Event Vaccination System is designed to capture the PVN and use it to identify a patient's vaccination record. If the state elects to use their own system, it is requested that the PVN be included with the patient vaccination record that is sent to the CDC.

#### 4.1.2 Logon Authentication for Data Exchange

Data exchange users will have a single level logon through SDN. The data exchange user will be assigned a Digital Certificate that will be specific to a user on a single machine. This mandates that the assigned machine be used for data transfer, and the SDN user initiates the transfer.

As indicated above, instructions for obtaining a Digital Certificate are provided in the document titled *CDC Secure Data Network User Enrollment Guide*.

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## 4.2 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,
- Administering vaccination and/or ordering quarantine.

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. 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 ID Numbers.
- Generation of and distribution of Fever, Rash & Severe Adverse Event call back phone numbers.
- Maintenance of data linkages between Cases, Contacts (Primary and Secondary) and Vaccinations.
- Report generation for efficient response efforts.
- Authentication and setup for data exchange.

### 4.2.1 Data entry of information gathered on Smallpox Response Forms

The response system should support the Smallpox Response forms that will be available from the Bio-Terrorism Smallpox Response website of the CDC. [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	<b>No</b>
Interviewer Contact/Site Summary Worksheet	Form 2B	State/Case ID	Yes
Contact Transportation Worksheet	Form 2C	State/Case ID	Yes
Smallpox Contact Tracing Form	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	<b>No</b>
Smallpox Source of Exposure Form	Form 3A	State/Case ID	Yes

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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

#### 4.2.2 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 the Contacts as well as to specimen and lab results.

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.

#### 4.2.3 Distribution and use of Smallpox Contact Tracing Form ID Numbers

Unique SCTF (Smallpox Contact Tracing Form) 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.

- It is imperative to keep the SCTF ID number unique from the Case ID number. Since both numbers have the same format it is possible for them to overlap.

An additional alpha character(s) is recommended in the SCTF ID. For example a SCTF ID of:

CA-S-12345678901

would keep it unique from a Case ID of

CA-12345678901

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.

#### 4.2.4 Generation and distribution of Fever, Rash & Severe Adverse Event 'Hotline' phone numbers

The Primary Contact and 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 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 symptoms – Fever over 101 Degrees F or Rash.
- Severe Adverse Event symptoms due to the vaccination.

#### 4.2.5 Maintenance of data linkages between Cases, Contacts (Primary and Secondary) and

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### **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 call back lists. The call back lists are used to contact patients to determine if their 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.

#### **4.2.6 Report generation for efficient response efforts:**

- Source of Exposure including Person & 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; Status of found Contacts.
- Household Surveillance Reports: Number of Contacts' household members; Number of Contacts' household members vaccination/ referred for vaccination
- Vaccination Take Call back Reports: the system should be able to generate 7 Day Take call back lists based on the date of vaccination
- Data Quality reports: Number of Case or Contact records that are complete versus incomplete

#### **4.2.7 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.

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## Appendix A – Pre-Event Vaccination Program

### Data Exchange Format Requirements

#### Export File Descriptions

Please Note: Required data fields (Req'd) are marked.

The export from the states consists of up to 4 sections. In order to capture all the necessary data, some of the sections are further divided into sub-sections (some of the sub-sections may also be divided). Each section, their sub-sections, and the applicable data elements are explained in the list below:

1. Header - Identifies global information such as the date of the extract and the sending state. There are 4 data elements in the header section of the export.
2. Clinic – Contains vaccination activity that occurred at the clinics for the export date indicated in the Header Section (data element #3). The Clinic section consists of 3 nested sections:
  - Clinic identification – Identifies the clinic with vaccination activity. Clinic identification data is contained in data elements #1-#20 of the Clinic Section Data Elements table.
  - Aggregate counts – Provides high-level aggregates of the clinic's activity (data elements #21-#27 of the Clinic Section Data Elements table).
  - Vaccination activity – This sub-section contains the complete records of the clinic's vaccination activity including the vaccine batch, patient referring organization, and patient data. Each of these are detailed in the list below:
    - Vaccine batch – Provides identification and some detail data about the vaccine given to the patients, including vaccine and diluent lots used to create the batch and the maximum number of doses in the batch. This information is contained in data elements #28-#37 of the Clinic Section Data Elements table.
    - Referring Organization – Identifies the organization (hospital or public health organization) that referred patients to be vaccinated. Data elements #38-#58 of the Clinic Section Data Elements table contain the referring organization information.
    - Patient – Identifies the patient and the event of vaccination. Patient identification, demographics, and vaccination details (including previous vaccination) are provided in data elements #59-#102 of the Clinic Section Data Elements table.
3. Take Response – Because the Take Response readings are taken 6-8 days after the vaccination, a separate schema has been provided. The Take Response section has two nested sections:
  - Take Response Location identification – Identifies the location where the take response readings occurred. This information is contained in data elements #1-#20 of the Take Response Section Data Elements table.
  - Patient Take Response results – Contains the take response results for each patient (linked to the Patient record using the Patient Vaccination Number). This information is in data elements #21-#31 of the Take Response Section Data Elements table.

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#### Cardinality and Repeatability

- The Header section occurs once per import; none of the data elements in the Header section may be repeated.
- Each import may contain data from more than one vaccination clinic; therefore, the Clinic section of the import may be repeated. There may be zero Clinic sections when only take response information is sent.
- Each clinic may vaccinate patients with vaccine from one or more vaccine batches per day; therefore, the Vaccination Activity sub-section (data elements #28-#102 of the Clinic Section Data Elements table) may be repeated in the Clinic section.
- Each clinic may vaccinate patients referred by zero, one, or more than one referring organizations within each vaccine batch; data elements #38-#102 may be omitted or repeated within each vaccine batch (#28-#37).
- Each clinic may vaccinate more than one patient within each referring organization per day; data elements #59-#102 will be repeated with each set containing the information for one patient.
- Each import may contain data from zero, one, or more than one take response location; data from zero take response location is also allowed when only vaccination or diary information is sent.
- Each take may contain data from one or more patients; therefore, data elements #21-#31 of the Take Response Section Data Elements table may be repeated with each set containing the information for one patient.

#### Export Data Elements

##### Header Section Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
1	Sending State	The state that sent the extract and to which the data contained in the extract belongs.	Character	2			Yes	Use USPS State abbreviation list	Assumes that each state only sends one extract per day. If a state sends more than one extract (by county, for example), the Sending Entity must be populated.
2	Sending Entity	The entity (county, city, etc) that sent the extract and to which the data contained in the extract belongs.	Alphanumeric						If null, the sending entity is assumed to be the State Department of Health.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
3	Extract Date	The date to which the data contained in the extract belongs	Date	10	yyyy-mm-dd		Yes		This date may not be the same as the Extract Create Date, e.g., the extract was created on 10/15/2002 but contains data collected on 10/14/2002, the Extract Date is 10/14/2002 while the Extract Create Date is 10/15/2002.
4	Extract Create Date	The date on which the extract(s) was created.	Date	10	yyyy-mm-dd		Yes		This date may not be the same as the Extract Date, e.g., the extract was created on 10/15/2002 but contains data collected on 10/14/2002, the Extract Date is 10/14/2002 while the Extract Create Date is 10/15/2002.

Clinic Section Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
1	Internal Identifier	A unique internal identifier assigned or used by the state system.	Integer			Yes	Yes		Provides uniqueness to the state's clinic records. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
2	Clinic Name	Identifies the clinic to which the counts apply.	Alphanumeric				Yes		

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
3	Clinic Street Address Line 1		Character						
4	Clinic Street Address Line 2		Character						
5	Clinic City		Character						
6	Clinic County		Character						
7	Clinic State		Character	2			<b>Yes</b>	Follow USPS 2-char State abbreviations	
8	Clinic Zip Code		Alphanumeric		'nnnnn' or 'nnnnn-nnnn'				Both the 5-digit and 5+4-digit codes will be accepted.
9	Clinic Phone Area Code		Number	3					Use Phone Type = "Work" in the xml schema.
10	Clinic Phone Exchange Number		Number	3					Use Phone Type = "Work" in the xml schema.
11	Clinic Phone Line Number		Number	4					Use Phone Type = "Work" in the xml schema.
12	Clinic Phone Number Extension		Number						Use Phone Type = "Work" in the xml schema.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
13	Clinic Fax Area Code		Number	3					Use Phone Type = "Fax" in the xml schema.
14	Clinic Fax Exchange Number		Number	3					Use Phone Type = "Fax" in the xml schema.
15	Clinic Fax Line Number		Number	4					Use Phone Type = "Fax" in the xml schema.
16	Clinic Contact Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "Contact" in the xml schema.
17	Clinic Contact First Name		Character				<b>Yes</b>		Use Name Type = "Contact" in the xml schema.
18	Clinic Contact Middle Name		Character						Use Name Type = "Contact" in the xml schema.
19	Clinic Contact Last Name		Character				<b>Yes</b>		Use Name Type = "Contact" in the xml schema.
20	Clinic Contact Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "Contact" in the xml schema.
21	Count Date	Identifies the date to which the counts apply.	Date				<b>Yes</b>		
22	Number Vaccinated	Number of patients receiving vaccination	Number						Can also be derived from patient detail if provided.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
23	Number scheduled for screening	Number of patients scheduled for vaccination screening	Number						
24	Number Screened	Number of patients receiving vaccination screening.	Number						May be derived from Number Not Vaccinated - Contraindications + Number Not Vaccinated - Non-Consenting + Number Vaccinated or Number Vaccinated + Number Not Vaccinated.
25	Number Not Vaccinated	The number of patients who did not receive the vaccination.	Number						Not needed if Number Not Vaccinated - Contraindications and Number Not Vaccinated - Non-Consenting populated.
26	Number Not Vaccinated - Contraindications	Number of patients not vaccinated due to contraindications (medical reasons).	Number						
27	Number Not Vaccinated - Non-consenting	Number of patients not vaccinated due to patient choice (no consent).	Number						
28	Vaccine Type							Vaccinia	Default to "Vaccinia".
29	Program	The name of the vaccination event under which the vaccines have been provided.	Alphanumeric				<b>Yes</b>		Values sent must match those recognized by the CDC (currently, "IND Laboratorian" and "IND Responder").
30	Batch Number	Unique identifier for a vaccine/diluent combination.							The vaccine/diluent combination represents the vaccine that is administered to the patient.
31	# of vaccines per batch	The maximum number of vaccines in the batch.	Number						

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
32	Dilution Strength	A ratio expressing the amount of vaccine lot mixed with diluent lot.	Alphanumeric		nn:nn				
33	Batch Date	The date the batch is ready to be administered to a patient (creation date or opened date if no mixing needs to take place).	Date		yyyy-mm-dd		Yes		
34	Vaccine Lot Number	The lot number on the vaccine lot container sent to the clinic in the vaccine kit.					Yes		
35	Vaccine Lot Manufacturer	The name of the vaccine lot manufacturer sent to the clinic in the vaccine kit.					Yes		
36	Diluent Lot Number	The lot number on the diluent lot container that may have been sent to the clinic in the vaccine kit if a diluent is needed with the vaccine lot.							Diluents may not be used, and, therefore, will not be in the kit.
37	Diluent Manufacturer	The name of the diluent lot manufacturer that may have been sent to the clinic in the vaccine kit if a diluent is needed with the vaccine lot.							Diluents may not be used, and, therefore, will not be in the kit.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
38	Internal Identifier	A unique internal identifier assigned or used by the state system.	Alphanumeric			Yes	Yes		Provides uniqueness to the state's referring organization records. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
39	Referring Organization Name	The organization that requested that the patient receive the current vaccination.	Alphanumeric				Yes		Assumed to be the work location of the patient.
40	Referring Organization Street Address Line 1								
41	Referring Organization Street Address Line 2								
42	Referring Organization City		Character						
43	Referring Organization County		Character						
44	Referring Organization State		Character	2			Yes	Follow USPS 2-char State abbreviations	

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
45	Referring Organization Zip Code		Alphanumeric		'nnnnn' or 'nnnnn-nnnn'				Both the 5-digit and 5+4-digit codes will be accepted.
46	Referring Organization Phone Area Code		Number	3					Use Phone Type = "Work" in the xml schema.
47	Referring Organization Phone Exchange Number		Number	3					Use Phone Type = "Work" in the xml schema.
48	Referring Organization Phone Line Number		Number	4					Use Phone Type = "Work" in the xml schema.
49	Referring Organization Phone Number Extension		Number	4					Use Phone Type = "Work" in the xml schema.
50	Referring Organization Fax Area Code		Number	3					Use Phone Type = "Fax" in the xml schema.
51	Referring Organization Fax Exchange Number		Number	3					Use Phone Type = "Fax" in the xml schema.
52	Referring Organization Fax Line Number		Number	4					Use Phone Type = "Fax" in the xml schema.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
53	Referring Organization Contact Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "Contact" in the xml schema.
54	Referring Organization Contact First Name		Character						Use Name Type = "Contact" in the xml schema.
55	Referring Organization Contact Middle Name		Character						Use Name Type = "Contact" in the xml schema.
56	Referring Organization Contact Last Name		Character						Use Name Type = "Contact" in the xml schema.
57	Referring Organization Contact Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "Contact" in the xml schema.
58	Referring Organization Category	Indicates if the referring organization is providing patients for the Hospital-based Response Team or Public Health Response Team	Character					See Referring Organization Category list	

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
59	Patient Internal Identifier	A unique internal identifier assigned or used by the state system.	Alphanumeric			Yes	Yes		Provides uniqueness to the state's patient record. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
60	Patient Vaccination Number	A unique value used to identify the patient vaccination record.				Yes	Yes		Generated by the PVS System and provided to the clinic; will be verified upon load.
61	Date of Vaccination	The date the current vaccination was given.	Date	10	yyyy-mm-dd		Yes		
62	Patient Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "Patient" in the xml schema.
63	Patient First Name		Character						Use Name Type = "Patient" in the xml schema.
64	Patient Middle Name		Character						Use Name Type = "Patient" in the xml schema.
65	Patient Last Name		Character						Use Name Type = "Patient" in the xml schema.
66	Patient Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "Patient" in the xml schema.
67	Patient State of Residence	The home state of the patient	char	2				Use the USPS state abbreviations.	

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
68	Patient Identifier Type							See Identifier Type valid values.	Default to SSN if not provided. If Id number is a driver's license number, populate with "DLN".
69	Patient Identification Number				nnn-nn-nnnn, if SSN	Yes, for given type.			If SSN is not collected, but another id (such as Driver's License number) is collected, send that number with Patient Identifier Type populated with "DLN" in the xml schema.
70	Patient Home Phone Area Code		Number	3					Use Phone Type = "Home" in the xml schema.
71	Patient Home Phone Exchange Number		Number	3					Use Phone Type = "Home" in the xml schema.
72	Patient Home Phone Line Number		Number	4					Use Phone Type = "Home" in the xml schema.
73	Patient Work Phone Area Code		Number	3					Use Phone Type = "Work" in the xml schema.
74	Patient Work Phone Exchange Number		Number	3					Use Phone Type = "Work" in the xml schema.
75	Patient Work Phone Line Number		Number	4					Use Phone Type = "Work" in the xml schema.
76	Patient Work Extension		number						Use Phone Type = "Work" in the xml schema.
77	Patient Cell Phone Area Code		Number	3					Use Phone Type = "Cell" in the xml schema.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
78	Patient Cell Phone Exchange Number		Number	3					Use Phone Type = "Cell" in the xml schema.
79	Patient Cell Phone Line Number		Number	4					Use Phone Type = "Cell" in the xml schema.
80	Patient Fax Area Code		Number	3					Use Phone Type = "Fax" in the xml schema.
81	Patient Fax Exchange Number		Number	3					Use Phone Type = "Fax" in the xml schema.
82	Patient Fax Line Number		Number	4					Use Phone Type = "Fax" in the xml schema.
83	Patient E-mail Address								
84	Patient Date of Birth		Date	10	yyyy-mm-dd				
85	Patient Gender		Character					See Gender valid values	
86	Patient Occupation		Character						
87	Vaccine Administered by Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "administeredBy" in the xml schema.
88	Vaccine Administered by First Name	The first name of the person who administered the current vaccine.	Character				<b>Yes</b>		Use Name Type = "administeredBy" in the xml schema.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
89	Vaccine Administered by Middle Name	The middle name of the person who administered the current vaccine.	Character						Use Name Type = "administeredBy" in the xml schema.
90	Vaccine Administered by Last Name	The last name of the person who administered the current vaccine.	Character				<b>Yes</b>		Use Name Type = "administeredBy" in the xml schema.
91	Vaccine Administered by Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "administeredBy" in the xml schema.
92	Previous Vaccination Date from Document		Date	10	yyyy-mm-dd				Mutually exclusive with Previous Vaccination Date from Recall, Previous Vaccination in Childhood, and Previous Vaccination Never. Use Previous Vaccination Source = "Document" in the xml schema.
93	Previous Vaccination Date from Recall		Date	10	yyyy-mm-dd				Mutually exclusive with Previous Vaccination from Document, Previous Vaccination in Childhood, and Previous Vaccination Never. Use Previous Vaccination Source = "Recall" in the xml schema.
94	Previous Vaccination in Childhood		Character	1				"Y" for Yes, "N" for no.	Mutually exclusive with Previous Vaccination from Document, Previous Vaccination Date from Recall, and Previous Vaccination Never. Use Previous Vaccination Source = "Childhood" in the xml schema.

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
95	Previous Vaccination Never		Character	1				"Y" for Yes, "N" for no.	Mutually exclusive with Previous Vaccination from Document, Previous Vaccination Date from Recall, and Previous Vaccination in Childhood. Use Previous Vaccination Source = "Never" in the xml schema.
96	Previous Vaccination Take Response Normal		Character	1				"Y" for Yes, "N" for no.	
97	Previous Vaccination Take Response No Take		Character	1				"Y" for Yes, "N" for no.	
98	Previous Vaccination Take Response Scar		Character	1				"Y" for Yes, "N" for no.	
99	Previous Vaccination Take Response Adverse Event		Character	1				"Y" for Yes, "N" for no.	
100	Previous Vaccination Take Response Equivocal		Character	1				"Y" for Yes, "N" for no.	

Take Response Section Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
1	Internal Identifier	A unique internal identifier assigned or used by the state system.	Alphanumeric			Yes	Yes		Provides uniqueness to the state's take response location record. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
2	Take Response Location Name	The organization where the take response was performed.							
3	Take Response Location Street Address Line 1		Alphanumeric						
4	Take Response Location Street Address Line 2		Alphanumeric						
5	Take Response Location City		Character						
6	Take Response County		Character						
7	Take Response Location State		Char	2			Yes	Follow USPS 2-char State abbreviations	

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
8	Take Response Location Zip Code		Alphanumeric		'nnnnn' or 'nnnnn- nnnn'				Both the 5-digit and 5+4-digit codes will be accepted.
9	Take Response Location Phone Area Code		Number	3					Use Phone Type = "Work" in the xml schema.
10	Take Response Location Phone Exchange Number		Number	3					Use Phone Type = "Work" in the xml schema.
11	Take Response Location Phone Line Number		Number	4					Use Phone Type = "Work" in the xml schema.
12	Take Response Location Phone Number Extension		Number	4					Use Phone Type = "Work" in the xml schema.
13	Take Response Location Fax Area Code		Number	3					Use Phone Type = "Fax" in the xml schema.
14	Take Response Location Fax Exchange Number		Number	3					Use Phone Type = "Fax" in the xml schema.
15	Take Response Location Fax Line Number		Number	4					Use Phone Type = "Fax" in the xml schema.

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
16	Take Response Location Contact Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "Contact" in the xml schema.
17	Take Response Location Contact First Name		Character						Use Name Type = "Contact" in the xml schema.
18	Take Response Location Contact Middle Name		Character						Use Name Type = "Contact" in the xml schema.
19	Take Response Location Contact Last Name		Character						Use Name Type = "Contact" in the xml schema.
20	Take Response Location Contact Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "Contact" in the xml schema.
21	Take Response Exam Date	The date the take response for the current vaccination (administered vaccination) is read.	Date	10	yyyy-mm-dd				

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
22	Patient Internal Identifier	A unique internal identifier assigned or used by the state system.	Alphanumeric			Yes	Yes		Provides uniqueness to the state's patient record. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
23	Patient Vaccination Number	A unique value used to identify the patient vaccination record.				Yes	Yes		Generated by the PVS System and provided to the clinic; will be verified upon load.
24	Take Response	The take response of the current vaccination.	Character					See Take Response valid values.	
25	Adverse Event Text	Text for any adverse events associated with the current vaccination.	Text						
26	Comment Text	Text for any comments associated with the current vaccination.	Text						

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Valid Values?	Notes
27	Take Response Examiner Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character						Use Name Type = "Examiner" in the xml schema.
28	Take Response Examiner First Name		Character				Yes		Use Name Type = "Examiner" in the xml schema.
29	Take Response Examiner Middle Name		Character						Use Name Type = "Examiner" in the xml schema.
30	Take Response Examiner Last Name		Character				Yes		Use Name Type = "Examiner" in the xml schema.
31	Take Response Examiner Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character						Use Name Type = "Examiner" in the xml schema.

**Valid Value Lists**

**Gender**

<b>Value</b>
Male
Female

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### Identifier Type

Value	Description
SSN	Indicates that the supplied Identifier is the Social Security Number
DLN	Indicates that the supplied Identifier is a Driver's License Number

### Name Type

Value	Description
administeredby	Indicates that the supplied name is for the person administering the vaccine to the patient (vaccinator).
contact	Indicates that the supplied name is the contact of the organization (Clinic, Take Response Location, or Referring Organization).
examiner	Indicates that the supplied name is for the person reading the Take Response.
patient	Indicates that the supplied name is for the person receiving the vaccine (patient).
provider	Indicates that the supplied name is for the medical care provider who the patient went to for an adverse event (collected from the Adverse Events Diary Card).

### Phone Type

Value	Description
Cell	Indicates that the supplied phone number is a cell number.
Fax	Indicates that the supplied phone number is a fax number.
Home	Indicates that the supplied phone number is a home phone number.
Work	Indicates that the supplied phone number is a work number.

**Previous Vaccination Source**

Value	Description
Childhood	Indicates that the patient received the previous vaccination in childhood, but either does not have a document for proof or doesn't recall the date of vaccination (date is not supplied).
Document	Indicates that the Previous Vaccination Date supplied was obtained from a document (e.g., vaccination record).
Never	Indicates that the patient has never been vaccinated (date is not supplied).
Recall	Indicates that the Previous Vaccination Date supplied was obtained from recall (the patient's memory).

**Referring Organization Category**

Value
Hospital-Based Response Team
Public Health Response Team
Not Applicable

**State**

Use the United States Postal Service (USPS) state abbreviations (AL, AK, AZ, ...).

**Take Response**

Value
Equivocal
Major
No Take

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## Appendix B – Post-Event Response

### Data Exchange Format Requirements

#### Export File Descriptions

Please Note: Required data fields (Req'd) are marked.

Data Exchange consists of up to 4 sections. Each section and the applicable data elements are explained in the list below:

1. Header - Identifies global information such as the date of the extract and the sending state. There are 4 data elements in the header.
2. Case – Contains case identifying, demographic, and limited clinical data collected about a Smallpox Case during the course of an investigation. This section mirrors Smallpox Form 1.
3. Travel Log – The Travel Log section contains information about the travel activities of the Smallpox case (form 2C – Case Transportation Worksheet).
4. Contact – Contains demographic, contact, and disposition information collected about any primary and secondary contacts of a Smallpox Case.

#### Cardinality and Repeatability

- The Header section occurs once; none of the data elements in the Header section may be repeated.
- Each data exchange may contain data from more than one Smallpox case; therefore, the Case section of the exchange (data elements #1-42 in the Case table below) may be repeated. There may be zero Case sections when only Travel or Contact information is sent; however, it is assumed that the Case information referenced in the Travel or Contact information has been previously sent.
- Each Case may have more than one nickname or alias; therefore, the Case Alias Name data element (#8) may be repeated for each Case.
- Each Case may have more than one race; therefore the Case Race data element (#32) may be repeated for each Case.
- If the Case Race data element (#32) is "Other", the Case Race Name data element (#33) must be populated. Case Race/Case Race Name data element combination may be repeated; the Case Race may be set to "Other" more than once and each occurrence of "Other" must have a companion Case Race Name.
- Zero, one, or more than one lab test may be performed for each Case. Therefore, the Lab Test Performed, Date Specimen Taken and Lab Result data elements (#40, 41, & 42) may be omitted or repeated for each Case.
- Each Case has only one Travel Log; therefore, the Case identifying information in the Travel Log data exchange structure (data elements #1 and #2 in the Travel Log table below) is sent once.
- Each Case's Travel Log may contain more than one type of transportation or trip. The travel data elements (#3 – 14) within the Travel Log record may be repeated.
- Each data exchange may contain information for zero, one, or many Contacts. The Contact Data Elements in the data exchange may be omitted or repeated. However, the information about the related Case (data element #41, Related Case Number, of the Contact Data Elements table below) and/or the related Contact (data element #41, Related Contact Number) must be either sent in a previous or the current data exchange in order to be able to link the Contact.

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- Each Contact may have more than one nickname or alias; therefore, the Contact Alias Name data element (#8) may be repeated for each Contact.
- Each Contact may have zero, one, or more than one other phone number; therefore the data elements that make up the other phone number, Contact Other Phone Area Code, Contact Other Phone Exchange Number, Contact Other Phone Line Number, and Contact Other Phone Type (#27-30), may be omitted or repeated for each Contact.
- If the data elements that make up the other phone number, #27-29, are populated, the Contact Other Phone Type data element (#30) must be populated.
- Each Contact may have more than one race; therefore the Contact Race data element (#36) may be repeated for each Contact.
- Each Contact may be a Contact of zero, one, or more than one Case; therefore the Related Case Number data element (#40) and the Contact Referral Basis data elements (Contact may be omitted or repeated (if populated, information for each related Case must either be in the Case Data Elements of the data exchange or sent in a previous data exchange).
- Each Contact may be a (secondary) Contact of zero, one, or more than one other, related Contact; therefore, the Related Contact Number data element (#41) may be omitted or repeated (if populated, information for each related Contact must either be in the Contact Data Elements of the data exchange or sent in a previous data exchange).

### Export Data Elements

#### Header Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repea- table?	Valid Values?	Notes
1	Sending State	The state that sent the extract and to which the data contained in the extract belongs.	Character	2			Yes		Use USPS State abbreviation list	Assumes that each state only sends one extract per day. If a state sends more than one extract (by county, for example), the Sending Entity must be populated.
2	Sending Entity	The entity (county, city, etc) that sent the extract and to which the data contained in the extract belongs.	Alphanumeric							If null, the sending entity is assumed to be the State Department of Health.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repea- table?	Valid Values?	Notes
3	Extract Date	The date to which the data contained in the extract belongs	Date	10	yyyy-mm-dd		Yes			This date may not be the same as the Extract Create Date, e.g., the extract was created on 10/15/2002 but contains data collected on 10/14/2002, the Extract Date is 10/14/2002 while the Extract Create Date is 10/15/2002.
4	Extract Create Date	The date on which the extract(s) was created.	Date	10	yyyy-mm-dd		Yes			This date may not be the same as the Extract Date, e.g., the extract was created on 10/15/2002 but contains data collected on 10/14/2002, the Extract Date is 10/14/2002 while the Extract Create Date is 10/15/2002.

Case Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
1	Case Internal Identifier	A unique internal identifier assigned or used by the state system.	Integer			Yes	Yes			Provides uniqueness to the state's records. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
2	Case Id	Unique identifier used to identify a smallpox case.	Alphanumeric		See note		Yes			Format: USPS abbreviation for the state that filed the case + a unique number.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
3	Case Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character							
4	Case First Name		Character				<b>Conditional</b>			Either Alias, First, or Last Name are required.
5	Case Middle Name		Character							
6	Case Last Name		Character				<b>Conditional</b>			Either Alias, First, or Last Name are required.
7	Case Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character							
8	Case Alias Name						<b>Conditional</b>	Yes		Either Alias, First, or Last Name are required.
9	Case Home Street Address Line 1		Character							P.O. Box addresses are not acceptable.
10	Case Home Street Address Line 2		Character							
11	Case Home City		Character							
12	Case Home County		Character							

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
13	Case Home State		Character	2			<b>Yes</b>		Follow USPS 2-char State abbreviations	
14	Case Home Zip Code		Alphanumeric		'nnnnn' or 'nnnnn-nnnn'					Both the 5-digit and 5+4-digit codes will be accepted.
15	Case Identifier Type								See Identifier Type valid values.	Default to SSN if not provided. If Id number is: driver's license number, populate with "DLN", Passport number populate with "PPN"
16	Case Identification Number				nnn-nn-nnnn, if SSN	Yes, for given type.	<b>Yes</b>			If SSN is not collected, but another id (such as Driver's License number) is collected, send that number with Patient Identifier Type populated with "DLN".
17	Case Home Phone Area Code		Number	3						
18	Case Home Phone Exchange Number		Number	3						
19	Case Home Phone Line Number		Number	4						
20	Case Work Phone Area Code		Number	3						

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
21	Case Work Phone Exchange Number		Number	3						
22	Case Work Phone Line Number		Number	4						
23	Case Work Extension		number							
24	Case Other Phone Area Code		Number	3						
25	Case Other Phone Exchange Number		Number	3						
26	Case Other Phone Line Number		Number	4						
27	Case Date of Birth		Date	10	yyyy-mm-dd					
28	Case Age Value		Number							
29	Case Age Unit		Character						See Age Unit valid values	
30	Case Gender		Character						See Gender valid values	
31	Case Ethnicity		Character						See Ethnicity valid values	

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
32	Case Race		Character					Yes	See Race valid values	A person may have more than one race.
33	Case Race Name		Character					Yes		Only valid if Case Race = "Other".
34	Date of Onset of Fever		Date	10	yyyy-mm-dd					Null value indicates no fever present.
35	Date of Rash onset		Date	10	yyyy-mm-dd					Null value indicates no rash present.
36	Severe Rash Type		Character						See Rash valid values	
37	Date Last Scab Fell Off		Date	10	yyyy-mm-dd					Null value indicates unknown.
38	Death Indicator		Character	1					"Y" for Yes and "N" for No.	
39	Date of Death		Date	10	yyyy-mm-dd					
40	Lab Test Performed		Character					Yes	See Lab Test valid values (under revision)	
41	Date Specimen Taken		Date	10	yyyy-mm-dd			Yes		

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
42	Lab Result		Character					Yes	See Lab Result valid values (under revision)	Valid values tied to lab test (see valid value list for specifics).

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Travel Log Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
1	Case Internal Identifier	A unique internal identifier assigned or used by the state system.	Integer			Yes	Yes			Provides uniqueness to the state's records. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
2	Case Id	Unique identifier used to identify a smallpox case.	Alphanumeric		See note		Yes			Format: USPS abbreviation for the state that identified the case + a unique number.
3	Travel Date	The date the case traveled.	Date	10	yyyy-mm-dd		Yes	Yes		
4	Travel Time	The time the travel began	Time					Yes		
5	Time of Day Type	Identifies if the time of travel is morning (am) or afternoon (pm).	Character	2			Yes	Yes	"AM" and "PM"	
6	Transportation Type	The type of transportation (bus, train, plane, car, etc).	Character					Yes		
7	Transportation Carrier/Company	The name of the company or carrier who provided the travel.	Alphanumeric					Yes		
8	Route/Flight #		Alphanumeric					Yes		
9	Origin City		Character					Yes		
10	Origin State		Character					Yes		
11	Origin Country		Character					Yes		

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
12	Destination City	The city of the final destination.	Character					Yes		
13	Destination State	The state of the final destination.	Character					Yes		
14	Destination Country	The country of the final destination.	Character					Yes		Only necessary if destination country is different than origin country.

#### Contact Data Elements

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
1	Contact Internal Identifier	A unique internal identifier assigned or used by the state system.	Integer			Yes	Yes			Provides uniqueness to the state's records. Used to match to previously received data in order to identify if the received record is new or needs to be updated.
2	Contact Id	Unique identifier used to identify the contact of a smallpox case. Also known as the Smallpox Contact Tracing Form (SCTF) or Field Record Number.	Alphanumeric				Yes			
3	Contact Name Prefix	Any text that precedes the name; this may be an academic title such as "Dr." or other title such as "Mr.", "Ms.", or "Mrs."	Character							

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
4	Contact First Name		Character				<b>Conditional</b>			Either Alias or First and Last Name are required.
5	Contact Middle Name		Character							
6	Contact Last Name		Character				<b>Conditional</b>			Either Alias or First and Last Name are required.
7	Contact Name Suffix	Any text that comes after the name; this may be an academic degree such as "M.D." or "R.N." or other suffix such as "Jr.", "Sr.", or "III".	Character							
8	Contact Alias Name						<b>Conditional</b>	Yes		Either Alias or First and Last Name are required.
9	Contact Home Street Address Line 1		Character							
10	Contact Home Street Address Line 2		Character							
11	Contact Home City		Character							
12	Contact Home County		Character							
13	Contact Home State		Character	2			<b>Yes</b>		Follow USPS 2-char State abbreviations	
14	Contact Home Zip Code		Alphanumeric		'nnnnn' or 'nnnnn-nnnn'					Both the 5-digit and 5+4-digit codes will be accepted.

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
15	Contact Identifier Type								See Identifier Type valid values.	Default to SSN if not provided. If Id number is a driver's license number, populate with "DLN".
16	Contact Identification Number				nnn-nn-nnnn, if SSN	Yes, for given type.				If SSN is not collected, but another id (such as Driver's License number) is collected, send that number with Patient Identifier Type populated with "DLN".
17	Contact Home Phone Area Code		Number	3						
18	Contact Home Phone Exchange Number		Number	3						
19	Contact Home Phone Line Number		Number	4						
20	Contact Work Phone Area Code		Number	3						
21	Contact Work Phone Exchange Number		Number	3						
22	Contact Work Phone Line Number		Number	4						
23	Contact Work Extension		number							
24	Contact Cell Phone Area Code		Number	3						

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
25	Contact Cell Phone Exchange Number		Number	3						
26	Contact Cell Phone Line Number		Number	4						
27	Contact Other Phone Area Code		Number	3				Yes		
28	Contact Other Phone Exchange Number		Number	3				Yes		
29	Contact Other Phone Line Number		Number	4				Yes		
30	Contact Other Phone Type	Identify the type of phone number (parent's, pager, etc) in the Contact Other Phone fields.	Character					Yes		Value will be ignored if there is no data in Contact Other Phone Area Code, Contact Other Phone Exchange Number, and Contact Other Phone Line Number.
31	Contact Date of Birth		Date	10	yyyy-mm-dd					
32	Contact Age Value		Number							
33	Contact Age Unit		Character						See Age Unit valid values	
34	Contact Gender		Character						See Gender valid values	
35	Contact Ethnicity		Character						See Ethnicity valid values	
36	Contact Race		Character					Yes	See Race valid values	

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#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
37	Contact Height	The approximate height, in feet and inches (e.g., 5 ft, 8 inches) of the contact.	Alphanumeric							
38	Contact Size/Build	The approximate weight or build of the contact (e.g., heavy, slim, thick, or 200#).	Alphanumeric							
39	Contact Hair	A description of the hairstyle and hair color of the contact (e.g., short brown curly, balding, blonde ponytail, weave).	Character							
40	Related Case Number		Alphanumeric				<b>Conditional</b>	Yes		A Contact may be the contact of more than one Case. For each Case, provide a priority, a type, and a location. The Related Case Number, the Related Contact Number, or both must be populated.
41	Related Contact Number		Alphanumeric				<b>Conditional</b>	Yes		A Contact may be the contact of the Primary Contact of a Case. For each Related Contact, provide a priority, a type, and a location. Only valid if the Contact Type is "Secondary". The Related Case Number, the Related Contact Number, or both must be populated.

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
42	Contact Priority	The highest priority of the Contact.	Number	1					See Contact Priority valid values	
43	Contact Type	Indicates if the contact is a direct (primary) contact of the Case (identified by the Related Case Number), a secondary contact of the Case (identified by the Related Case Number), or a (secondary) contact of a primary contact of a case (identified by the Related Contact Number).					<b>Yes</b>		See Contact Type valid values.	Case Contact Type + Case Contact Location derived from Referral Basis on Form 1.
44	Contact Location	Indicates if the Contact is in the jurisdiction or out of the jurisdiction of the investigating agency.							See Contact Location valid values	Case Contact Type + Case Contact Location derived from Referral Basis on Form 1.
45	Contact Disposition		Alphanumeric				<b>Yes</b>		See Disposition valid values	
46	Contact Previous Vaccination Date		Date	10	yyyy-mm-dd					Only valid if Contact Disposition = "1E".
47	Contact Previous Vaccination Take Status		Character						See Take Status valid values.	Only valid if Contact Disposition = "1E".

#	Data Element Name	Description	Data type	Size	Format?	Unique?	Req'd?	Repeatable?	Valid Values?	Notes
48	Contact Move Destination	Indicates the (new) location of the Contact if the Contact has moved from the jurisdiction of the investigating agency.	Alphanumeric							Only valid if Contact Disposition = "2B".
49	Contact Disposition Other Text	Clarifying text provided if Contact Disposition is Other (4).	Alphanumeric							Only valid if Contact Disposition = "4".
50	Contact Smallpox Case ID	The smallpox case number of the Contact.	Alphanumeric		See note		<b>Yes</b>			Format: USPS abbreviation for the state + a unique number. Only valid if Contact Disposition = "1B", "1C", or "3A".

**Valid Value Lists**

**Age Unit**

Value
Days
Months
Years

**Contact Location**

Value	Name	Description
INJ	In Jurisdiction	A contact who is located in the jurisdiction of the investigating agency.
OOJ	Out of Jurisdiction	A contact who is located out of the jurisdiction of the investigating agency.

### Contact Priority

Value	Name	Description
1	Highest priority	Case household contacts: All immediate family members; others spending more than 3 hours in the household since case's onset of rash.
2	Close contact - long time	Non-household contacts with close contact (<6 feet) with Case with rash for more than 3 hours.
3	Close contact - short time	Non-household contacts with close contact (<6 feet) with Case with rash for 1 to 3 hours.
4	Close contact - < 1 hour	Non-household contact with close contact (<6 feet) with Case with rash for <1 hour.
5		Non-household contact with contact greater than 6 feet with Case with rash for more than 1 hour.
6		Non-household contact with contact >6 feet with Case with rash for < 1haour or non-household contact with Case with fever only (no rash).

### Contact Type

Value	Description
Primary	Someone who is the contact of a case of smallpox
Secondary	Someone who is the contact to a contact of a case of smallpox.

### Disposition

Value	Description	Note
1A	Located - Referred for vaccination - fever, rash, or cough not present.	

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Value	Description	Note
1B	Located - Referred for clinical assessment - fever, rash, or cough present.	Provide Smallpox case ID.
1C	Located - Already hospitalized as suspected case - fever, rash, or cough present.	Provide Smallpox case ID.
1D	Located - Isolated, not vaccinated (within last 6 months) - fever, rash, or cough not present.	
1E	Located - Previously vaccinated (within last 6 months) - fever, rash, or cough not present.	Provide vaccination date and take status.
2A	Unable to locate contact.	
2B	Moved from jurisdiction of the investigating agency.	Provide location moved to.
3A	Deceased - Smallpox suspected	Provide Smallpox case ID.
3B	Deceased - unrelated to Smallpox	
4	Other disposition	Provide clarification

#### Ethnicity

Value
Hispanic
Non-Hispanic

#### Gender

Value
Male
Female

#### Identifier Type

Value	Name
SSN	Social Security Number
DLN	Driver's License Number

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### Lab Result

Value	Note
Detected	Valid only for Lab Test = "PCR".
Not Detected	Valid only for Lab Test = "PCR".
Pending	
Positive	Valid only for Lab Test = "Culture".
Negative	Valid only for Lab Test = "Culture".
Indeterminate	Valid only for Lab Test = "Culture".

Note: values under revision

### Lab Test

Value
PCR
Culture

Note: values under revision

### Race

Value	Name
AI/AN	American Indian/Alaska Native
AI/AN	Asian
B	Black/African American
H/PI	Native Hawaiian/Pacific Islander
W	White
O/U	Other or Unknown

### Rash

Value	Name	Description
Ordinary	Ordinary	Raised, pustular lesions
Confluent	Ordinary - Confluent - Face and other site	Confluent ordinary rash on face and forearms. Subtype of Ordinary.
Semi	Ordinary - Semi-confluent - Face only	Confluent rash on face, discrete elsewhere. Subtype of Ordinary.
Discrete	Ordinary - Discrete	Areas of normal skin between pustules, even on face.
Modified	Modified Type	Like ordinary type but with an accelerated course.

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Value	Name	Description
Flat	Flat Type	Pustules remain flat; usually confluent or semi-confluent, usually fatal.
Hemorrhagic	Hemorrhagic	Widespread hemorrhages in skin and mucous membranes.
Early	Hemorrhagic Type - Early	Hemorrhagic with purpuric rash, always fatal. Subtype of Hemorrhagic.
Late	Hemorrhagic Type - Late	Hemorrhagic with hemorrhage into base pustules, usually fatal. Subtype of Hemorrhagic.

**Take Status**

Value
Major
Equivocal
None
Unknown