Centers for Disease Control and Prevention   **Draft: January 18, 2003**

Annex 6

Smallpox Vaccination Application

DRAFT
Smallpox Vaccination Program Guidance: Annex 6
Pre-Event Vaccination Application Functional Requirements and Process Flows
Version 1.2

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1.   Introduction

The guidelines in this document describe functional requirements and clinic data workflow for systems implemented to manage Pre-event vaccination administration. This information provides the basis for vaccination record repositories and reporting systems that are needed to support pre-event vaccination administration.

Pre-event vaccination is oriented to the support of a campaign conducted to ensure preparedness in the possible event of a smallpox outbreak. The program assumes that the Vaccine Adverse Events Reporting System (VAERS) will be used to collect severe adverse events information, as is the current practice for other licensed vaccines.

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.   Requirements

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:

2.1.1   Organization Data

- Organization data should be stored for organizations that participate in the program.
- Organizations that participate include: Clinics, Referring Organizations (hospitals), State and Local Health Departments.
- Organization data includes: Organization name and address, contact name, phone number, fax number, type of organization (clinic, hospital…)
- Individuals assigned to an organization in support of this program should be captured, for example Vaccinators and Take Readers.
- This data will allow the Public Health Department (Grantee) to run reports by clinic and hospital to show how many people have been vaccinated at each clinic, how many people have been vaccinated from each hospital, and other statistical data that may indicate that there is an issue with the vaccine or the vaccination staff at a particular clinic (i.e., if there is a higher rate of No Take responses at a given clinic, corrective action may be taken).

2.1.2   Patient Administration Data - Unique Identification

- Patient Demographic Data
  - o The patient demographic record must be uniquely identified to maintain uniqueness and eliminate duplication of patient information.
  - o Patient demographic data includes: name, address, date of birth, gender, phone number, fax number, other pertinent numbers (cell phone, email), state of residence, ethnicity, race and occupation. Additional identifiers such as SSN, driver's license number, or passport number could be included to validate the

uniqueness of the patient. Patient identifying data is not required, but recommended.

o The contact information can assist in contacting the patient if he/she does not return for their take response reading or in the event that an issue is found with a particular lot or clinic.

o The occupation is needed to determine the composition of potential response teams.

o These data will be used at the Public Health Department (grantee) level, to run reports and generate statistics for vaccination activities.

- Current Vaccination Data

o The system must allow entry and tracking of the current vaccination event data.

o Vaccination data is associated with the current pre-event vaccination campaign.

o Vaccination records are linked to the patient record, and the vaccine batch.

o The vaccination record should also be linked to adverse events recording in VAERs, through the use of a PVN number.

o Vaccination data includes: the date of vaccination, the vaccinator, the referring organization, and take reading.

o Take Reading includes: take response, take reader and adverse events.

o Take responses can be: Major, Equivocal, or No Take.

o This information is used to track when the patient should return for a take response reading, to determine who was vaccinated with a certain batch in the event of issues with a batch, a clinic, a vaccine lot, a diluent lot, and for statistical analysis.

- Vaccination History Data

o The system should support storing previous vaccination records for vaccinia.

o Vaccination history data includes: date vaccination received and take response.

o Date can be an actual date or a general value like childhood.

o This data will be used to determine if previous vaccinations have an impact on the take response for the current vaccination. This data will also be used for statistical analysis.

- Adverse Events Data

o Adverse events include site specific skin findings, non-site specific skin findings, encephalitis, etc. These should be recorded in VAERs

o It is requested that the VAERs record be identified with the Patient Vaccination Number (PVN) or a substitute equivalent number.

o Adverse events data can be used to determine appropriate treatment for a patient.

o Adverse events data can also be used for statistical analysis to determine if there is an issue with a particular vaccine or diluent lot, or if a specific clinic has a high number of adverse events.

- Re-vaccination Data

o The system must support multiple vaccination events for a patient, under the campaign.

o The re-vaccination data is the same as the current vaccination data.

o The system must link the revaccination record to the original patient record.

- o A revaccination is recommended for patients with No Take on their initial vaccination under this campaign.
- o Patients with a No Take on a revaccination will be medically referred to their physician. The patient's physician will need to make a determination on how to proceed based on the patient's medical history and medical profile.
- o Revaccination data can also be used in statistical analysis to determine impact of revaccination on Take response, and to evaluate vaccine efficacy.

2.1.3 Patient Vaccination Number Support

- Each vaccination event should have a unique Patient Vaccination Number (PVN), or equivalent.
- The PVN format has a 3 digit alpha prefix of 'PVN' followed by a 10 digit number.
- If a PVN equivalent is substituted for the CDC designed stickers, the format should **NOT** begin with PVN. The PVN substitute is alphanumeric 20 and has no other restrictions in format.
- Each Patient Vaccination Number is unique across organizations, and therefore any PVN substitute would have to be unique across organization's name space.
- This number is in addition to any patient identification numbers, and is a reference to the actual vaccination event.
- For this campaign, the patient may have multiple vaccination events: an initial vaccination, and a revaccination. Additional vaccinations may be given as determined by the patient's physician. A unique PVN (or equivalent) will be assigned to each vaccination event.
- Preprinted labels with PVNs in text and barcode format can be included with the vaccine forms. Six labels can be printed for each PVN. The PVN should be placed on the hardcopy vaccination forms for each patient. This will provide the link that ties the forms together for a vaccination event.
- Vaccination events must be linked to the patient.
- Vaccination events should be identified by the patient, date of vaccination, batch and lot of the vaccine and diluent, vaccination administrator, administering clinic, and referring organization.

2.1.4 Vaccine/Diluent Batch, Lot, and Manufacturer Data

- Valid vaccine lots should be stored in the system.
- Valid diluent lots should be stored in the system.
- The diluent lots and vaccine lots should be identified by their manufacturer.
- The valid vaccine and diluent lots should be used to create selection lists when a vaccine batch is created. This will ensure consistency of lot numbers and reduce the possibility of incorrectly entered lot numbers.
- A vaccine batch is created by a clinic when they reconstitute a lyophilized vaccine. Vaccine batch information includes: date of reconstitution, clinic where the batch was created, and maximum possible number of doses that can be delivered from the batch.
- The vaccine batch is linked to the vaccination event for each patient.
- This link between patient and batch can be used to trace batch issues to a vaccine lot, a diluent lot, or potentially to the clinic or the vials that the clinic has received.
- This data will support reporting by batch or lot, and can be used to calculate wastage. The system should track the vaccine and diluent manufacturer and lot data. As batches of vaccine are created and used, information about the batches should also be maintained such as the date of reconstitution and the clinic where the batch was used.

2.1.5 Patient Record Matching/Duplicate Patient Record Minimization

- The system should support the ability to match patient records based on meaningful identifiers

such as a PVN or equivalent.

- Matching will reduce duplication of patient data in the system.
- Each patient should be assigned a unique system supplied Patient Identification Number (PIN). Clinics may choose to use the PVN (or equivalent) for the initial vaccination event as the PIN for the patient.
- Unique identification of patient records will support contact tracing if an adverse reaction occurs. In addition, unique identification of patients will ensure that vaccination totals are calculated correctly and response team compositions are derived correctly.

2.1.6 Record Search and Retrieval

- The system should allow search and retrieval of patient and vaccination records.
- This will assist in minimizing duplicate record entry as noted above.
- Search and retrieval capability will also allow authorized users to efficiently retrieve an existing record that requires updates.

2.1.7 Report Generation

- The system must support the ability to generate detailed and aggregate reports.
- Detailed patient reports should be used for Quality Assurance of data entry.
- Reports by Public Health Department (grantee) may be used to show preparedness across the grantee's jurisdiction.
- Reports by referring organization may be used to show response team composition within the referring organization.
- Aggregate reports for each grantee's jurisdiction showing the number of patients vaccinated, the number of patients not vaccinated, the number of patients with no take on the first vaccination event, will be summarized on a national level, and used to validate overall preparedness.

### 2.1.8 Central Records Repository

- Each Public Health Department (grantee) will require a central repository for vaccination records.
- The centralized repository should, for this campaign, hold the vaccination data described in this document.
- The System used by the grantee should incorporate a backup process that can be used in the event that the system is temporarily unavailable, for example paper forms.
- The central repository will store the data against which reports will be run at the detail and aggregate level.
- The centralized repository will maintain the data links that support retrieving patient and vaccination records, and linking them to a vaccine batch.
- The repository will be used to validate preparedness in the event that response is required to contain an outbreak of smallpox.

2.1.9 Support for Data Export

- The system must support the ability to produce a data export in the prescribed format.
- Export functionality is required to exchange data with other authorized organizations such as the CDC.
- The prescribed format is a XML schema that is included in a separate document that describes the data types, format, and data linking requirements.

3.   Vaccination Clinic Process Flows
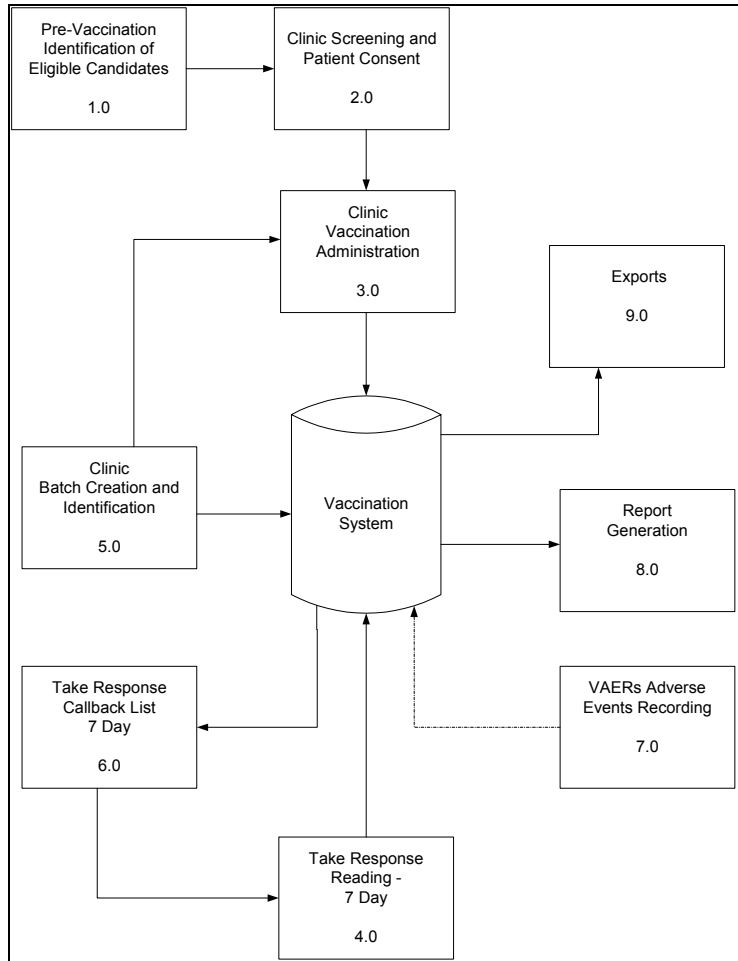
3.1 Overview

1.0 Pre-Vaccination Identification of Eligible Candidates
Pre-vaccination screening is performed by referring organizations, such as hospitals, and includes identifying and educating potential candidates. Also included is, coordination of eligible candidate lists with the public health department, and the coordination of schedules between the referring organization and the clinic.

2.0 Clinic Screening and Patient Consent
Clinic screening is performed at the clinic, and includes completion and review of medical history & consent form, reinforcement of adverse events education, answering patient questions, and obtaining patient consent, as appropriate.

3.0 Clinic Vaccination Administration
Clinic Vaccination Administration applies to consenting patients. It includes completion and processing of patient forms, patient vaccination, educating patients (on wound care, adverse

events, take response, and take reading), and data entry.

4.0 Take Response Reading -7 Day
The vaccine Take Response Reading is performed 6-8 days after the vaccination is given. This flow includes reading the take response, initiating a revaccination for negative first vaccinations, and recording the Take Reading both on paper (forms and patient vaccination card) and in the system.

5.0 Clinic Batch Creation and Identification
The clinic creates or identifies the vaccine batch to be used on each day. The batch information is included on the Medical History & Consent form that will be completed by eligible candidates who have come to the clinic to receive their vaccination.

6.0 Take Response Callback List 7 Day
The clinic generates Take Response Callback Lists to remind patients to return for their Take Reading. Take Response Callback Lists include patient name and phone number and can be derived based on a due date for when Take Responses should be read.

7.0 VAERs Adverse Events Recording
It is expected that VAERs will be used to record adverse events. The VAERs form will include a field to record the PVN of the patient experiencing the adverse event.

8.0 Report Generation
Clinic reports include detailed clinic vaccination and take reading activity, as well as aggregate counts. CDC reports include Public Health reports and National Vaccine Monitoring reports.

9.0 Exports
Export of batch data to be uploaded to the CDC for vaccine safety monitoring, and response team identification.

3.2   1.0   Pre-Vaccination Identification of Eligible Candidates

3.2.1 Workflow
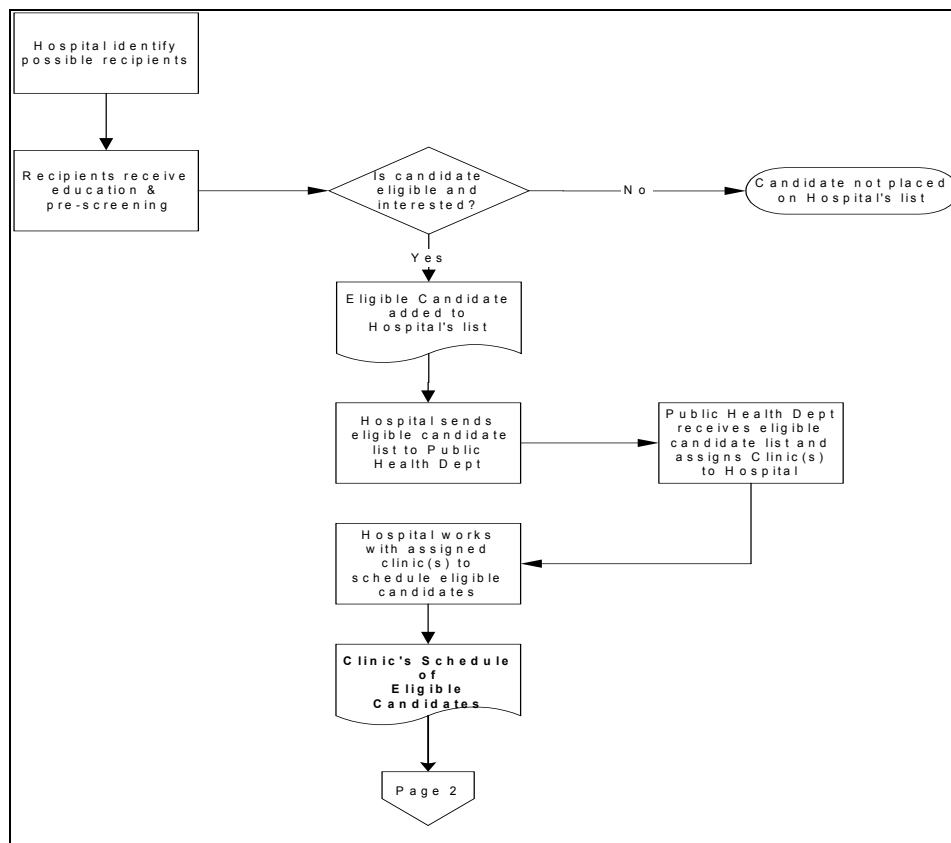
3.2.2 Description

- Hospitals will identify possible candidates.
- Hospitals will educate and pre-screen identified candidates on benefits, risks, contraindications, and procedures for smallpox vaccination.
- Candidate may need to consult with their personal physicians and/or receive tests to rule out contraindications.
- Candidates who pass pre-screening and volunteer to be vaccinated will be placed on the eligible candidate list for the hospital.
- Hospitals will send their eligible candidate lists to the Public Health Department.
- The Public Health Department will receive, organize, and manage lists from multiple hospitals and determine which clinic a hospital should use and provide the clinics with hospital eligible candidate lists.
- The Public Health Department will also be responsible for informing hospitals of the clinic(s) with which they should coordinate scheduling.
- Each hospital will coordinate scheduling with their assigned clinic(s). The hospital will be responsible for informing eligible candidates of the clinic, date, and time to report for vaccination.
- The eligible candidate list will hold the name and contact information for the hospital contact(s) who may be called to resolve any eligibility or scheduling issues that may exist when the patient arrives at the clinic.

### 3.3   2.0   Clinic Screening and Patient Consent

3.3.1   Workflow
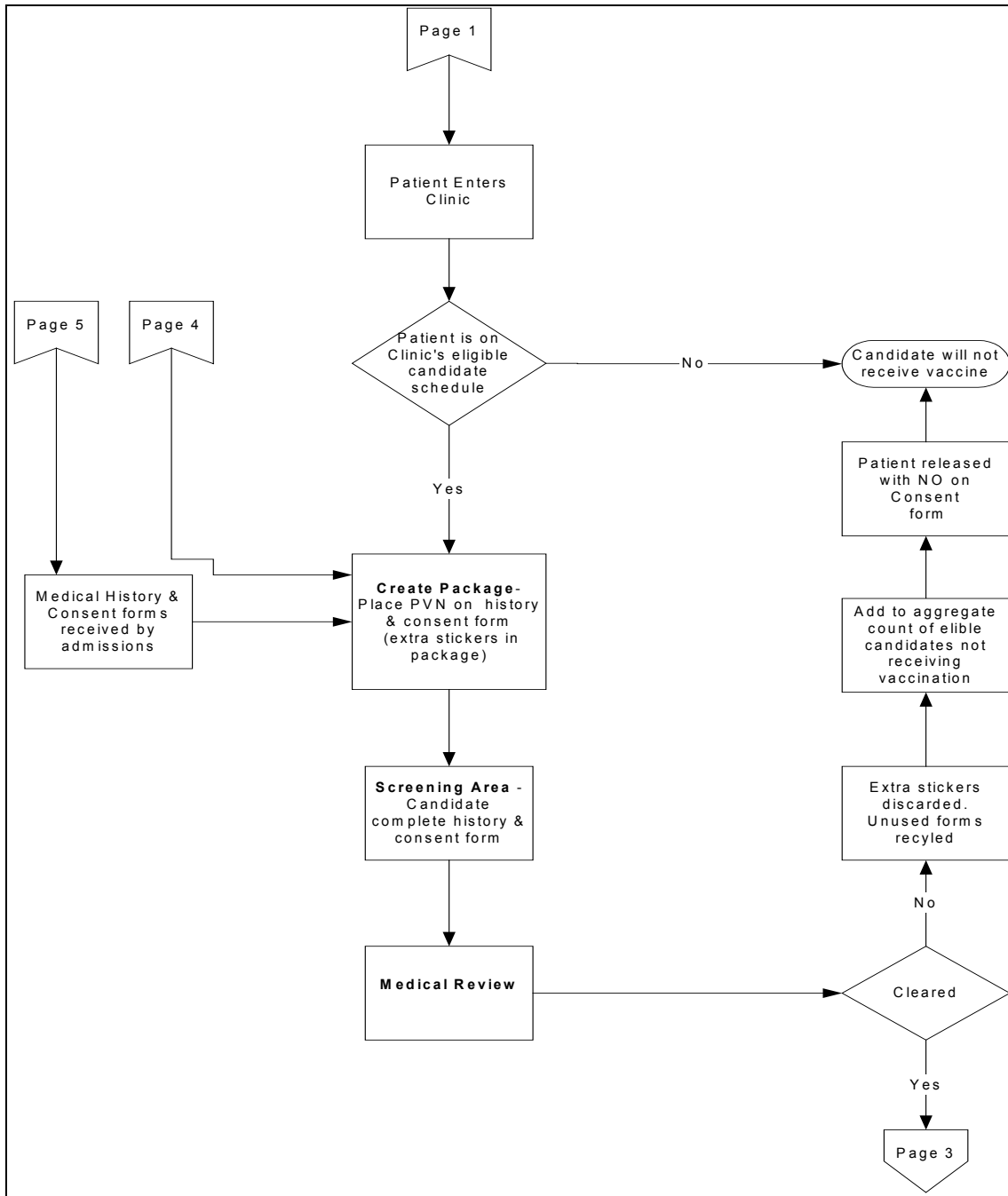
3.3.2 Description

- Patient arrives at clinic based on appointment.
- Clinic checks patients who arrive against the eligible list from the Public Health Entity for the specified appointment date.
- Patients not on the list may be investigated with the hospital, if they are not eligible, they will be sent home. No paperwork will be recorded for these individuals.
- Patients will be provided with and asked to review educational materials concerning smallpox disease risk, and smallpox vaccination benefits, risks, contraindications, and procedures.
- Patients who are on the list will have a package of forms and information created that consists of:
    o Medical History & Consent Form
    o Vaccination Card
- The Medical History & Consent form should include the information that comprises a vaccine batch: Vaccine Lot/Manufacturer, Diluent Lot/Manufacturer, Reconstitution Date for lyophilized vaccines, and system supplied Batch_ID.
- The clinic's system should either support printing vaccination clinic and batch information, or the clinic and batch information should be manually included on the medical history and consent form and copied. Vaccination Clinic and Batch information is required for each patient that receives the vaccination.
- Sets of six Patient Vaccination Number stickers will be provided.
- One patient vaccination number (PVN) sticker (or equivalent) will be placed on each page of the Medical History & Consent form. Any extra stickers will be reserved with the package.
- The patient will complete the history form and review the informational materials.
- The Medical History & Consent form consists of several pages:
    o Patient Demographic and Vaccination History page
    o Patient Medical History page
    o Vaccination and Take Response page
    o Medical Consent page will include pre-printed vaccine batch information (vaccine manufacturer/lot, diluent manufacturer/lot, patient demographics, vaccination history, and information about the current vaccination event.
- A clinic screener will reiterate the education provided as a part of pre-vaccination screening, review patient's medical history, and determine if a patient is cleared to receive the vaccination.
- If cleared and willing to receive the vaccination, the patient will sign the medical history & consent form. The patient is now a consenting patient.
- If not cleared or not consenting, the patient will be sent home, the extra stickers will be discarded and the forms will be stacked either in a no-consent due to contraindications, or a no-consent due to not-willing. These will be tallied at the end of the day and entered as aggregate figures in the system.

3.4   3.0 Clinic Vaccination Administration

3.4.1   Workflow
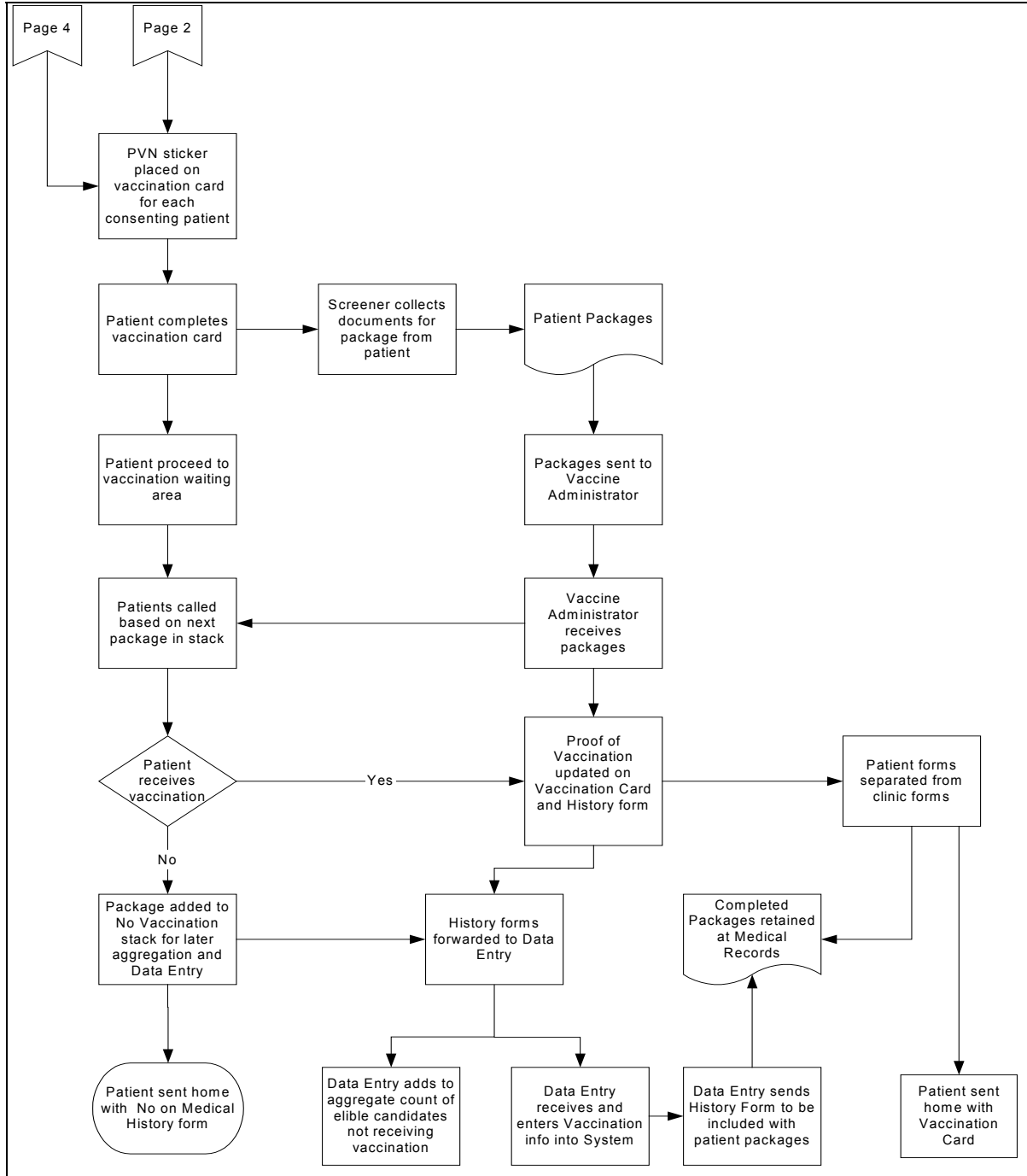
3.4.2 Description

- If the patient has been cleared and has consented, they will complete the demographics on the vaccination card.
- PVN stickers (or their equivalents) will be placed on the demographics form. Extra stickers may remain and can be used to support clinic flow or patient medical care.
- The completed patient packages will be delivered to the vaccinator.
- The vaccinator will call patients based on the package queue, verify their information, and verify the consent signature.
- Patients who opt out at this time will be indicated as such on their consent form and history form, and their packages will be separated for later aggregation.
- Patients receiving the vaccination will then be given their vaccination card.
- Patients will receive education on site care, potential adverse events and how to report an adverse event. The clinic may choose to schedule patients to return for their Take Reading at this time.
- When a pre-determined number of vaccinations have been completed, the demographic and vaccination pages of the medical history & consent form will be given to Data Entry to be entered into the system.
- Data Entry will enter available patient demographics, vaccination history, and vaccination batch information into the system. They will then return the Medical History & Consent forms to Vaccination Administration to be re-filed into the patient packages.
- Aggregates of no-consents will be entered into the system by Data Entry at the end of each day.

Please Note: This is a general clinic flow that does not attempt to include implementation details that the clinic may choose to implement to maximize efficiency, or improve education. For example: batching of patients for education and throughput, intake greeters, fast-track vaccination path for patients with no contraindications, frequently asked question list in send home package, color card of normal Take Response in send home package.

### 3.5   4.0   Take Response Reading – 7 Day

3.5.1   Workflow
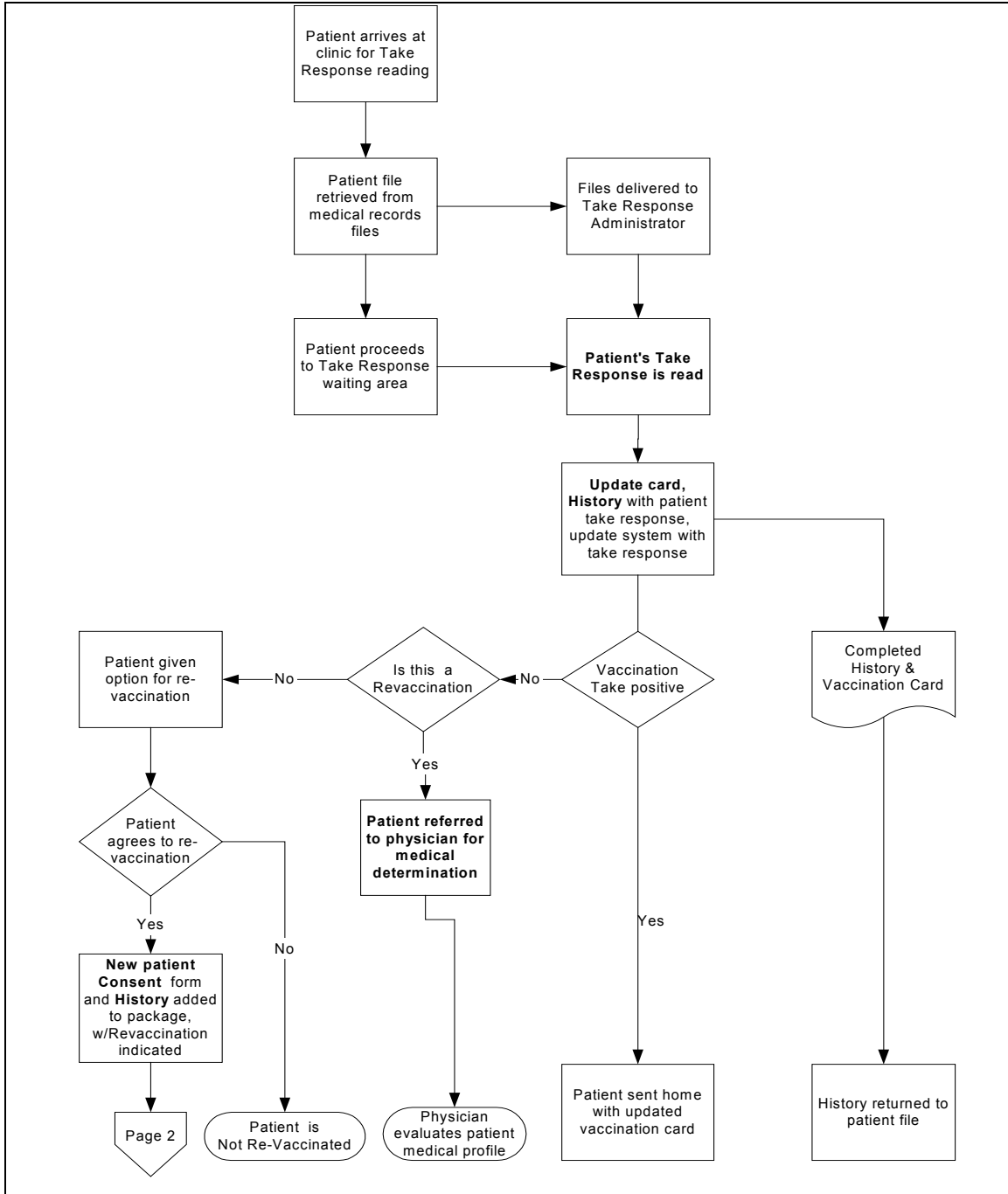
3.5.2 Description

- Patients will return to the clinic where the vaccine was administered.
- The clinic will mark patients on the Take Response Callback List as their take responses are read.
- The Vaccination Card will be updated, and the Medical History & Consent form will be updated with the Take Response.
- If there was no take, and this is a revaccination, then the patient will be directed to their physician. Their physician will make a medical determination on how to proceed.
- If there was no take, and this is their first vaccination of Vaccinia then the patient will be given the option to be revaccinated.
- If a patient with No Take chooses to be revaccinated, a new set of forms will be added to their package with the revaccination flag selected.
- It is very important that the new Medical History & Consent form hold both the original PVN (or equivalent) and the revaccination PVN (or equivalent). The original PVN (or equivalent) identifies the patient. The new PVN (or equivalent) identifies the revaccination event.
- The set of revaccination forms should be marked to indicate revaccination.
- The patient would complete the revaccination consent form, and the revaccination Medical History & Consent form.
- The patient's package would then be included in the medical screening queue.
- If a patient with No Take chooses no to be revaccinated, they are sent home with their vaccination card, which will indicate that No Take occurred.
- If the patient has a positive take response, then they are sent home with their vaccination card, which will indicate that they had a positive Take Response to the vaccination.
- The Medical History & Consent form will be used to enter the information into the Pre Event Vaccination Application, and will be retained in the patient's medical record.
- Any patients on the Take Response Callback List that do not show up for their take reading should be re-contacted.

3.6   5.0 Clinic Batch Creation and Identification

3.6.1 Workflow
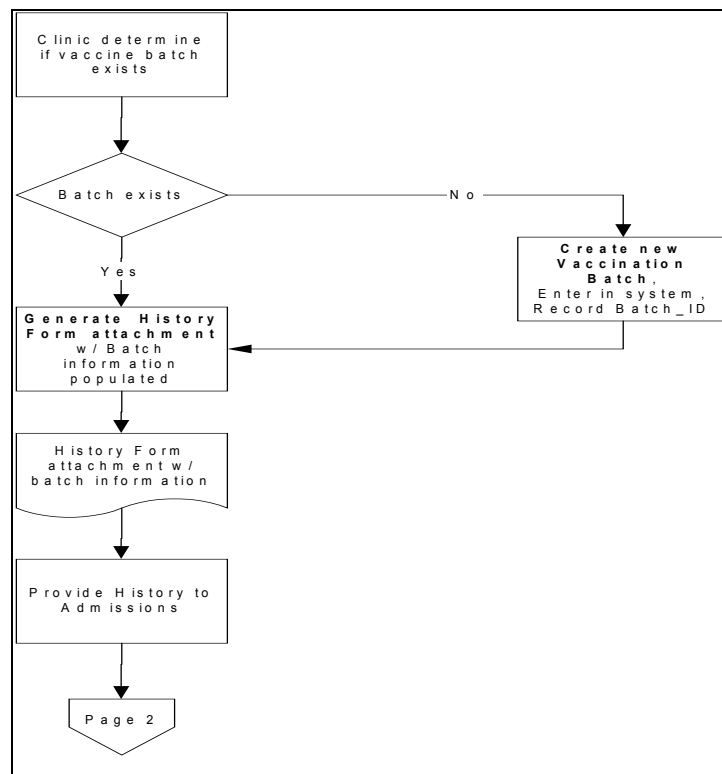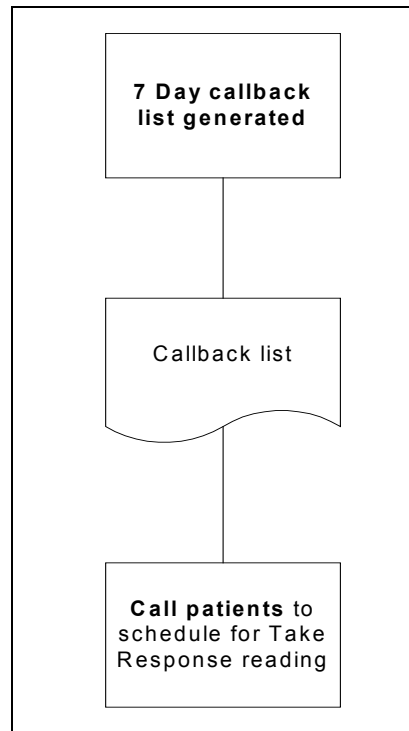

3.6.2 Description

- At the beginning of the day, a vaccination batch (see Section 2.1.4 for definition of a batch) will either be created, or an existing vaccination batch(es) identified for use during that day.
- It is possible that multiple batches will exist for the same day, and this should be accommodated by the system used at the clinic and considered in the clinic's process flow.
- The batch is identified by Vaccine Lot/Manufacturer, Diluent Lot/Manufacturer, Clinic, and Batch Created Date/Time (Hours & Minutes) . This is the same as the reconstitution date for Dryvax, ACAM1000, ACAM2000.
- The clinic's system should be able to hold the above batch information as well as a unique identifier that is specific to the batch. This will allow traceability back to a batch to support: wastage tracking, issues that may be batch specific, and to increase efficiency in the process.
- If the system is able to generate the batch and clinic information, it should be attached to the Patient Medical History & Consent form. This batch information should include the Batch_ID and lot information for the Batch that was created or selected.
- The generated forms would be delivered to Admissions to be included in patient packages.
- The vaccination batch will be delivered to the Vaccinator.
- The Clinic will be responsible for attaching the correct vaccine batch insert to the Patient's Medical History & Consent form, and ensuring that the vaccine batch administered to the patient matches the vaccine batch on the patient's history form.
  - o Vaccine batches for the licensed vaccine have a 1:1 dilution, and will deliver 100 doses, if no wastage occurs.
  - o If wastage occurs, the clinic must make sure that any extra forms are destroyed..

    o   The clinic may need to print or copy extra forms due to the fact that only a subset of eligible candidates will receive the vaccination.

3.7 6.0 Take Response Callback List – 7 Day

3.7.1 Workflow

3.7.2 Description

- A report will be generated by the clinic to list patients who should return for take response reading.
- Each individual will be called by the clinic and scheduled or requested to return to the vaccinating clinic for the take response reading on the 6th to 8th day following vaccination. If the clinic scheduled the Take Reading appointment when the vaccination was given, then the call will serve as a reminder for the patient to return to have their Take Response read.

## 3.8   7.0 VAERS Adverse Events Recording

3.8.1   Workflow
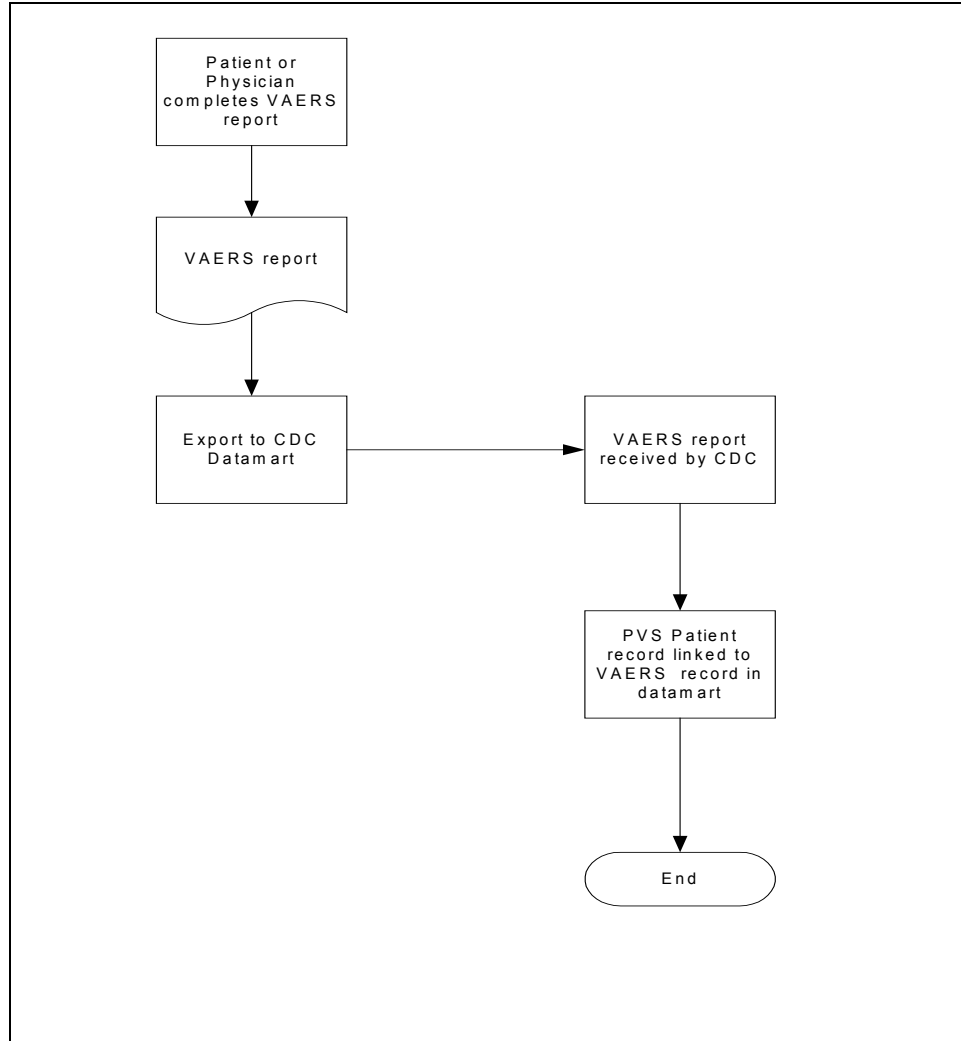
3.8.2   Description

- The patient or physician will create a vaccine adverse events report in VAERS.
- The patient's PVN or PVN equivalent will be included on the report.
- VAERS reports are uploaded to the CDC Datamart on a daily basis.
- The CDC datamart will link the VAERS report to the patient in PVS based on the PVN or equivalent.

3.9   8.0 Report Generation

3.9.1   Workflow
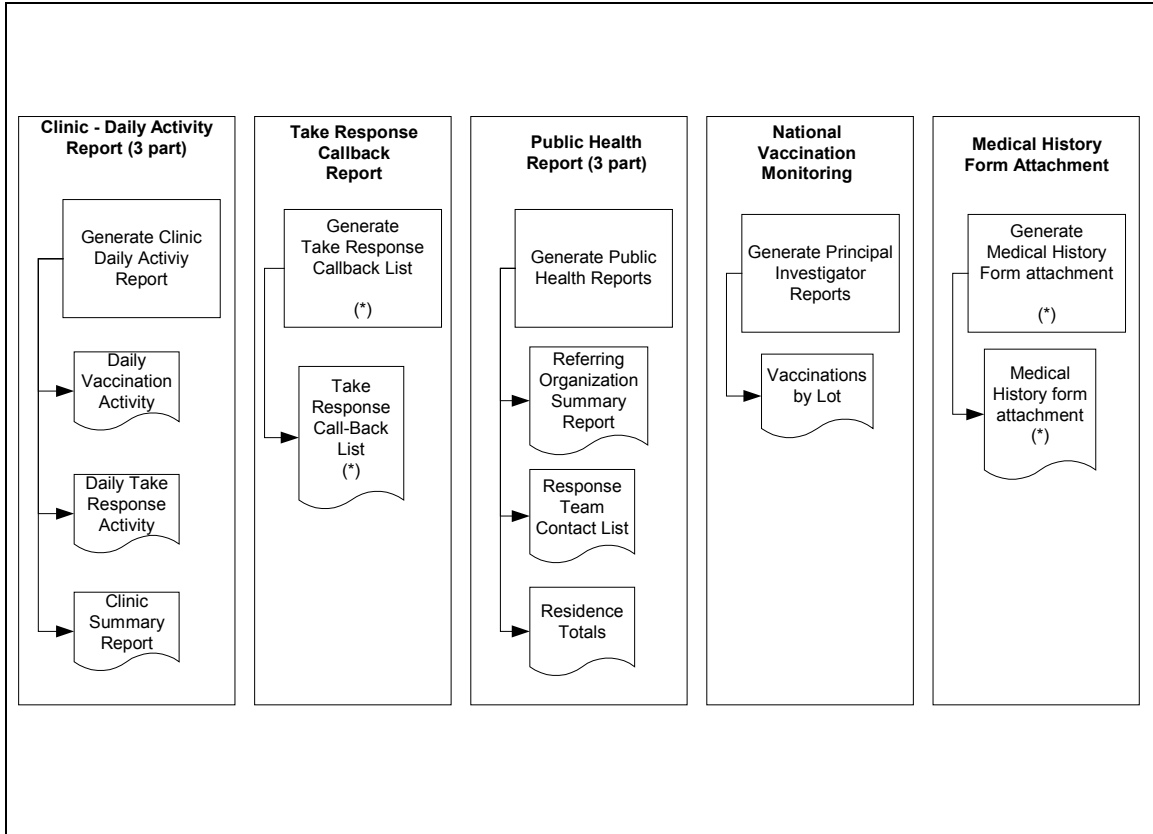
3.9.2   Description

3.9.2.1 Clinic Activity Report

The clinic is responsible for generating clinic reports, and any system implemented by the clinic should be able to provide the information described below.

3.9.2.1.1   Daily Vaccination Activity

This report is a complete record of all vaccinations performed at the clinic on the day for which the report is run. This report includes all data captured for each patient. It is intended to be used for quality assurance of the input data and to provide a complete record of the clinic's vaccination activity.

3.9.2.1.2   Daily Take Response Activity

This report is a complete record of all take response readings performed at the clinic on the day for which the report is run. This report includes all data captured for each patient. It is intended to be used for quality assurance of the input data and to provide a complete record of the clinic's take response activity.

3.9.2.1.3   Clinic Summary Report

This report is a summary report for a clinic. This report includes but is not limited to the total number of vaccinations, total number of take response readings, and a count at each take response level (no take, major, and equivocal).

3.9.2.2 Take Response Callback Report

3.9.2.2.1   Take Response Call-Back List

The Take Response Call-Back List provides a list of vaccinees who need to be called as a reminder to have their take responses read. This report is sorted by number of days since vaccination, descending. This report will also have space to capture the data from the take response in preparation for data entry.

(*) This report is integral to the clinic flow and is covered in detail under a separate process flow.

3.9.2.3 Public Health Reports

The Public Health Department (Grantee) will generate these reports.

3.9.2.3.1   Referring Organization Summary Report (Part I)

The Referring Organization Summary Report provides aggregate counts of people vaccinated by referring organization with take responses and cumulative counts (including occupation totals). This report is intended to provide a list of protected people for building the public health and hospital based response teams in the event of an outbreak.

3.9.2.3.2   Response Team Contact List (Part II)

This report is a list of people who are protected, based on having a major take on their initial vaccination or revaccination. This report is intended to provide a list of protected people for building the public health and clinical response teams in the event of an outbreak. Because a physician has to determine through testing if an individual with a no-takes or equivocal takes is protected, this report will not include those individuals.

3.9.2.3.3   Residence Totals (Part III)

The Residence Total report provides an aggregate count of residents of a state (1) who have been vaccinated, (2) their take response reading, and (3) the number of people protected (see protection criteria above).

3.9.2.4 National Vaccination Monitoring Report

The CDC, based on information provided by clinics, will generate this report.

3.9.2.4.1   Vaccinations by Lot Report

The Vaccinations by Lot report will be used to summarize vaccination activity across all states. The report can be run for a single date or a date range, and it can be run for a single vaccine lot or all vaccine lots.

The report includes a detail version and a summary version. The detail version lists all patients vaccinated with a vaccine lot and the summary version summarizes the total number of patients vaccinated at a clinic, for all clinics within a state, and for all states for a given lot.

3.9.2.5 Medical History & Consent Form

The Medical History & Consent form is a part of the patient package at each clinic. The clinic's system should either support printing a Medical History & Consent form attachment that is pre-populated with the identifying information that comprises a batch, or the batch information should be manually included on the medical history & consent form for each patient receiving the vaccine batch. Batch information includes the: system supplied Batch_ID, the Vaccine Lot Number and Manufacturer, the Diluent Lot Number and Manufacturer, the Batch Creation Date (Date of reconstitution for lyophilized vaccine), and the Clinic's name.

(*) This report is integral to the clinic flow and is covered in detail under a separate process flow.

3.10   9   Export

3.10.1 Description
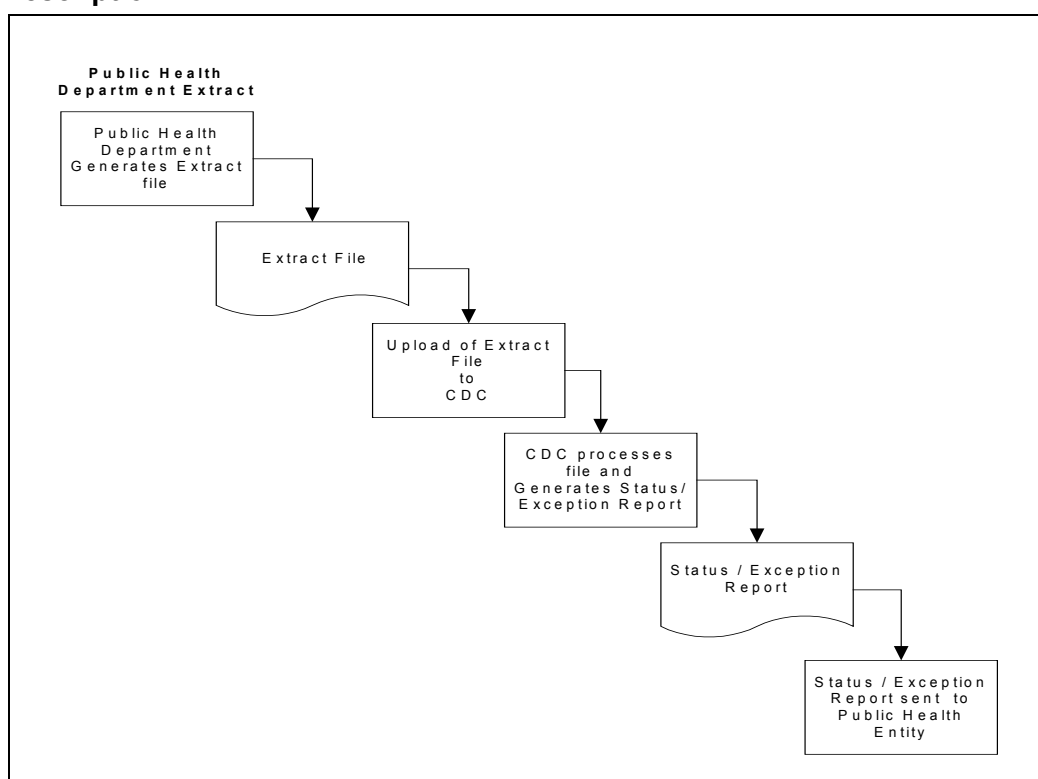
3.10.2 Description

3.10.2.1   Public Health Department (Grantee) Upload

- The Public Health Department's system should support generating an extract of vaccination data.
- The extract must be uploaded to the CDC once a day.
- The extract should be in XML, and adhere to the CDC provided format for data exchange.
- The Public Health Department will be responsible for uploading the extract to the CDC – this will require a digital certificate supplied by the CDC's Secure Data network group.
- The extract will include linked data in a nested format for clinic organizations, vaccine batches, vaccinations administered, and take responses read.

- The PVN or its equivalent is included in this format and is crucial to uniquely identifying the data brought together from many systems. This assimilated data set will be used to perform statistical analysis that provides the basis for vaccine safety monitoring at the CDC.