

# Data and Information Management of the Smallpox Vaccine Program

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I appreciate the time today to be a representative for the information resource management office. I'd like to talk with you about the PVS system and the security surrounding that and the importance of the data you'll be collecting as this program moves forward.

# Data and Information Management

- **Learning Objectives:**
  - Describe the roles for, and importance of, vaccination information systems
  - Identify local, state, and federal roles in vaccine data management
  - Describe the components of a fully functioning vaccine administration system



# Data and Information Management

- **Learning Objectives:**
  - Describe options states have for meeting vaccination administration data needs
  - Identify the resources and support mechanisms for the different options



# Importance of Vaccination Data

- **Support the vaccination campaign**
- **Provides baseline information on vaccine safety**
- **Tracks personnel who are protected and able to participate in smallpox response efforts**



So to begin with, I'd like to talk a little bit about the importance of vaccination data. Number one, most importantly, we need to support the vaccination strategy and program itself. It's important to be aware that the vials of vaccine are being used appropriately, that clinic flow is working efficiently and effectively as referred to by Mr. Koops and also that vaccination verification is taking place and that we're able to track adverse events as they take place. This data will provide us baseline information on vaccine safety. We do want to know if "takes" are actually happening and if adverse events are occurring. Finally, and probably most importantly for the states, we want to be able to be aware that personnel are protected and that they're able to participate in smallpox response efforts should there be a need for response teams to reply.

# Data Reporting Activities

- **For states:**
  - **Pre-Event Vaccination System (PVS)**
    - **With identifiers**
    - **Without identifiers**
  - **Certified alternative state system**
- **At the CDC:**
  - **Aggregate, un-named data collection and analysis**



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Let's talk a little bit about data reporting activities. The data reporting activities that surround this particular program not only fall into the hands of the CDC, but they also are very important for states. The first of those for states is the pre-event vaccination system or the PVS system. One of the things we have looked to is to be able use the PVS system with patient identification or without. There also is a possibility of being able to use a certified alternative state system, be that state developed or commercial. I'll talk more after this part of the presentation about those actual systems and give you a little bit of a broader understanding of their functionality and what we're expecting from our end. CDC is responsible for aggregate unnamed data collection and analysis. It's important for us to be able to respond to our Administration as well as the Department, HHS, and understand how many people have been vaccinated, the number of vaccine “takes” that have taken place, the number of adverse events that are happening and the actual usage of the vials of vaccine. And, again, the CDC will be responsible for collecting this in an aggregate format.

## **CDC Developed Vaccination Support System for States (PVS)**

- **The Pre-Event Vaccination System (PVS) is part of a model of clinic process and management**
- **Includes forms, unique vaccination event numbers and stickers, and process workflow**



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Discuss other components, e.g., VAERS, vaccine surveillance datmart, etc. in talk.

Let's talk about the functionality of the PVS system. It's been in development for approximately the last five months. As part of that development process, we worked very closely with the National Immunization Program to understand how clinic operations will take place so that the system actually supports the flow of people through a vaccination clinic and then the data into the system. So we've been modeling it after the clinic process as well as the management of it. The PVS system itself includes forms, such as the medical history form. That very first form has most of the data entry form on it that we will need for the PVS system. Also important in this whole process are the unique vaccination event numbers. These unique numbers actually tie the patient to their records within the database so that we can understand where and when and with what batch they had been vaccinated. Also regarding that are the PVN stickers, the patient vaccination number stickers that Glen Koops alluded to earlier. These stickers will be distributed via the National Pharmaceutical Stockpile and available for states to use, whether they use or system or not, to keep track of the individuals who are vaccinated. Finally, just to make sure that the PVS system flows with the work flow of the clinic so they're not interruptions and trying to capture the data, but to make sure the patient or the volunteer can flow through the clinic without being hindered by our data collection efforts.

## **CDC Developed Vaccination Support System for States (PVS)**

- **Includes Vaccination Roster and Data Import from External Systems (VAERS, state systems)**
- **Web-based with a browser interface**
- **Secure data exchange through SDN**



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Included in the PVS system is what we call the vaccination roster. It includes the name of the clinic, the vaccination batch, which includes the manufacturer, the lot numbers, date of reconstitution and the date that the vial will no longer be viable, as well as the ability to import data from external systems. We have not mentioned this yet in this presentation, but VAERS which is the adverse events reaction reporting system, is a system that we will be connected to. We will be able link to these individuals to their adverse events with their patient vaccination numbers. This is a web-based application that will run either through Internet Explorer or through Netscape. It's a secure data exchange over a secure data network. We need to make sure we are able to secure this data and make it available to the appropriate individuals only.

# PVS Components

- **Data input screens**
  - **Vaccinee information**
  - **Vaccine batch information**
  - **“Take” response recording**
  - **Adverse events recording**
  - **Organizational information**



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Since PVS is a web-based application, there are data input screens. Some of the data input screens that we have available for those working at the clinics are the vaccinee information screen, the vaccine batch information, again which includes your vaccine lot, diluent manufacturer and reconstitution dates. Also, “take” response recording information, adverse events recording and organizational information about the actual clinics that are doing those vaccinations.



# PVS Components

- **Reports for clinic, state, and federal levels**
- **Data loads**
  - **Vaccine lots**
  - **Diluent lots**
  - **Organizations**



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It's also important to not only put data into the system, but also to retrieve it from the system. We have a number of reports at the clinic, state, and federal levels that will be available as well as data exports that will be available to the state so they can do their own data analysis. Some of those reports include a “take” callback report to ensure that six to eight days from date of vaccination, the individual can be called and asked to return for their “take” check. The vaccination report by date, so that the individuals working within the clinic can understand how many people actually passed through the clinic itself. Finally, it includes the medical history form, which can be preprinted at the beginning of the day as the patients are scheduled to come in so that the batch that is being used to vaccinate that individual is preloaded into that form. For more information on the reports, for clinic, state and federal levels, you can refer to the annex of the state guidance document that was distributed last week. Also, one of the things we provide through the PVS system are data loads. We work closely with the National Pharmaceutical Stockpile here at CDC. We are privy to the vaccine lots and diluent lots that will be used for this program. We've been able to preload that information into the system so that when data entry is done, there are fewer data entry mistakes in trying to enter the numbers into the system. Finally, we can load organizational data before the actual program begins so that you don't have to enter this while you are working in the clinic.

# PVS Support Requirements

- **Internet Explorer 5.0 and above or Netscape 6.0 and above**
- **Windows 98, NT 4.0+, 2000, and XP**
- **Computer resolution: 800x600**
- **Hardware requirements: Pentium 2 or above**



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Since this is a computer program, there are going to be PC requirements that go along with it. Internet Explorer, 5.0 or above, and Netscape 6.0 or above, are the two browsers that we're looking to use. Windows 98 or above should work just fine with this program. Your computer monitor resolution should be 800 by 600. We're looking for a PC or a laptop that has a Pentium 2 or above processor to allow for ease and speed of getting the data into the system.

# PVS Support Requirements

- **Internet speed: 56k Modem or above**
- **Personnel requirements**
  - **Recommend at least 2 administration and data management people per clinic**
- **Cost: Free**
- **Availability: On the Web, 24 / 7**



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You're also going to be concerned depending on where you're located about your internet speed. We wanted to assure you that a 56k modem or faster will work. A T1 line is always good, would be good for your internet speed to be able to send the data through the PVS. In terms of personnel requirements we recommend at least two administration and data management people per clinic. You can't ever be aware of how many forms you'll have to put in at certain points of the day, as well as the fact that one of those individuals may not be specific on an available day and you need to make sure you have a backup. We've been asked through a number of webcasts that we've done previously what the cost of the system is. We're happy to say we are providing this free of charge for use during this program. That also includes not only the software itself, but the digital certificate that you will need to be able to come in securely through the secured data network to load the data. Since PVS is on the web, it's available 24 hours a day, 7 days a week.

# Certified State Systems

- **State-developed or commercial systems will be certified as compliant based upon the following criteria:**
  - **Basic system functionality is met**
  - **Data exchange is tested and verified for inserts, deletions, and updates**
  - **Patient Vaccination Numbers (PVN) or an equivalent are used to identify unique vaccination events**



Now that we've talked about the pre-event vaccination system created by CDC, I want to make you aware of the fact that state-developed and commercial systems can be used if you so choose. But there are criteria that must be passed before it's deemed compliant to work with the PVS system and be in the program. Number one, the basic system functionality must be met. In the annexes of the guidance document there's a full set of functional specifications and you should be able to meet those basic system functionalities. Most importantly, data exchange will be tested and verified for insertions, deletions and updates to make sure that as that data is sent through the secure data network, it's appropriately updating the database. And finally, the use of PVN or patient vaccination numbers or an equivalent is extremely important because that is our one link to be able to identify that individual as having been vaccinated as well as a link back to any adverse events that may occur for that patient that may come in through the VAERS system.

# Certified State Systems Data Requirements

- **CDC will provide an upload utility to assist states in exchanging data files**
- **Data exchange format requirements have been identified and published**
- **Identify desire to use certified system in Preparedness Plan**
- **Identify state system contact**



CDC will be providing an upload utility to assist the states when they want to exchange the data files. In your guidance material you'll find a package that includes the requirements. These have been identified and published. They include the availability of the state to use the system either in a named or unnamed identifying fashion. Two important notes, these last two bullets on this slide refer to your submission of your plans that are due on Monday. We would require that you identify whether you're going to be using the PVS system within your state or whether you plan to go for certification for a state developed or commercial system, as well as the identification of system contacts within your state. It's important for us to understand who will be using these data systems so that we can get the digital certificates assigned appropriately and make sure we have a contact to go back to and talk with to make sure the certification process goes smoothly if that's that you choose to do.

# Data Management Roles

- **Clinic system users**
  - **Collect patient and vaccine information**
  - **Enter information into a vaccination support system**
    - **Maintains vaccine and diluent batch data**
    - **Maintains vaccination records**
    - **Records “take” response and adverse reactions**
  - **Generate reports**



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Let's talk about the people now - the people that are involved and have roles in all of this data management and information management collection. First there are the clinic system users that will be collecting patient and vaccination information and also entering that information into the support system. It's important to maintain the vaccine and diluent batch data, to maintain vaccination records, to record the take responses and adverse events and to have someone who has the ability to generate reports for your clinic, as well as your clinic managers and state governments.

# Data Management Roles

- **State “Principle Investigator”**
  - Responsible for all clinics within the state
- **Co-Principle Investigators**
  - Represents the principle investigator to the vaccination programs
  - Generates reports
  - Analyzes data
- **Local administrator**
  - Manages the data extract from certified state vaccination systems



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Also within the state are your principle and co-principle investigators who will want to be able to look at the data for your state and all the clinics. An important note, I'll talk more about this in the securities section is that the information or data that is input into the system will be separated according to states. You will be able to view your state's data and analyze it, but you will not be able to view the data of other states and their clinics. Finally, a local administrator. It's important to note that someone will have to be responsible for understanding whether records have to be deleted and make that decision as well as being the person responsible for the data extract if you decide to use a state certified system.

# Data Management Roles

- **CDC – Accumulates aggregate data**
  - **Receives data from certified state systems**
  - **Enters PVS set-up data: Manufacturer and lots, clinic data, organization data, roles, user IDs, and passwords**
- **CDC - SDN Administrator**
  - **Creates, approves, and distributes Digital Certificates for secure data exchange**
  - **Provides user support**



Explain digital certificates in talk.

The states have roles, but so does the CDC. In terms of data management roles, our largest role in this whole process is to accumulate aggregate data. We will receive data from certified state systems and work through PVS for the states who choose to use that and most importantly, will be entering the manufacturer and the lots, the clinic data, organizational data and roles. We'll also be responsible for that second layer of security and authentication into the patient vaccination system by identifying user IDs and passwords for those users. Finally, we will have SDN administrators, security data network administrators who will create, approve and distribute certificates. I'll talk more about this later. We wanted to provide the best user support that we can.



# Data Security

- **Secure Data Network (SDN) used to encrypt and exchange data with strong security for PVS system and for data uploads**
- **PVS system – selective access to data by jurisdiction**
- **Named data used for state purposes only (unless identified for active surveillance program in coordination with participating state)**



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A Secure Data Network (abbreviated as SDN) is part of the CDC Surveillance System Integration Project.

SDN is a secure Internet connection and gateway facility that protects the transmission of sensitive or critical data.

Where is data housed?

How the system protected against hackers?

So, moving on to data security. The secure data network that we'll be using is through the CDC. It will encrypt and exchange the data with strong security for either a PVS system or data uploads. No matter which option your state chooses, you will still need to have digital certificates to do this data exchange. Within the PVS system, there's selective access to data by jurisdiction, according to the states. Named data, if the state so chooses to send that through PVS, will be available for state purposes only. CDC will not be using the name data, but will be interested in the aggregate data information. There is a possibility that at some point there may be an active surveillance program that could be put into place and if that indeed is true, then the states would be confirmed that their name data, they would like to have that used with that particular program and that information would be shared with the active surveillance program.

# Support

- **CDC Helpdesk**
  - **Website – webcast archive available**
  - **Documents – Annexes in State Guidance**
  - **Training**
    - **Webcasts (To be scheduled)**
    - **No registration required**
    - **Training materials available on CDC website in PDF format**
- [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox)**



As a service organization the Information Resource Management Office most importantly wants to provide the appropriate support for these systems. So we have established a CDC Help Desk with individuals who are well aware of the data exchange requirements as well as the capabilities of the pre-event vaccination system, all of the stickers that go with it as well as any information or questions that you might have. We have on a website some webcasts of some PVS demonstrations that we have done. That website is [www.genesis.com](http://www.genesis.com). And that particular website, again, has archived webcasts of previous demonstrations we've done of PVS, as well as documents that we have within the annexes in the state guidance, review of the PVS system, and listings of reports. The data exchange information and then finally, training. One of the things we are going to do above and beyond this particular program is to provide several webcasts along with training materials in PDF format that will allow the data entry people within clinics to take a class before the system comes to them for their use.

In conclusion, what I'd like to remind you that the plans are due on Monday, December 9th. The most important criteria within those plans are the decision that you're going to make as a state as to whether you're going to use the PVS system, whether that's with identifiers or without and then as well, if you're going to choose a state certified system. We also need your clinic contacts and are looking forward to offering you training opportunities, which we will communicate to you through e-mails and websites. We want to give you the support that you need to make this a successful program. I appreciate your time. Thank you.

# Summary

- **Plans due by December 9<sup>th</sup>**
- **Criteria:**
  - **PVS (identifiers), PVS (no identifiers),  
Certified State System**
  - **Clinic contacts (at least 2)**
- **Training opportunities – Watch for email**
- **Support – CDC Helpdesk**



# For More Information

- **CDC Smallpox website**  
[www.cdc.gov/smallpox](http://www.cdc.gov/smallpox)
- **National Immunization Program website**  
[www.cdc.gov/nip](http://www.cdc.gov/nip)

