

Pre-Event Vaccination System	Draft Version: 1.2
Overview	Date: 1/21/2003

**Centers for Disease Control and Prevention
Draft: January 15, 2003**

<p>Annex 8</p> <p>Pre-Event Vaccination System (PVS)</p> <p>Overview</p>

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Smallpox Vaccination Program Guidance: Annex 8

Pre-Event Vaccination System (PVS) Overview Version 1.2

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Pre-Event Vaccination System

1. Introduction

The Pre-Event Vaccination System Overview document describes the CDC developed application that includes the baseline functionality deemed necessary to manage pre-event vaccination data for smallpox. Pre-event data is used to ensure preparedness in the event of a possible outbreak of smallpox by including the ability to identify response teams that have received the vaccination.

2. Pre-Event Vaccination System Overview

The Pre-Event Vaccination System (PVS) is one part of a total solution designed to manage vaccinations that are administered in preparation for handling a possible outbreak of smallpox resulting from a bioterrorism event. From a system standpoint, the total solution includes:

- ❖ The Vaccination Roster
- ❖ Data Uploaded from External Systems
- ❖ Vaccination Adverse Events Recording (VAERS)
- ❖ Vaccination Surveillance Datamart

The PreEvent Vaccination System (PVS) encompasses the Vaccination Roster and the Data Import from External Systems.

The Vaccination Roster will be used by participating Healthcare clinics to record lot information for vaccines and diluents and to record information about each vaccinated patient. Patient information for this application includes patient demographics, vaccination history, and the current vaccination event (including the take response to the vaccination).

The Data Upload from External Systems is designed to accept data from those States that are certified to use their own vaccination system en lieu of the PVS application.

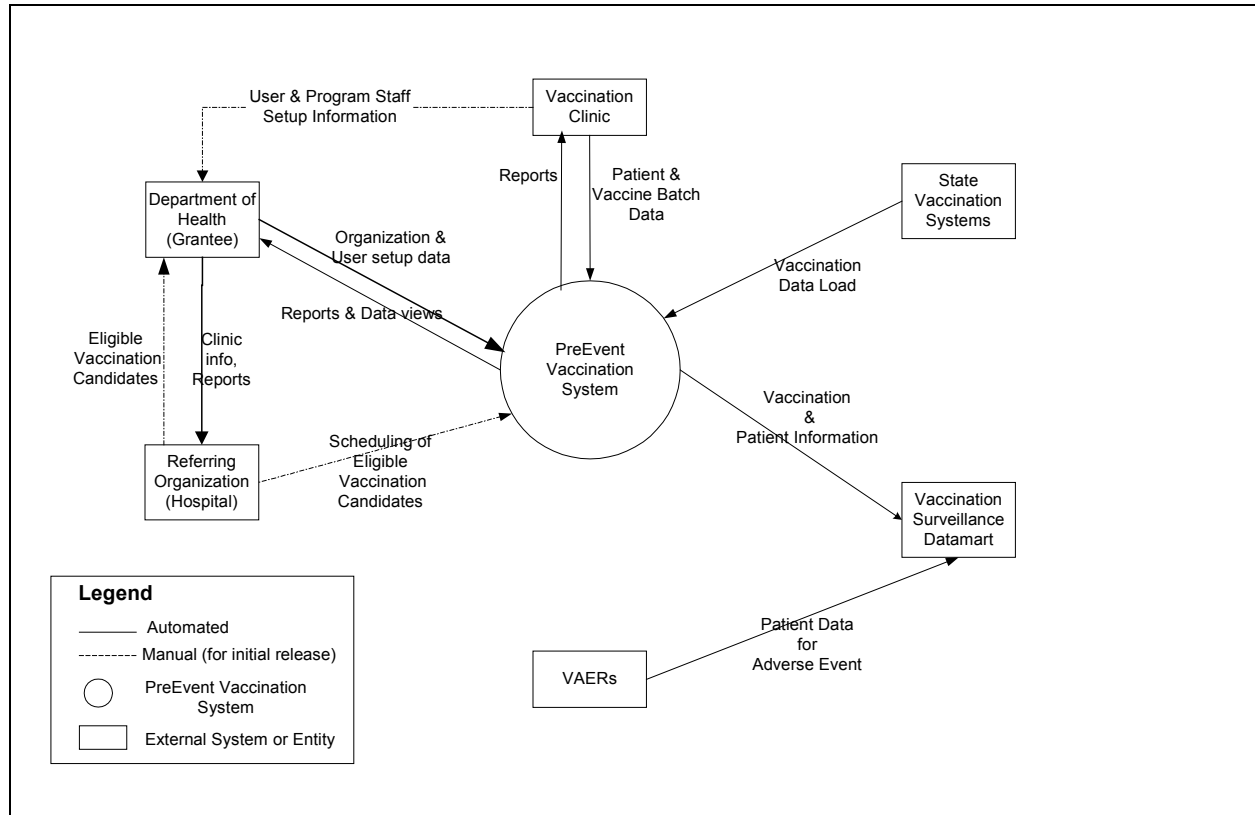
The system is Web based with a browser interface. A centralized administrator is responsible for creating User Ids and Passwords, creating and assigning roles to users, and creating organization and clinics records for any entity that needs to access the system.

The PVS application includes a number of different components:

- Data input screens for patient information, vaccine batch information, adverse events recording, and organization management (where organizations include clinics, hospitals, and State or Local Departments of Health)
- Data loads for vaccine lots, diluent lots, and organizations
- Reports designed for use at the clinic, state, and federal levels
- Data Upload, as mentioned above, designed to accept data from those States that are certified to use their own vaccination system en lieu of the PVS application
- Data exports to the Vaccination Surveillance Datamart
- Data exports to Public Health Departments (Grantees)

The conceptual model of the PVS system is found in the next section along with descriptions of each of the systems mentioned above.

2.1 Conceptual Model



System/Entity Name	Description	Type of Interface
Public Health Department –(Grantee)	<p>Prior to initiating vaccinations, the Public Health Department will identify and submit:</p> <ul style="list-style-type: none"> ➤ Affiliated organizations (vaccination clinics and referring organizations) ➤ PVS users and their role in PVS (viewer, administrator) <p>This information will be submitted in a Microsoft Access application that will be sent to each Grantee.</p> <p>During this campaign, Public Health Departments will receive lists of Eligible Candidates from multiple hospitals. Eligible Candidates are individuals who have been identified by a hospital, given pre-vaccination screening and education on the vaccine, and volunteer to receive the vaccination. The DOH will specify with which clinics a hospital should coordinate scheduling.</p>	Manual

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System/Entity Name	Description	Type of Interface
Referring Organization (Initial Phase – Hospitals, Public Health Departments)	Referring Organizations will identify potential candidates, provide pre-vaccination screening and education, and determine eligibility to receive the vaccine. The Referring Organization will communicate with the Public Health Department to learn with which clinics they should coordinate scheduling.	Manual
Vaccination Clinic	Vaccination Clinics will coordinate scheduling with the DOHs and Hospitals. They will screen patients, vaccinate consenting patients with no contraindications, record take responses, and record adverse events in VAERS.	User Interface screens to record patient and vaccination data.
Vaccination Surveillance Datamart	The Datamart will be the recipient of patient, vaccine batch, and VAERS adverse events data. The datamart will serve as the centralized collection point where VAERS reports are linked to PVS vaccination records. Data Analysis will be performed on this assimilated set of vaccination surveillance data to determine trends and curtail issues.	Automated Export – Batch File Transfer
VAERS	The Vaccination Adverse Events Reporting system will be manually updated with patient information in the initial release	Manual for initial release
Public Health Vaccination Systems	If a Grantee chooses to use their own vaccination system en lieu of the PVS, then a file will be requested in a pre-defined format specified by the program. The PVS will import provided files into the CDC central database. The specifications for the upload have been provided under the document titled <u>Pre-Event Vaccination Administration Support and Data Exchange Requirements Overview</u>	Automated Upload – Batch File Transfer

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3. PreEvent Vaccination Modules

The following section describes the application modules that make up the PreEvent Vaccination System. Each module contains one or more functions that are also described in this section. In this sense, a function may be a screen, report, data load, data extract, manual process, or automated process.

3.1 Application Module Descriptions

The main modules in the PVS application and the types of users that interact with the system are listed in the table below. Each module and type of user is described in detail in the following sections.

Note: The system is designed for use with or without Patient Identifiers such as name, date of birth, and phone number. However, the functionality inherently available in the system is far greater when identifying information is included, as noted throughout this section of the document.

Pre-Event Vaccination Modules		
Module ID	Module Name	User Role)
1.0	Setup Administrative Functions	Administrator, Secure Data Network (SDN) Administrator
2.0	Maintain Vaccine Batch	Local Administrator, Local Viewer, Public Health Administrator, Public Health Viewer
3.0	Maintain Patient	Local Administrator, Local Viewer, Public Health Administrator, Public Health Viewer
4.0	Generate Reports	Local Administrator, Local Viewer, Public Health Administrator, Public Health Viewer, Non-PVS Viewer
5.0	Upload/Extract Data	Non-PVS Administrator, Public Health Administrator
6.0	Upload Logon/ Authentication	All Users

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7.0	Analyze Data	Principle Investigators
8.0	View Analytical Reports	Public Health Administrator, Public Health Viewer, Non-PVS Administrator, Non-PVS Viewer

The user types and modules in the PVS application and the associations between the modules are illustrated in the diagram below.

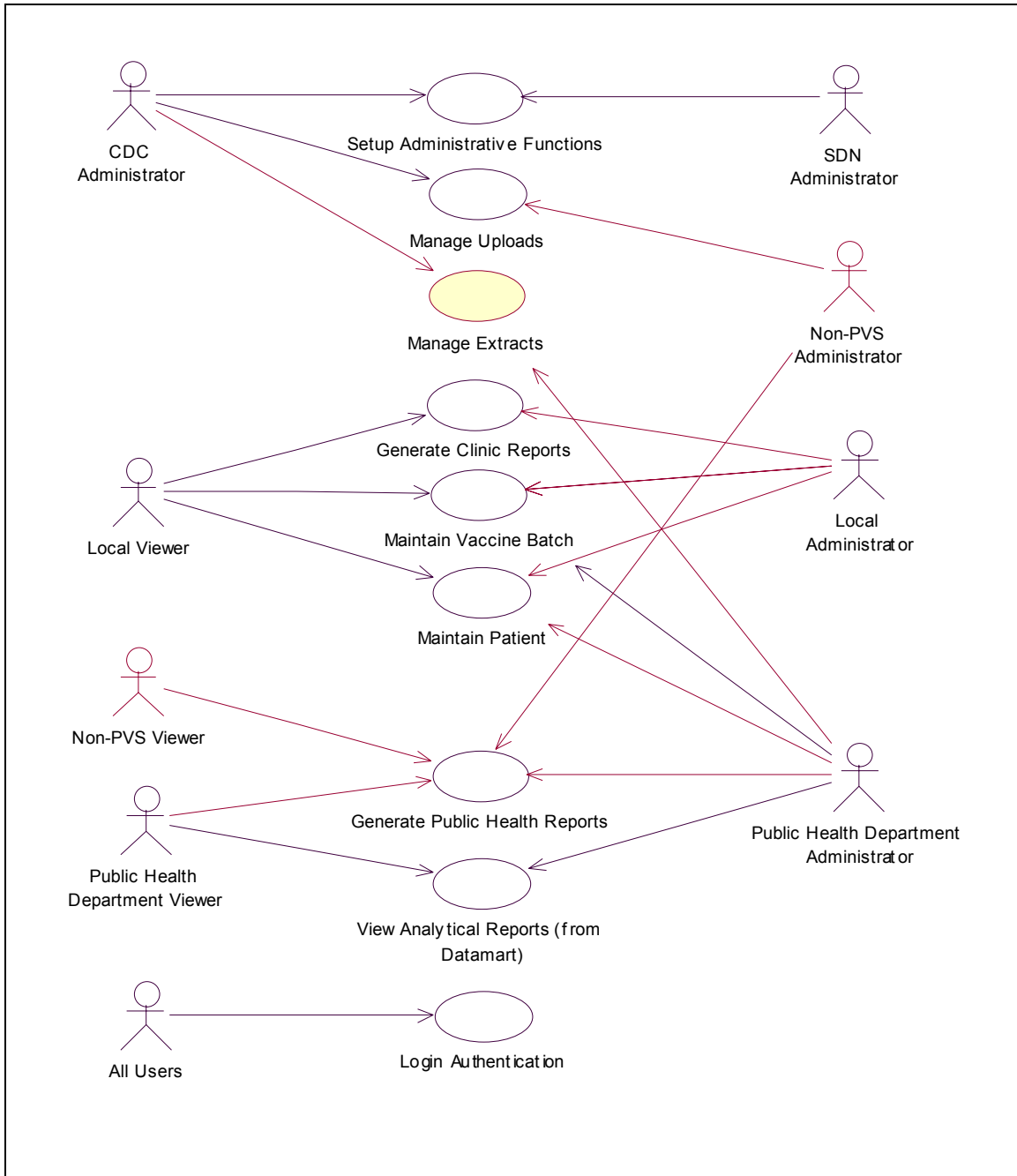





Figure 3.0 Pre-Event Vaccination Application Context Diagram

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Legend

	User Type :	A user that is in a role that specifies what they do and what data they can see within the system. (In UML Notation this is an Actor)
	Process or Module:	A set of system functionality that is logically grouped together. (In UML Notation this is an Use Case)
	Relationship:	The interaction between a user and a module or process.

Module	Functionality	Description
1.0 Setup Administration Functions	Maintain User's Profile	'Contact Us' option from site to request changes to user profile including name, email address, or forgotten password.
	Maintain Organizations & Clinics & Assign Program Staff	Setup of clinic and clinic contact information. Supports adding new clinics and modifying existing clinics. Supports adding and updating State & Local DOHs, and other referring organizations (hospitals & DOHs, initially) that are tracked within the system. Supports assigning program staff (vaccinators, contacts, and take readers) to clinics with their defined responsibility to the clinics. Program Staff responsibilities provide the lookups for vaccinator and take reader within the PVS.
	Maintain Users, Roles, User Roles, and Organization Assignment	Setup of User IDs, Roles and assignment of roles to the user. User IDs and Passwords are used within the application and tied to roles that control what a user can do and see within the application. Supports assigning organizations to a user. These are typically clinics whose data the user can access.
	Maintain URLs and Role URLs	Setup of URLs and the URLs that a role can access. The URLs are used to identify pages within the application that a role can access. This prevents users from accessing pages to which they shouldn't have access. URLs are also used to enforce page controls – like a save button that supports creating or updating a record.
	Maintain Patient Vaccination Numbers (PVNs)	Creation of a valid set of PVNs that correspond to bar coded stickers. The PVNs are stored in a table and used to validate Patient Vaccination IDs that are entered into the system
	Maintain Digital Certificates	Creation, distribution and support of Digital certificates by the SDN group. These are used to control access to the base application.

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Module	Functionality	Description
2.0 Maintain Vaccine Batch	Maintain Vaccine/Diluent Batch	Supports creating, viewing and updating vaccine batches in the clinic. A vaccine batch is identified by a vaccine lot number and manufacturer, a diluent lot number and manufacturer, the date the batch is created (reconstitution date for lyophilized vaccine), and the clinic where the batch was created.
3.0 Maintain Patient	Maintain Patient Demographics, vaccine history, and vaccine	Streamlined setup of a new patient with identifying information, one patient vaccination record, and one patient history record. Note- if the clinic decides to omit patient identifiers when entering data into the system (i.e. name, ssn, dob, phone, gender) then the clinic is required to link the record in PVS with the patient identifiers maintained outside the system. The system is able to provide aggregate data to the clinic, but detailed vaccination data is of limited use without the identifiers.
	Edit/Add Patient Vaccination History	Edit an existing vaccination history record, or add a new vaccination history record for an existing patient.
	Edit/Add Patient Vaccine & Take Response	Edit an existing vaccination record, and add World Health Organization (WHO) Take response for a patient that received a vaccination. Also supports adding a new vaccination record, for example for revaccinations.
	Edit Patient	Supports updating an existing patient's demographic record.
4.0 Generate Reports	Clinic Daily Activity Log	Three part report of: <ul style="list-style-type: none"> Daily Vaccinations for a clinic on a date Daily Take Readings for a clinic on a date Clinic Summary (Aggregate totals) Note - if the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use.
		Public Health Report
	Vaccinations by Lot	Report of vaccinees by lot and state generated from the CDC datamart. Includes aggregate totals. Report is available to grantees.
		Note - if the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use.
Take Response Callback List	Report of all vaccinees by hospital and clinic that are due to have take responses read in a pre-defined number of days. Report includes phone number and space to record take response.	

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Module	Functionality	Description
		Note - if the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use.
	Medical History & Consent Form Attachment	Patient history & consent form attachment generated at the beginning of the day from PVS, or manually updated based on the selected vaccine batch outside of PVS. Form holds the Vaccine Batch ID used for vaccinations during the day. Vaccine Batch info is included on the form.
5.0 Extract Data	Extract for Vaccination Surveillance Datamart	Comma separated extract of vaccination batch and patient data and take response used in analytical reporting.
	Extract for Public Health Department	Format and design for extracting and sending vaccination data to a public health entity (grantee)
6.0 Upload Data	Upload Public Health Department (Grantee) Data	XML format and design for receiving a patient/vaccination batch from a grantee certified to use their own vaccination system and send vaccination data to PVS.
	Import Organization/Program Staff	Import and load organization data and people assigned to an organization. Organization setup information is provided by the Grantee and loaded by the CDC Administrator.
	Import Vaccine and Diluent Lots, and NDC relationships	CDC Administrator imports valid lot numbers, manufacturers, and NDC numbers for vaccines and diluents. These are used to provide lookup lists and to validate vaccine and diluent lot numbers entered in the Maintain Batch module.
7.0 Logon/ Authentication	SDN Logon	Initial logon where user is prompted to enter the challenge phrase that goes with their digital certificate.
	SDN Authentication	SDN System determines if the username/challenge phrase has access to the PVS application website. User is passed through to the application if successfully authenticated.
	Application Logon	Application Logon where user is prompted to enter a username/password for the application.
	Application Authentication	Application determines if username/password is valid, and retrieves roles that are assigned to the user. Roles dictate what the user can do and what data the user can see within the application.
8.0 Analyze Data/View Analytical Reports	Analyze Data/View Analytical Reports	Data Analysis is done from the assimilated data that is extracted from the PVS and the vaccine adverse event system and sent to the datamart. Reports will be available to Grantees.

3.2 User Types

User Types who represent individuals or other systems that use the application include the following:

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- CDC Administrator
- SDN Administrator
- Local Administrator (Clinic Administrator)
- Local Viewer (Clinic User)
- Patient
- Public Health Department Administrator (Administrator at the Grantee DOH)
- Public Health Department Viewer (State-PI at the Grantee DOH)
- Non-PVS Administrator (Upload User)
- Non-PVS Viewer (Report User)
- All Users

3.2.1 Administrator

An Administrator is a CDC representative responsible for entering setup data into the system. This includes System support information such as Manufacturers and Lots, Clinic Data, Organization Data (Hospitals and State/Local DOH), Roles, User IDs and Passwords.

3.2.2 SDN Administrator

A SDN Administrator is responsible for orchestrating the creation of, approval of, and distribution of Digital Certificates. The SDN Administrator also provides support to users that have questions concerning their certificate.

3.2.3 Local Administrator

A Local Administrator is responsible for data entry of patient and vaccination information. A Local Administrator can maintain organization records and program staff records for organizations assigned to them. The Local Administrator can generate clinic reports and forms. .

3.2.4 Local Viewer

A Clinic User is assigned to a clinic as a Local Viewer. For assigned organizations, the clinic user can view vaccine and diluent batch data, as well as patient records and patient vaccination records including take responses. Local Viewer can also run clinic reports and clinic forms.

3.2.5 Patient

A patient is the recipient of a vaccination. Patients also participate in the 7 day follow-up response to the vaccination.

3.2.6 Public Health Department Administrator (Administrator at the Grantee DOH)

The Public Health Administrator is a user at a Grantee DOH that holds administrative rights. The administrator can edit and maintain program staff for all affiliated organizations (vaccination clinics and referring organizations within their jurisdiction). In addition, they can view vaccine batch, patient, and patient vaccination records for all vaccination clinics within their jurisdiction. The Public Health Administrator can run public health reports and access analytical reports that have been generated from the CDC datamart in support of this campaign.

3.2.7 Public Health Department Viewer (Public Health Department User at the Grantee DOH)

The Public Health Viewer is a user at the Grantee DOH that is able to view organization records for affiliated organizations (vaccination clinics and referring organizations within their jurisdiction). In addition, they can view vaccine batch, patient, and patient vaccination records for all vaccination clinics within their jurisdiction. The Public Health Administrator can run public health reports and access analytical reports that have been generated from the CDC datamart in support of this campaign.

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3.2.8 Non-PVS Administrator (Upload User)

A Non-PVS Administrator is a user at a Grantee DOH that has been certified to use their own vaccination system. Upload users will have the ability to upload vaccination data, run public health reports, and access analytical reports that have been generated from the CDC datamart in support of this campaign.

3.2.9 Non-PVS Viewer (Report User)

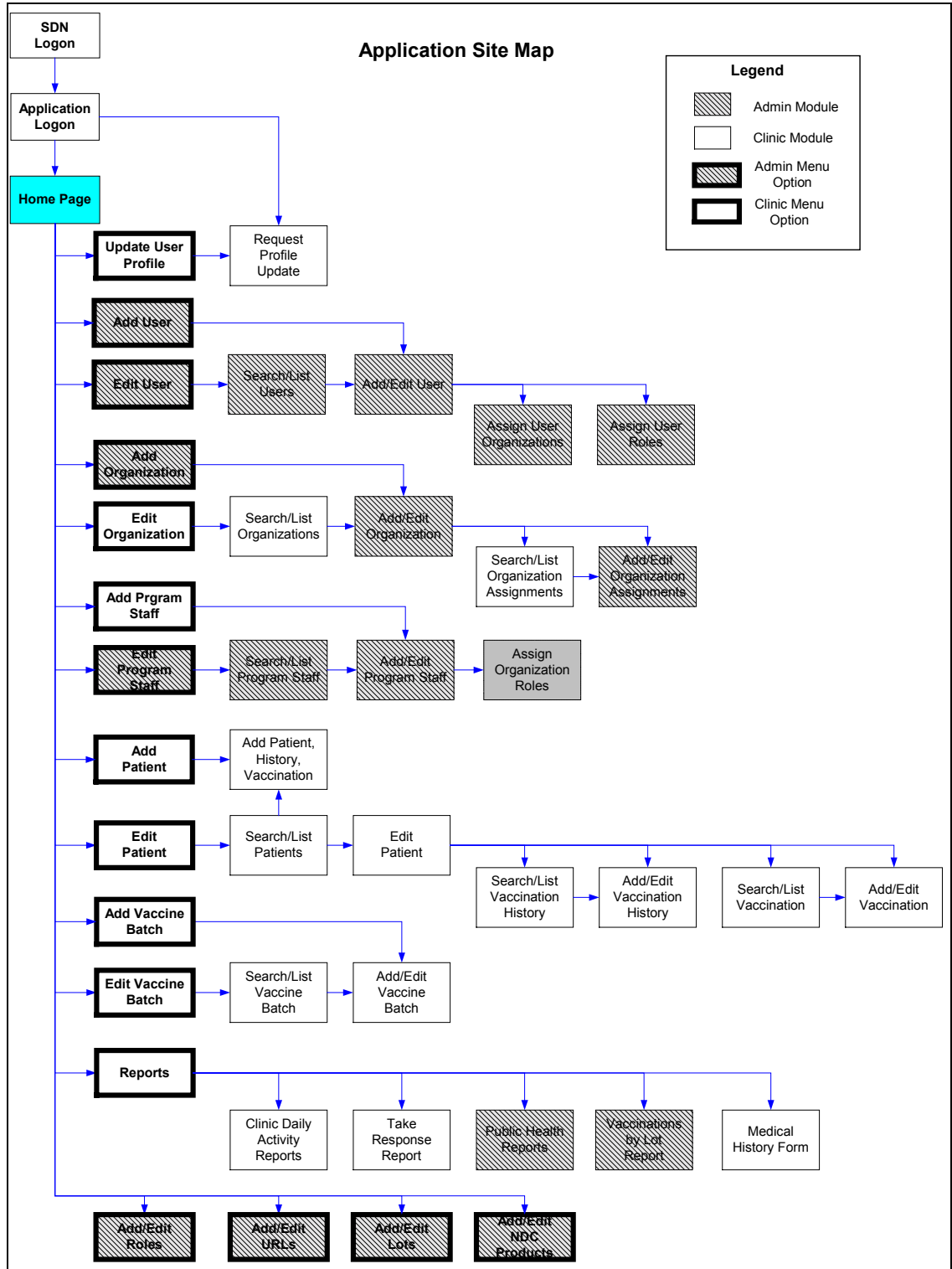
A Non-PVS Viewer is a user at a Grantee DOH that has been certified to use their own vaccination system. Non-PVS Viewers can run public health reports, and access analytical reports that have been generated from the CDC datamart in support of this campaign.

3.2.10 All Users

This is a general term that refers to any user of the system regardless of whether they are an application user or a user responsible for uploading data.

3.3 Application Site Map

The Site Map for the PVS application depicts the complete set of application modules. As reflected in the legend, the administrator manages some of the modules, and others are available for clinic and state users. For the purposes of this diagram, modules are defined as menu items, screens, or reports. A system user will only have access to those modules available through their assigned role. **Note:** Extracts and imports are intentionally omitted from the site map.



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3.3.1 Clinic Reports

Daily Vaccination Activity – (Clinic Activity Report Part I)

Description

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

Report Assumptions

1. Only Clinics (locations where vaccinations occur) have a report.
2. Only "active" clinics will have a report.
3. If the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use in quality assurance.
4. Only users who are local administrators and local viewers assigned to the clinic can run the clinic's Daily Vaccination Activity reports; an unauthorized user cannot see the report for a clinic.

Daily Take Response Activity – (Clinic Activity Report Part II)

Description

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 contains all data captured for each patient. The intended use of this report is for quality assurance of the input data and to provide a complete record of the clinic's take response activity.

Report Assumptions

1. Only locations where take response exams occur will have a Daily Take Response Activity report.
2. Only "active" clinics will have a report.
3. If the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use in quality assurance.
4. Only users who are local administrators and local viewers assigned to the clinic can run the clinic's Daily Vaccination Activity reports; an unauthorized user cannot see the report for a clinic.

Clinic Summary Report (Clinic Activity Report Part III)

Description

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).

Report Assumptions

1. Only clinics with daily activity have a report.
2. Only "active" clinics will have a report.

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3. Only users who are local administrators and local viewers assigned to the clinic can run the clinic's Daily Vaccination Activity reports; an unauthorized user cannot see the report for a clinic.

Take Response Call-Back List

Description

The Take Response Call-Back List provides a list of vaccinees that 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 also has space to capture the data from the take response in preparation for data entry.

Report Assumptions

1. Vaccination clinics have the responsibility of calling vaccinees for take responses; therefore, only clinics where vaccinations occur have a report.
2. Only users who are local administrators and local viewers assigned to the clinic can run the clinic's Daily Vaccination Activity reports; an unauthorized user cannot see the report for a clinic.
3. If the clinic decides to omit patient identifiers (including phone number) when entering data into the system, this report is of limited use in providing a call-back list.

Medical History & Consent Form Attachment

Description

The Medical History & Consent form is generated at each clinic. The form is generated after a vaccination batch is created, or an existing vaccination batch is identified for use during the day. The system supports printing a Medical History & Consent form attachment that is pre-populated with the identifying information that comprises a batch. This 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 name.

Report Assumptions

1. Local Administrators and Local Viewers will have access to generate this form.

3.3.2 Public Health Reports

Referring Organization Summary Report (Part I)

Description

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.

Report Assumptions

1. Each Public Health Department (Grantee) is able to run a report for the referring organizations under their jurisdiction.
2. The report will only include those individuals from the referring organizations that were vaccinated at clinics within the Grantee's domain.

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3. Only the Grantee can see the report for affiliated referring organizations. A Grantee cannot see the report for another Grantee

Response Team Contact List (Part II)

Description

This report is a list of people who have had a major take during the initial or revaccination event. This report will not include those individuals who have been medically referred to their physician following a no take or an equivocal take on their revaccination event. 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.

Report Assumptions

1. Each Public Health Department (Grantee) will be able to run a report for vaccinees referred through organizations within their jurisdiction.
2. Only the grantee can see the report; a grantee cannot see the report for another grantee.
3. If the clinic decides to omit patient identifiers when entering data into the system, this report is of limited use in providing response team contact lists.

Residence Totals (Part III)

Description

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).

Report Assumptions

1. Only the Public Health Department (Grantee) can see the report; a public health department cannot see the report for another state.
2. Each Public Health Department is able to run a report for residents living in their state.
3. This report will be generated from the CDC Datamart, and made available to Grantees.

3.3.3 National Vaccination Monitoring Report

Vaccinations by Lot Report

Description

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 summary summarizes the total number of patients vaccinated at a clinic, for all clinics within a state, and for all states for a given lot.

Report Assumptions

1. This report will be generated from the CDC Datamart, and made available to Grantees.

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3.4 Data Imports & Exports

3.4.1 Extract for Vaccination Surveillance Datamart

A data extract is generated from the PVS on a predefined basis. The extract includes a subset of the vaccination data stored in PVS and is combined with adverse events data reported to VAERS. Non-identified data is stored in the datamart and used for data analysis. The analytical reporting supports surveillance of vaccine efficacy and adverse events, based on diluent lot, vaccine lot, gender, age, vaccination history, and other significant attributes.

3.4.2 Extract of Public Health Data for Grantees

Public Health Departments (Grantees) will be provided an extract of PVS data in a pre-defined format. The PVS data extract will include vaccine batch, patient, and patient vaccination information for all vaccination clinics that fall under the jurisdiction of the Public Health Department.

3.4.3 Upload of Public Health Data from Grantees

Public Health Departments (Grantees) that are certified to use their own vaccination system are responsible for uploading daily extracts of vaccination data to PVS. Additional information will be provided to Grantees upon request. PVS will import this data and include it in the dataset used to monitor and support the program. The Public Health Department extract will be required to follow the pre-defined XML data format included in the document [Pre-Event Vaccination Administration Support and Post-Event Response Systems Functional Needs and Data Exchange Requirements Overview](#).

3.4.4 Import Organization/Assignees

The PVS requires set up of organization information prior to deployment. This includes:

- Vaccination clinic names, addresses and contacts.
- Vaccination teams – specifically vaccinators and take readers assigned to each vaccination clinic.
- Referring organizations, addresses and contacts – hospitals for the initial phase.
- DOH contact information.

The information will be requested in an access database that will be provided to grantees. Grantees will be responsible for collecting organization setup information, recording it in the access database and returning it to the CDC. In support of the short timeline for the Responder campaign, this setup data will be pre-loaded into PVS. This pre-loading of data reduces the individual set up effort that is required of each grantee before deployment of the application.

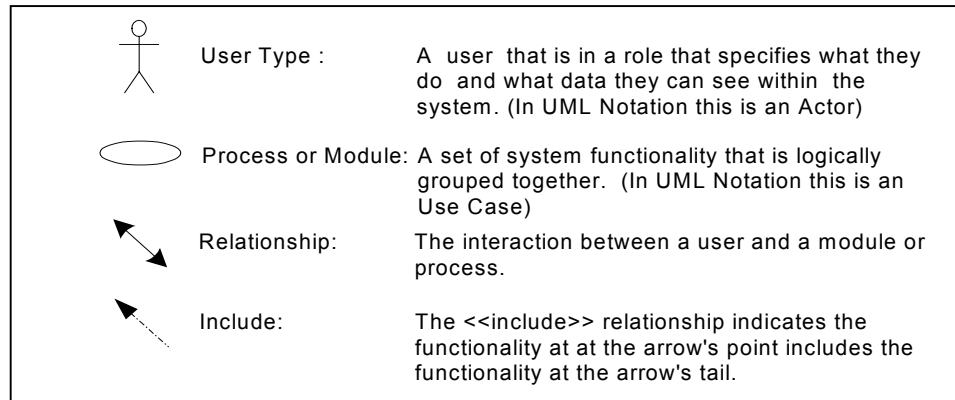
3.4.5 Import Vaccine and Diluent Lots, and NDC relationships

Valid vaccine and diluent lots data are preloaded into the PVS application. This information is available in lists of values when a Vaccine Batch is created at the clinic. Validation of lot numbers is intended to reduce the high incident of invalid lot number entry commonly associated with manual entry of these fields.

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3.5 Logon Authentication

Legend



3.5.1 Description

The PVS application uses a two-step login process:

1. CDC Secure Data Network (SDN) Logon.
2. Application Logon.

The first step in the PVS security authentication is the SDN logon. This requires the user to install a digital certificate on the machine used to access the PVS. Digital Certificates are managed and distributed by the SDN group at CDC and are specific to a user on a machine. When the user initiates the PVS URL, they are prompted for the password (challenge phrase) that corresponds to the digital certificate. The authentication process validates that the user has access to the application. Once validated, the user is given access to the PVS application. The PVS application prompts the user for a second level of authentication. This same validation for SDN is required for state data importation.

The second step of the security authentication prompts the user to enter an application username and password. This second level of authentication determines the roles that have been assigned to the user. The roles dictate what the user can do and what data the user can see within the system. The CDC PVS System Administrator manages application level logons.

3.6 Analyze Data

Data Analysis is completed from the assimilated data that is extracted from the PVS and the VAERS systems and sent to the datamart. This data is used to evaluate vaccine and diluent lot efficacy, determine adverse event trends, pinpoint adverse event causes where possible, and prompt intervention that may be required to treat significant side-effects that may result from this vaccine.

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4. Supplementary Requirement Specifications

4.1 Usability

Ref #	Requirement	Description/Example
4.1.1	Web Pages will display in 800x600 resolution.	
4.1.2	The interface for the application is web-based.	The clinic users, administrators, state users, and principal investigators can access the website by 'browser'.
4.1.3	The web browsers supported by the application are I.E. 5.5 and above and Netscape 6.0 and above.	The listed browsers and versions support the navigation and site features.
4.1.4	The operating systems supported by the application and specific web browsers are limited to Windows 98, Windows NT 4.0+, Windows 2000 & Windows XP	These are the operating systems supported by this application.
4.1.5	The code used to support the features and functionality of the application is JAVA, JSP, XML and HTML based.	The appropriate industry standard development languages used in the development of the application.
4.1.6	Clinics and Organizations must have a unique identity on the system.	Each clinic and organization is uniquely identified when set up by CDC.
4.1.7	Users must have a unique identity on the system	Each user is associated with an organization or clinic and is uniquely identified with a UserID.
4.1.8	User profiles need to be added to, deleted from, and modified in the system	User information includes: Username Password Email Address Phone numbers Name
4.1.9	PDF reader software (such as Adobe Acrobat Reader) should be installed for of PVS reports	Reports generated from PVS are in PDF format.