

DRAFT

**Pre-Event Vaccination Application Functional
Requirements and Process Flows**

Version 1.0

Pre-Event Vaccination Application Functional Requirements and Process Flows	Draft Version: 1.0
	Date: 11/13/2002

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

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- The contact information is needed in case the patient does not return for their take response reading or in the event that an issue is found with a particular lot or clinic.
- The occupation is needed to determine the composition of potential response teams.
- These data will be used at the State level, to run reports and generate statistics for vaccination activities.
- **Current Vaccination Data**
 - The system must allow entry and tracking of the current vaccination event data.
 - Vaccination data is associated with the current pre-event vaccination campaign.
 - Vaccination records are linked to the patient record, and the vaccine batch.
 - The vaccination record may also be linked to adverse events recording (from the voluntary adverse events diary)
 - Vaccination data includes: the date of vaccination, the vaccinator, the referring organization, and take reading.
 - Take Reading includes: Take response, take reader and adverse events.
 - Take responses can be: Major, Equivocal, or No Take.
 - 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 or a clinic, and for statistical analysis.
- **Vaccination History Data**
 - The system should support storing previous vaccination records for vaccinia.
 - Vaccination history data includes: Date vaccination received and take response.
 - Date can be an actual date or a general value like childhood.
 - 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**
 - Adverse events recording capability should exist in the system.
 - Adverse events include site specific skin findings, and non-site specific skin findings. Adverse events also include overall symptoms such as fever, fatigue, muscle pain, and others.
 - The full list of adverse events that are tracked for vaccinia are found on the Adverse Events Diary Card.
 - It will be requested that adverse events be recorded on the Adverse Events Diary Card that is given to the patient. The diary is voluntary for licensed vaccines.
 - Adverse events data can be used to determine appropriate treatment for a patient.
 - 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**
 - The system must support multiple vaccination events for a patient, under the campaign.
 - The re-vaccination data is the same as the current vaccination data.

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- The system must link the revaccination record to the original patient record.
- A revaccination is recommended for patients with No Take on their initial vaccination under this campaign.
- Immunity is assumed if there is No Take on a revaccination; so for this vaccination campaign a patient will have no more than two vaccinations.
- 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.
- The format must be followed if a PVN equivalent is substituted for the CDC designed stickers.
- Each Patient Vaccination Number is unique across organizations, and therefore any PVN substitute would have to be unique across all organizations.
- This number is in addition to any patient identification numbers, and is a reference to the actual vaccination event.
- The patient may have multiple vaccination events. For this campaign, the patient may have as many as two vaccination events: an initial vaccination, and a revaccination. 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 combination of name, birth date, and phone number or alternatively a unique identifier

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like driver's license number or Social Security Number.

- 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 state may be used to show preparedness across the state.
- Reports by hospital may be used to show response team composition within the hospital.
- Aggregate reports for each state 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

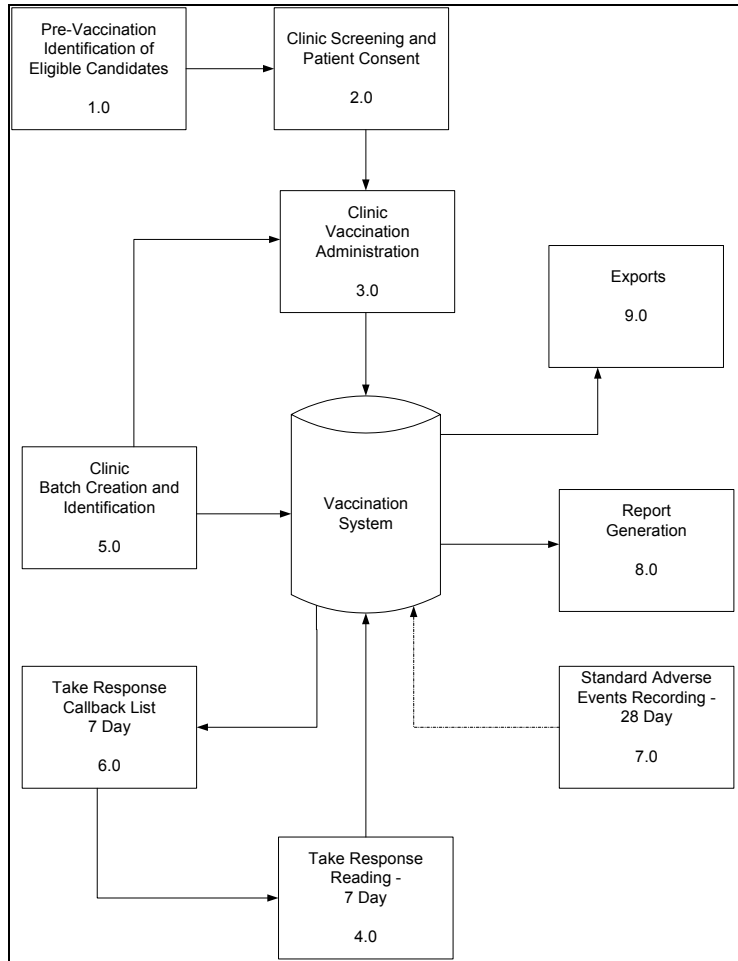
- Each state will require a central repository for vaccination records.
- The centralized repository should, for this campaign, hold the vaccination data described in this document.
- The System used by the state should incorporate a backup that can be used in the event that the system is temporarily 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.

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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 state 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 forms, reinforcement of adverse events education, and patient consent.

3.0 Clinic Vaccination Administration

Clinic Vaccination Administration applies to consenting patients. It includes completion and processing of patient packages, patient vaccination, and data entry.

4.0 Take Response Reading -7 Day

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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 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 forms 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 Standard Adverse Events Recording -28 Day

An Adverse Events Diary form will be sent home with each Patient. The patient will be educated on how to complete the Diary form, including directions on returning the Diary form to the proper location. The patient will complete the Diary form starting on the day they receive the vaccination (day 0) and finishing on the 27th day following the vaccination. Since this is a licensed vaccine, the Diary form will be optional and the patient will be instructed to return the completed form to the CDC. Adverse Events forms received by the CDC will be entered into the Pre-Event Vaccination System.

8.0 Report Generation

Clinic reports include detailed clinic vaccination and take reading activity, as well as aggregate counts.

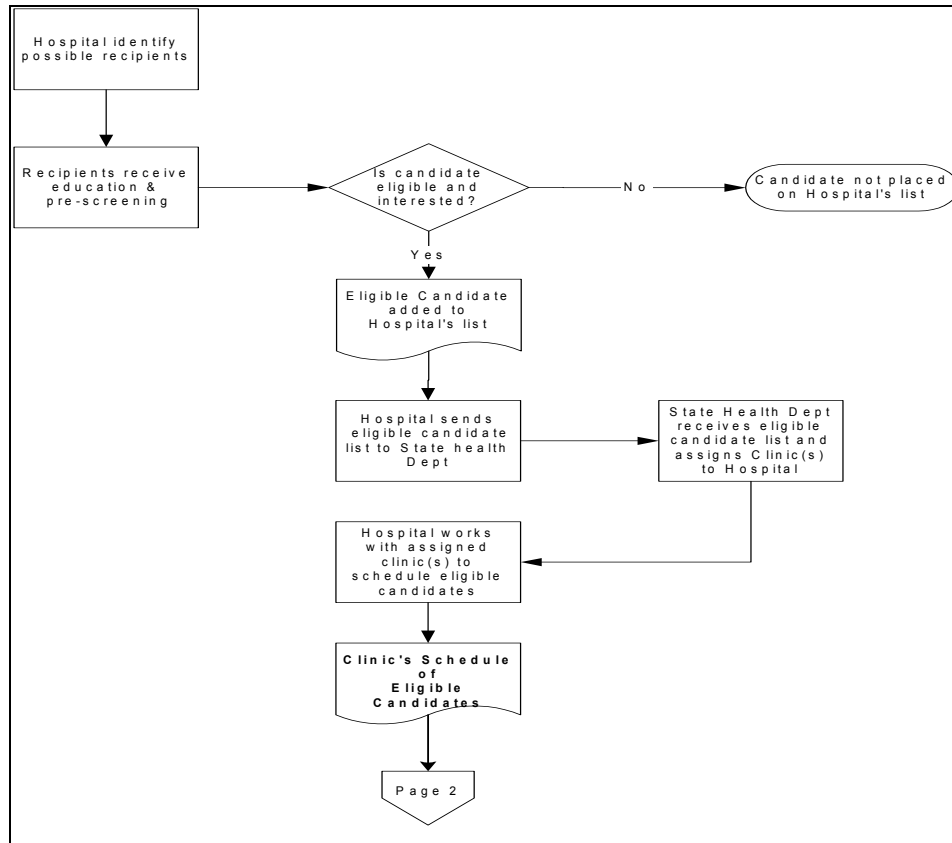
CDC reports include Public Health reports and National Vaccine Monitoring reports.

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

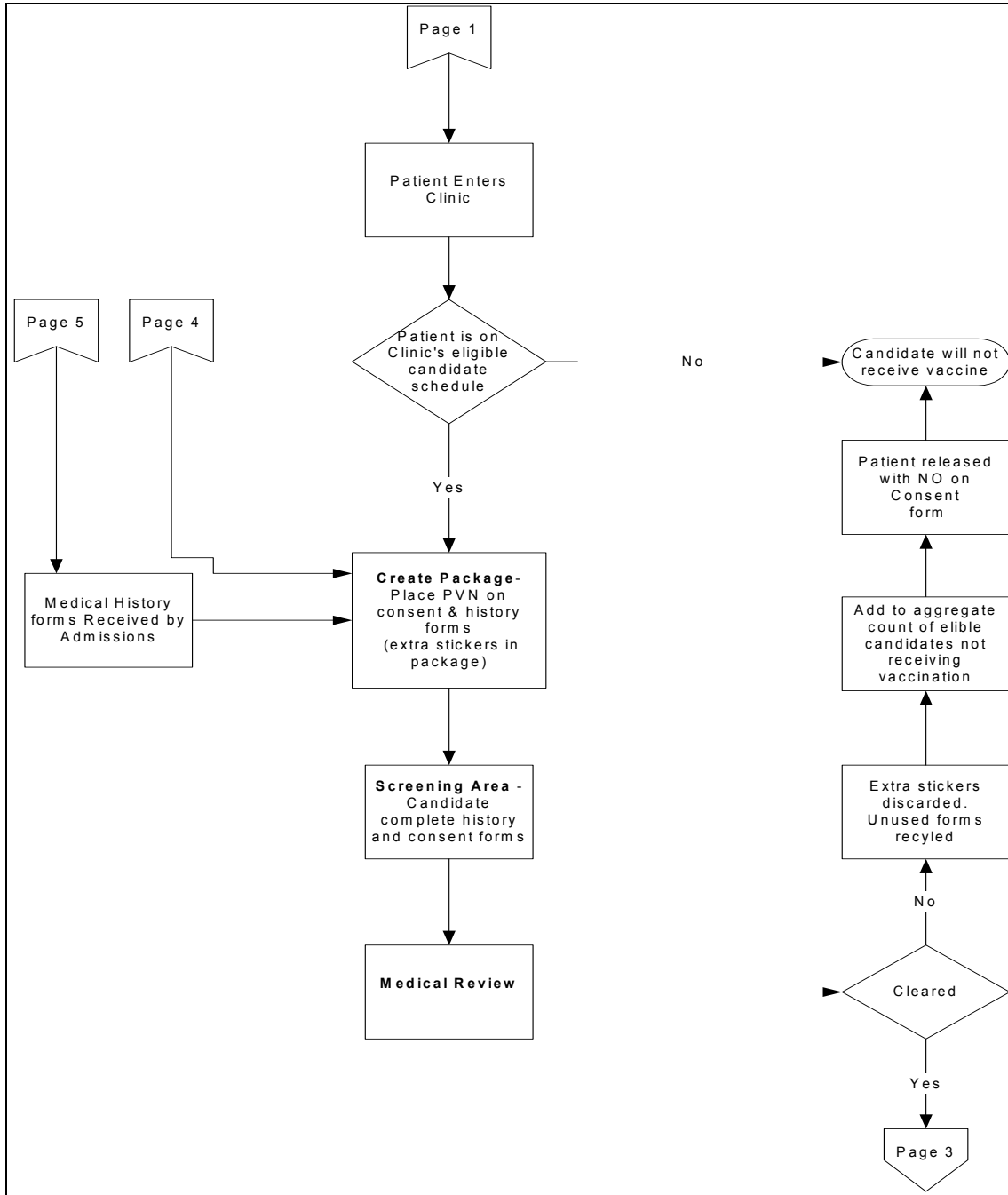


3.2.2 Description

- Hospitals will identify possible candidates.
- Hospitals will educate and pre-screen identified candidates on benefits and risks of the smallpox vaccination.
- Candidate may need to consult with their personal physicians and receive tests to rule out contraindications.
- Candidates who pass pre-screening and are interested will be placed on the eligible candidate list for the hospital.
- Hospitals will send their eligible lists to the State Health Department.
- The State Health Department will receive lists from multiple hospitals. They will be responsible for organizing and managing the lists, determining which clinic a hospital should use and providing the clinics with hospital lists.
- The State 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



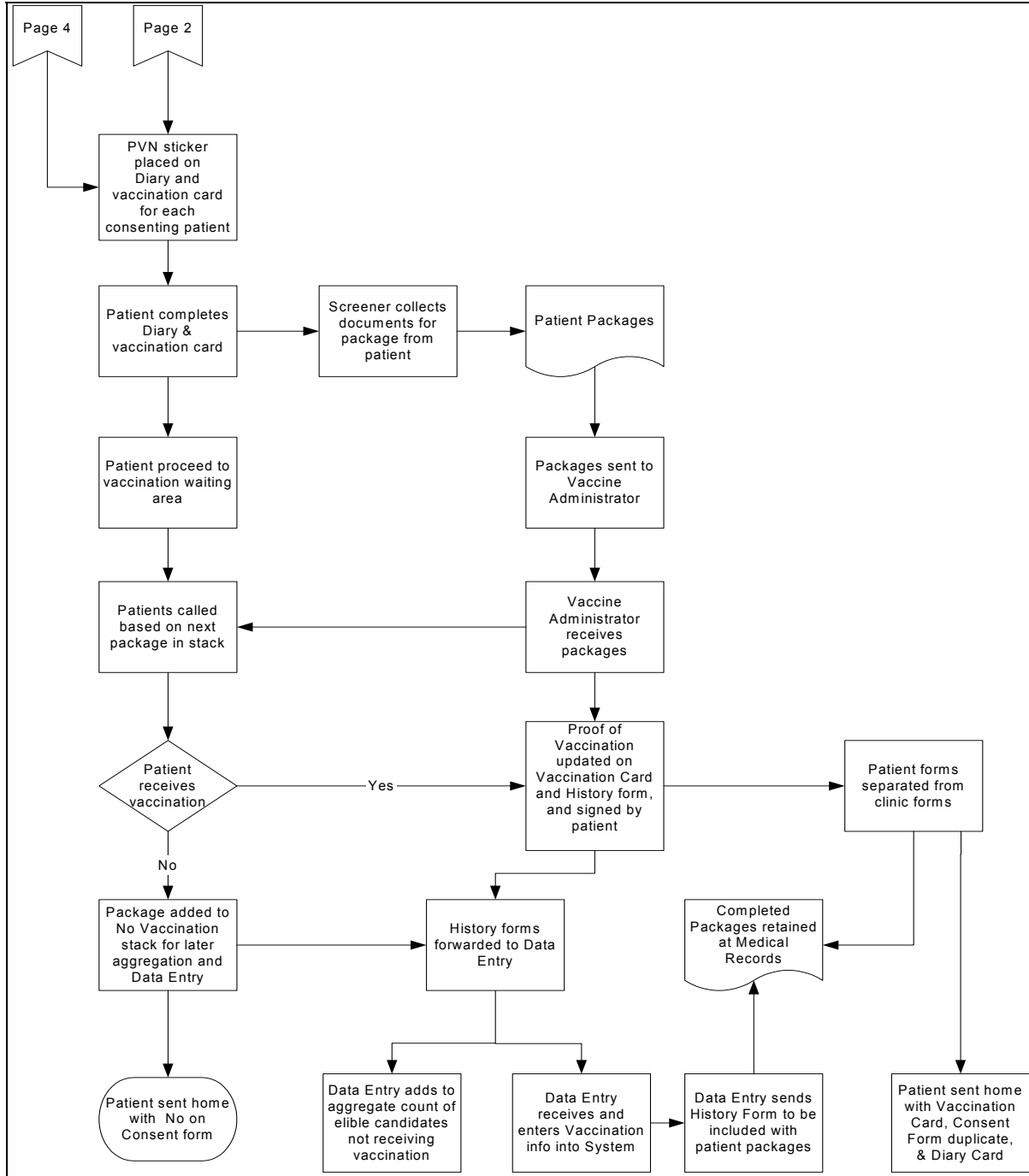
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3.3.2 Description

- Patient arrives at clinic based on appointment.
- Clinic checks patients who arrive against the eligible list from the State 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 who are on the list will have a package created that consists of:
 - Consent Form with two signature pages
 - Medical History Form
 - Standard Adverse Events Diary
 - Vaccination Card
- The Medical History form will 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 Medical History forms that are pre-populated with the identifying information that comprises a batch, or the batch information should be manually included on the medical history form for each patient receiving the vaccine batch.
- Sets of six Patient Vaccination Number stickers can be provided.
- One patient vaccination number (PVN) sticker (or equivalent) will be placed on each signature page of the Consent form, and one on the Medical History form. The extra 3 stickers will be reserved with the package.
- The patient will complete the history form and read the consent form.
- The Medical History form will consist of two pages:
 - Page 1 will include pre-printed vaccine batch information (vaccine manufacturer/lot, diluent manufacturer/lot, patient demographics, vaccination history, and information about the current vaccination event.
 - Page 2 will include the medical history for the patient.
- A medical reviewer will reiterate the education provided as a part of pre-vaccination screening, and determine if a patient is cleared to receive the vaccination.
- If cleared and willing to receive the vaccination, the patient will sign the consent form. They are 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



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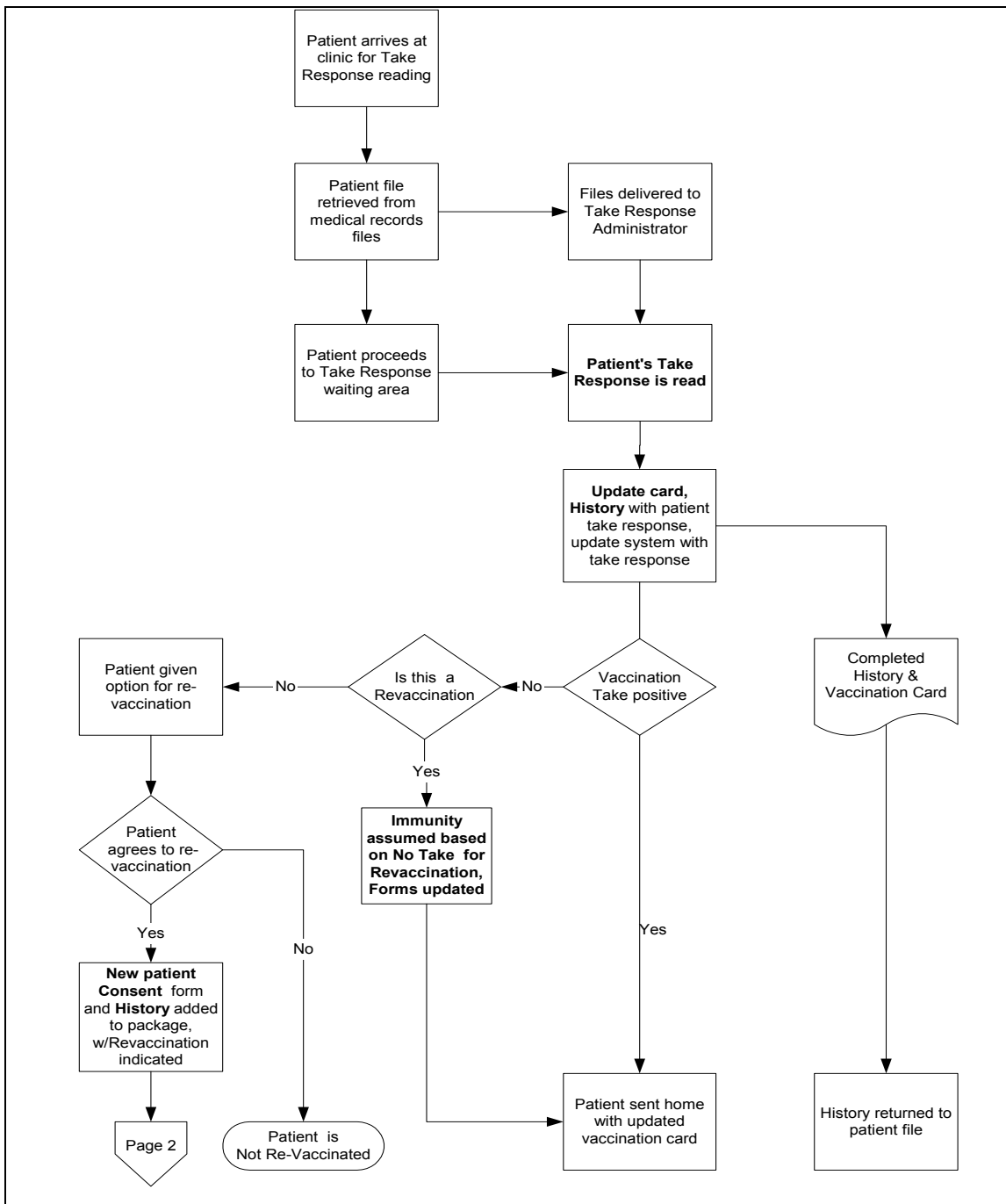
3.4.2 Description

- If the patient has been cleared and has consented they will complete the demographics on the diary and on the vaccination card.
- PVN stickers (or their equivalents) will be placed on the diary and the demographics form. One extra sticker will remain.
- The completed patient packages will be delivered to the vaccination administrator.
- The vaccine administrator 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 a copy of their consent form, history form, and diary form.
- Patients will receive education on site care, potential adverse events will be reviewed, and instructions on completing the diary will be provided. 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, page 1 of the medical history form will be given to Data Entry to be entered into the system.
- Data Entry will enter patient demographics, vaccination history, and vaccination batch information into the system. They will then return the Medical History 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



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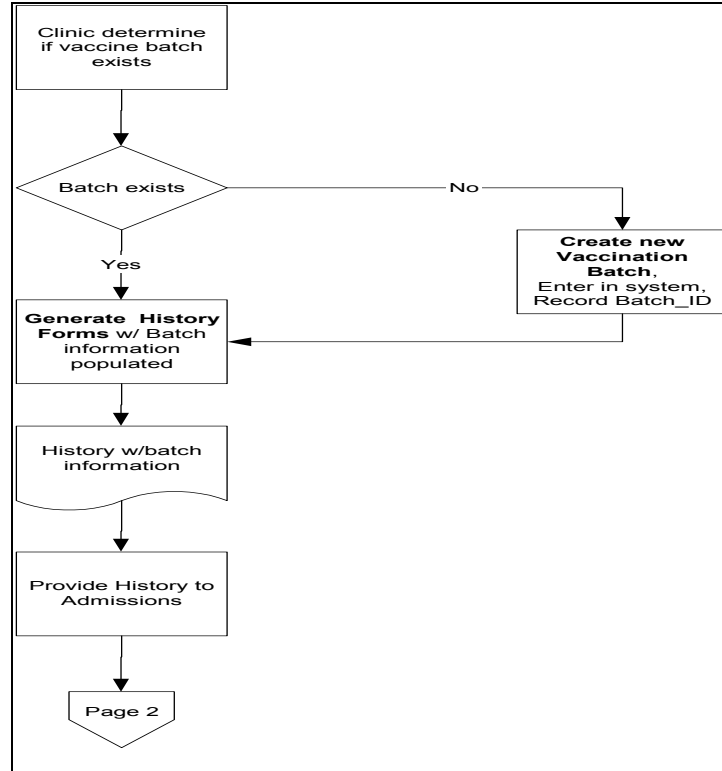
3.5.2 Description

- Patients will return to the clinic where the vaccine was administered.
- The clinic will mark patients on the report as their take responses are read.
- The Vaccination Card will be updated, and the Medical History form will be updated with the Take Response.
- If there was no take, and this is a revaccination then it will be assumed that the patient has immunity. This will be indicated on their vaccination card and history form.
- 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 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 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 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 report that do not show up for their take reading could be re-contacted.

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3.6 5.0 Clinic Batch Creation and Identification

3.6.1 Workflow



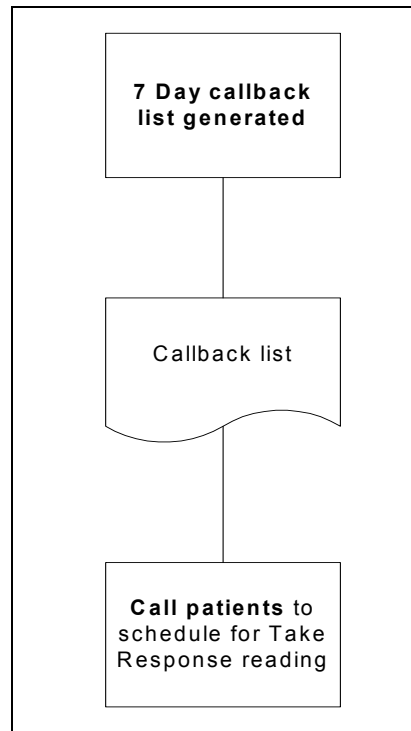
3.6.2 Description

- At the beginning of the day, a vaccination batch will either be created, or an existing vaccination batch 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 Date Batch Created (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.
- The system will then be used to generate a set of Medical History forms. These pages will hold the Batch_ID and lot information for the Batch that was created or selected.
- The History forms will be delivered to Admissions to be included in patient packages.
- The vaccination batch will be delivered to the Vaccination Administrator.
- The Clinic will be responsible for providing the appropriate number of History forms for a vaccine batch, and ensuring that the vaccine batch administered to the patient matches the vaccine batch on the patient's history form.
 - Vaccine batches for the licensed vaccine have a 1:1 dilution, and will deliver 100 doses if no wastage occurs.
 - If wastage occurs, then the clinic must make sure that any forms with no corresponding vaccine batch are replaced with forms containing the new vaccine batch.
 - The clinic may need to print extra forms due to the fact that only a subset of eligible candidates will receive the vaccination.

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3.7 6.0 Take Response Callback List – 7 Day

3.7.1 Workflow



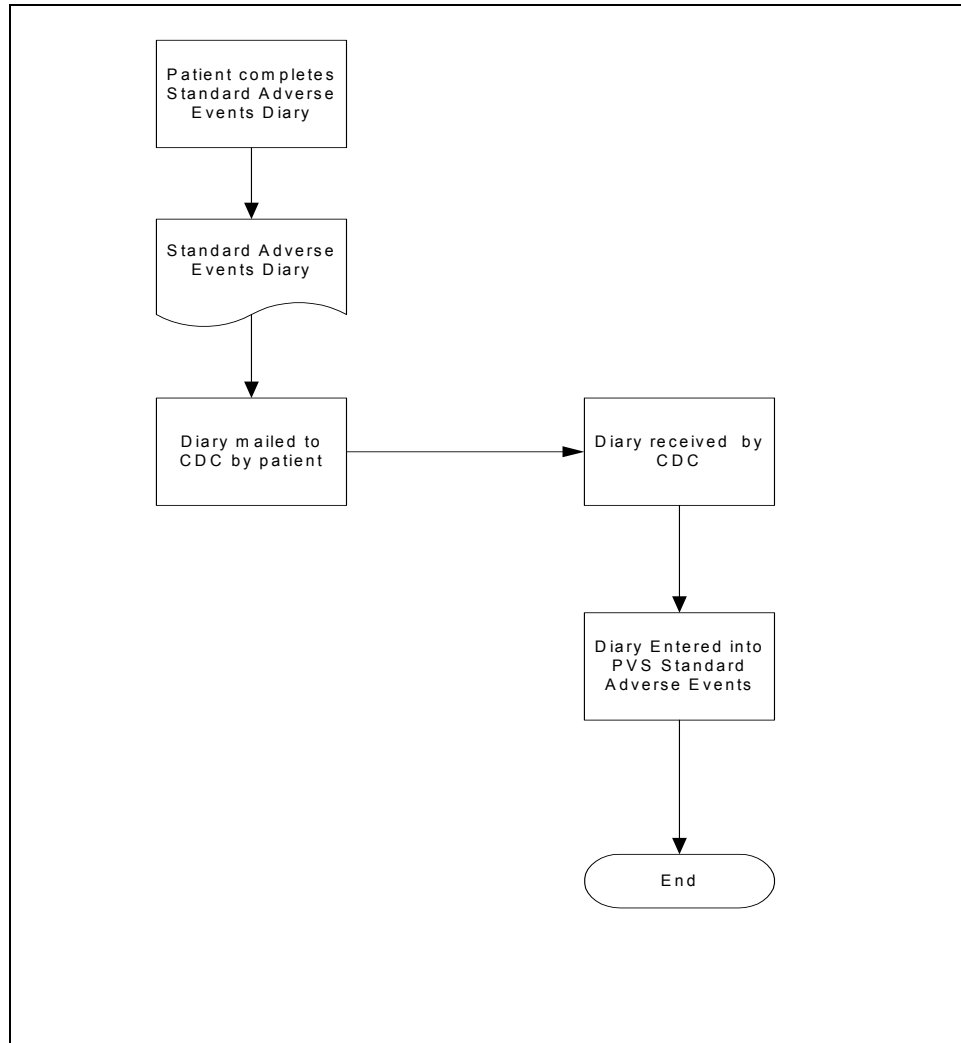
3.7.2 Description

- A report should exist to list patients who should return for take response reading.
- Each individual will be called and scheduled to return to the vaccinating clinic for the take response reading. 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.

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3.8 7.0 Standard Adverse Events Recording – 28 Day Diary

3.8.1 Workflow

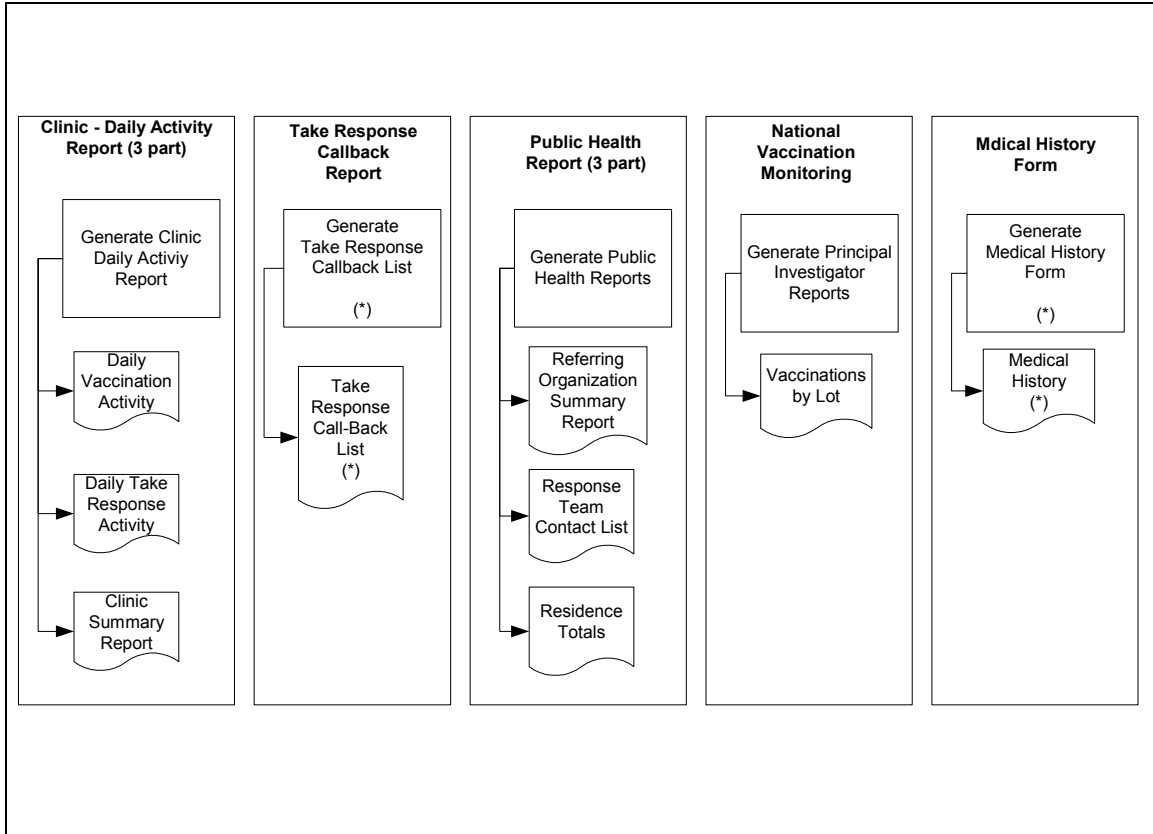


3.8.2 Description

- An Adverse Events Diary form will be sent home with each Patient.
- The patient will be educated on how to complete the Diary form, including directions on returning the Diary form to the proper location.
- The patient will complete the Diary form starting on the day they receive the vaccination (day 0) and finishing on the 27th day following the vaccination.
- Since this is a licensed vaccine, the Diary form will be optional and the patient will be instructed to return the completed form to the CDC.
- Adverse Events forms received by the CDC will be entered into the Pre-Event Vaccination System.

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

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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 CDC, based on information provided by clinics, 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, either (1) have been vaccinated and have had a positive take response (not 'no take') or (2) have been vaccinated twice during the vaccination round and have had a take response of "no take" for both vaccinations. 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.

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.

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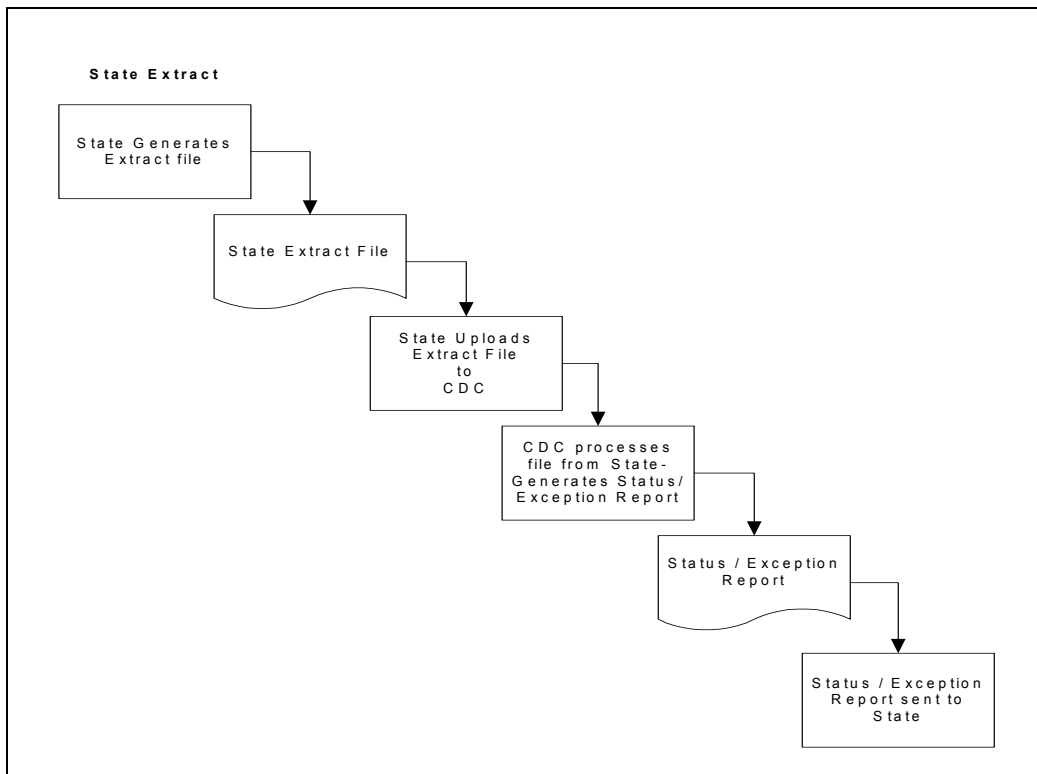
3.9.2.5 Medical History Form

The Medical History form is a part of the patient package at each clinic. The clinic's system should either support printing Medical History forms that are pre-populated with the identifying information that comprises a batch, or the batch information should be manually included on the medical history 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 10 Export

3.10.1 Description



3.10.2 Description

3.10.2.1 State Extract

- The state/clinic system should support generating an extract of vaccination data.
- The extract should be sent to the CDC once a day.
- The extract should be in XML, and adhere to the CDC provided format for data exchange.
- The state 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.

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- 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.