PHIN Preparedness

(DRAFT for discussion)

COUNTERMEASURE AND RESPONSE ADMINISTRATION

FUNCTIONAL REQUIREMENTS

AND PROCESS FLOWS

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TABLE OF CONTENTS

1 INTRODUCTION 4

2 COUNTERMEASURE AND RESPONSE ADMINISTRATION FUNCTIONAL REQUIREMENTS 4

2.1 Campaigns 5
2.2 Organizations 5
2.3 Pharmaceutical Countermeasures 7
2.4 Patients 7
2.4.1 Patient Demographic Data 7
2.4.2 Historical Data 9
2.4.3 Current Treatment Data 9
2.4.4 Patient Follow Up 11
2.4.5 Adverse Event 12
2.4.6 Isolation and Restriction Monitoring 12
2.5 Reporting 14
2.6 System Integration and Data Exchange 15
2.7 Vocabulary Standards 16
2.8 Operations 16
2.9 System Security and Availability 16
2.10 Privacy 17

3 PROCESS FLOWS 18

3.1 Overview 18
3.1.1 Workflow 18
3.2 Report Generation 21
3.2.1 Workflow 21
3.2.2 Description 21
3.3 Active Surveillance 24
3.3.1 Workflow 24
3.3.2 Description 24
3.4 VAERS Adverse Event Reporting 25
3.4.1 Workflow 25
3.4.2 Description 25

TABLE OF FIGURES

Figure 3-1: Process Flow Overview 18
Figure 3-2: Generate Reports 21
Figure 3-3: Active Surveillance 24
Figure 3-4: VAERS Adverse Event Reporting 25

1 INTRODUCTION

This document describes functional requirements and general workflows for systems implemented to manage countermeasure and response administration. Countermeasure and Response Administration (CRA) refers to specific actions taken to prepare for or respond to public health emergencies. Countermeasures include vaccination and other types of drug prophylaxis, as well as non-drug actions such as patient follow up activities and isolation and restriction monitoring. The recipients of the countermeasures may include potential responders from the public and the private sector, identified exposed individuals, and the general public.

This document identifies minimum functional requirements to support a Countermeasure and Response Administration system and should in no way preclude a system from incorporating additional functionality beyond what has been covered in this document.

Definitions of terms and acronyms used in this document may be found in the PHIN Glossary.

2 COUNTERMEASURE AND RESPONSE ADMINISTRATION FUNCTIONAL REQUIREMENTS

The following requirements describe baseline functionality for any system implemented to manage countermeasure and response administration data.

2.1 Campaigns: A CRA campaign is a set of specific actions taken to provide protection for a potential public health emergency or contain and respond to a known emergency. It may involve multiple agents, countermeasures and population groups and have multiple jurisdictions participating. The characteristics of a specific campaign may affect its functional and data collection requirements.

2.2 Organizations: Organizations may participate in CRA campaigns in one or more roles, such as that of state, metropolitan or local health department, treatment facility, take response location, patient follow up facility, pharmaceutical distribution center, countermeasure preparation site, restriction monitoring location, and referring organization. Example referring organizations are hospitals, police and fire departments, private doctors, outbreak management teams, etc.

2.3 Pharmaceutical Countermeasures: Pharmaceutical countermeasures include vaccines, antibiotics, anti-virals, and other drugs, as well as medical supplies such as respirators and IV sets.

2.4 Patients: The primary purpose of a CRA system is to track the patients treated and the treatments they receive during CRA campaigns. The information collected might be used to conduct statistical analysis of the progress and efficacy of a campaign, identify patients at risk from having received a treatment of questionable safety or efficacy, or build response teams of protected individuals. A user-friendly interface for retrieving previously entered patient information should be provided to reduce the occurrence of duplicate patient records and improve the validity of patient and treatment counts. Additionally, managing CRA information includes tracking patient restriction, active surveillance, and assisting with adverse event monitoring.

2.5 Reporting: Detailed and aggregate reports of the CRA data should be available. Detailed reports may be used for quality assurance of data entry, to assist with any

required follow up activities, or to provide lists of response team members for referring organizations. Aggregate reports may be used to show campaign progress and preparedness across the entire jurisdiction.

2.6 System Integration and Data Exchange: The CRA data should reside in a secure central repository. A CRA system should be able to exchange the data within the repository with partners using standardized data exchange formats and protocols.

2.7 Vocabulary Standards: Standard vocabulary lists and data structures have been defined by various organizations. Where they exist, CRA systems should utilize them. As additional standards are defined, they should be accepted and implemented.

2.8 Operations: Personnel, roles, and responsibilities necessary to support CRA systems should be clearly defined**.**

2.9 System Security and Availability: Security of the CRA data repository includes the protection of data from corruption and access by unauthorized individuals, as well as the protection of a CRA system itself from sabotage or other failure. There must be a backup plan for continuing campaign activities when CRA systems are unavailable.

2.10 Privacy: Patients and organizations must be protected from fraudulent and unauthorized use of their information.

2.1 CAMPAIGNS

2.1.1 Information about the characteristics of each campaign shall be captured.

2.1.1.1 Campaign information must include: a unique campaign identifier, the campaign name, agent(s) involved, the sponsoring entity, start and end dates, a campaign type (preparedness or response), population(s) to be treated, potential countermeasure(s), and jurisdiction(s) participating.

2.1.1.2 Campaign-specific information such as whether outbreak monitoring, treatment history collection or response team building is included should also be stored.

2.1.2 Multiple concurrent campaigns must be supportable, as well as merging multiple campaigns into one, splitting a campaign into multiple campaigns, and linking campaigns.

2.1.3 The linking of CRA campaign data with corresponding campaign data in other systems (outbreak management systems, etc.) must be supported.

2.1.4 Flexibility should allow for collection of additional data items defined during a campaign. An example of this would be responses to a set of questions devised as a result of statistical analysis of follow up data.

2.1.5 In the event of a mass exposure, it must be possible to redefine the set of required data to support the collection of a reduced amount of information.

2.2 ORGANIZATIONS

2.2.1 Basic information about all organizations that participate in a CRA campaign must be captured and stored in a local instance of a Public Health Directory.

2.2.1.1 Every organization must have a global identifier unique across all CDC partner jurisdictions.

2.2.1.2 All organizations with roles in CRA campaigns should be entered into a local instance of a Public Health Directory.

2.2.1.2.a Organization data for a local instance of a Public Health Directory includes: a globally unique object identifier known as an OID, the organization name and address (including street address, city, state or province, country, zip code, and county or parish), contact name, phone number, fax number, and type of organization (state agency, local agency, hospital, …).

2.2.2 In addition to the organization information stored in a local instance of a Public Health Directory, the functional roles of the organization within a campaign (treatment facility, take response location, pharmaceutical distribution center, restriction location, referring organization, …) and any referring organization categories within a campaign (healthcare response team, public health response team, …) are required.

2.2.3 Every recorded treatment, patient follow up, take response reading, restriction monitoring, or other type of patient encounter must be linked to the participating organization to promote tracing of possible safety and efficacy issues related to the organization where the encounter occurred. See Section *2.4.3 Current Treatment Data* for more information.

2.2.4 Information about all individuals who serve as staff for an organization in support of CRA campaigns must be captured.

2.2.4.1 Every staff member must have a global identifier unique across all CDC partners.

2.2.4.2 All staff members with roles in CRA campaigns should be entered into a local instance of a Public Health Directory.

2.2.4.2.a Public Health Directory staff data includes a global unique object identifier (OID), the individual's name and an identification number.

2.2.4.3 In addition to the staff information stored in a local instance of a Public Health Directory, the assignment of a staff member to multiple roles within multiple organizations must be supported. Examples of staff roles are: contact, treatment administrator (e.g., vaccinator or other drug administrator), patient follow up personnel, and medical examiner (take reader).

2.2.5 It is essential that the organization is able to trace the electronic records of staff members to the actual people they represent.

2.2.6 Every record of a treatment, patient follow up, take response reading, restriction monitoring or other type of patient encounter must include the staff person involved in the encounter to promote tracing of possible safety and efficacy issues related to the staff member involved in the encounter. See Section *2.4.3 Current Treatment Data* for more information.

2.3 PHARMACEUTICAL COUNTERMEASURES

2.3.1 All pharmaceuticals administered must be identified by lot number and manufacturer.

2.3.2 Pharmaceuticals inventory should be captured in order to identify and respond to issues with availability of pharmaceuticals and to track the distribution and use of controlled substances.

2.3.2.1 Inventory information must include: a unique identifier of the inventory record, the manufacturer, the lot number, and the expiration date.

2.3.2.2 Inventory information may include: the generic name, the brand name, packaging information, quantity, manufacture date, shelf life, shipped date, received date, and current location.

2.3.3 Integration with pharmaceutical stockpiles should be provided.

2.3.4 Validation of lot numbers must be used when recording countermeasure usage. This will ensure consistency and reduce the possibility of incorrect lot numbers.

2.3.5 Information about specific containers of prepared countermeasures, such as vaccine batch vials or large pill containers from which multiple patients may be treated, must be stored.

2.3.5.1 Information about a prepared countermeasure container must include: unique identifier of the container, countermeasure name, date and time of re-packaging or alteration (e. g., reconstitution, first usage), facility where re-packaging or alteration occurred, resulting amount of substance in the container, pharmaceutical name(s), lot number(s) and manufacturer(s), and maximum number of patient treatments that can be delivered from the container.

2.3.6 Support for the sharing of prepared countermeasure containers by multiple treatment facilities is required.

2.3.7 It must be possible to deactivate a prepared countermeasure container and record the reason for and date of deactivation.

2.3.8 Every patient treatment event shall be linked to any countermeasure(s) administered to the patient during the campaign to promote tracing of possible efficacy and safety issues related to the pharmaceutical lot or the prepared countermeasure container. See Section *2.4.3 Current Treatment Data* for more information.

2.4 PATIENTS

2.4.1 Patient Demographic Data

2.4.1.1 Demographic information about all patients treated in a CRA campaign must be collected.

2.4.1.1.a Each patient in a CRA system must be identified by a patient identification number unique within the partner's jurisdiction.

2.4.1.1.b Demographic data must include: patient identification number, year of birth (though the full date of birth may be captured, only the year of birth is specifically required), gender, state, and occupation.

2.4.1.1.c Demographic data may include: contact information (name, address, home and work phone numbers, fax number, other pertinent communication paths including cell phone, pager, and email), date of birth, zip code, county and country of residence, ethnicity and race.

2.4.1.1.d Additional identifiers such as social security number, driver's license number, and passport number may be included to validate the uniqueness of the patient.

2.4.1.1.e For patients who may be serving as responders in a campaign, information on referring organization, occupation, expertise and role on a response team should be collected.

2.4.1.1.f Whether specific demographic data items are required may be determined by the characteristics of the campaign under which a treatment is being delivered.

2.4.1.2 Information must be available to assist in contacting a patient who does not return for a follow up visit, must be monitored for compliance, or might have received a treatment for which an issue has been discovered.

2.4.1.3 The flexibility must exist to specify demographic data items as required or optional based on the characteristics of the campaign under which a treatment is being delivered.

2.4.1.4 Every patient should be represented only once.

2.4.1.4.a Patient record search and retrieval functionality is required to promote the elimination of multiple patient records for the same patient and allow authorized users to efficiently retrieve an existing record to be updated.

2.4.1.4.b Matching functions must be provided to match patient records based on meaningful identifiers in order to reduce duplication of patient data in a CRA system.

2.4.1.4.c In order to accurately represent the level of preparedness, it must be possible to verify that responders are represented only once in CRA systems and to validate all their agent protections.

2.4.1.5 Sufficient information about patients must be captured electronically to link patient records to the actual people they represent, either manually or by the use of identifying information stored within a CRA system.

2.4.1.5.a This link is necessary to support public health investigations, including contact tracing, and to communicate with patients who need to receive treatments or who require post-treatment follow up, including safety and efficacy follow up.

2.4.1.6 It must be possible to link patient records to corresponding case and/or contact records in systems used to manage outbreak data.

2.4.1.7 Patients who are willing to participate in more extensive follow up including detailed surveys and photos should be identifiable electronically.

2.4.2 Historical Data

2.4.2.1 Collection of historical information such as treatment history (e.g., vaccination), disease history, and other medical history including but not limited to medications and pre-existing medical conditions must be supported.

2.4.2.2 The need for historical data may vary based on the campaign or the countermeasure involved in the current treatment. For example, the data may be used in statistical analysis to determine whether previous treatment has an impact on the result of the current treatment.

2.4.2.3 Historical information collected must include a unique historical identifier, the patient involved, and the campaign during which the history was collected.

2.4.2.4 In addition to the general historical information, treatment history data may include the date of the historical treatment, the result (take response or outcome) of the historical treatment, and the occurrence of adverse events.

2.4.2.4.a Treatment history date may be an actual date, a year, or a general value (e.g., childhood or adulthood).

2.4.2.4.b In addition to specific information for each historical treatment, aggregate historical treatment information such as the number of previous treatments will be captured.

2.4.2.5 Disease history must include the name of the disease (from a standard list of diseases), date or timeframe (childhood or adulthood) when the patient had the disease, and some comments about the progression of the disease.

2.4.2.6 Medication information must include the name of the medication (from a standard list of medications), the reason for taking the medication, the timeframe and dose taken, and additional collected information.

2.4.3 Current Treatment Data

2.4.3.1 Entry and tracking of current treatment data must be provided.

2.4.3.2 Every treatment record will be identified by at least one unique treatment identifier, such as the Patient Vaccination Number (PVN) used to identify vaccination events in the National Smallpox Preparedness Program. The identifier must be unique within the partner's jurisdiction.

2.4.3.3 Every treatment record is to be linked to the campaign under which it was administered.

2.4.3.4 Each treatment record must be tied to the original patient record.

2.4.3.5 Treatment data must include: a unique treatment identifier, a description of the treatments, vaccinations, antidotes, or prophylaxis used to counteract the agent of an outbreak on exposed or possibly exposed subjects, recommended dosage and frequency of administration of the treatment, the campaign under which the treatment is occurring, the patient receiving the treatment, the countermeasure, each countermeasure container that is the source of pharmaceuticals administered to the patient, the agent for which the countermeasure is being used, the date of the treatment, the treatment facility, and the person administering the treatment.

2.4.3.5.a The specific protocol for a campaign or a drug may require that additional demographic information be collected; for example, the location on the subject's body where the vaccination was administered may be captured, the weight and exact age at treatment might be required for children receiving the countermeasure, and CRA must include the flexibility to collect protocol specific information.

2.4.3.5.b For patients referred for treatment as preparation for serving on a response team, the identity of the referring organization must be captured.

2.4.3.6 The capture of the use of more than one countermeasure during a treatment event is required. An example of this is the use of both antibiotics and vaccination to treat a patient exposed to inhalational anthrax.

2.4.3.7 The recording of multiple treatment events for a patient under a specific campaign must be supported. Additional treatments might be re-treatment with the same countermeasure, or administration of additional countermeasures.

2.4.3.8 Each treatment event will be linked to all the specific prepared countermeasure containers (such as specific vaccine vials) from which the treatment was dispensed to the patient. Through the prepared countermeasure container, the treatment can be traced to all pharmaceutical lots used.

2.4.3.9 Each treatment record will be traceable to the specific treatment facility and treatment administrator involved in the treatment.

2.4.3.10 Sufficient treatment information is required to identify all patients treated at a specific facility, by a specific person, or from a specific container, in the event of issues arising with the facility, the treatment administrator, the container, or the pharmaceutical lots in the container.

2.4.3.11 Sufficient treatment information must be recorded to determine when a patient should return for a follow up visit for an additional treatment or an evaluation, such as a smallpox take response reading.

2.4.3.12 The acceptance of potentially incomplete patient and patient treatment information from external sources such as systems used to manage outbreak data must be supported. This might consist of an electronic request to treat a patient or an electronic record of a treatment that has already occurred.

2.4.3.13 The participation of a patient in more than one campaign will be supported. For example, a CRA system must be able to record that a single person received a smallpox vaccination during the National Smallpox Preparedness Program and anthrax prophylaxis during an anthrax response campaign.

2.4.3.14 It must be possible to track a patient's progress through a series of treatments, such as the anthrax vaccination series, in which the appropriate time between treatments varies depending on how many vaccinations have been received previously.

2.4.3.15 If an affected person receives vaccination or prophylaxis to protect against the outbreak but shows no signs of benefit, this information should be captured.

2.4.3.16 Although contraindications are typically used to disqualify a person from treatment (and their information is not retained), it may be necessary to collect contraindication information during some campaigns. In cases where the side effects of treatment pose less risk to the patient than the event itself, treatment may be given. However, the patient may require a heightened level of monitoring to track their increased risk of side effects.

2.4.4 Patient Follow Up

2.4.4.1 Functionality to conduct and record the results of patient follow up is required and must have the flexibility to support follow-up that is specific to the treatment provided.

2.4.4.1.a The follow up event may be a telephone contact with a patient or an actual in-person encounter.

2.4.4.1.b The follow up event may address an additional treatment, response to medications, symptom tracking, compliance monitoring and other activities such as reading and recording a take response to a vaccination.

2.4.4.2 Each patient follow up record will be linked to the corresponding treatment record.

2.4.4.3 Treatment follow up information may include: a unique follow up event identifier, the corresponding treatment event, the patient involved, responses to follow up questions, reason for non-availability of information, adverse event information, general comments, the facility where the follow up event occurred, the identity of the staff member conducting the follow up, and the date the follow up event occurred, as applicable.

2.4.4.3.a The capability to record responses to sets of follow up questions provided as a part of campaign or countermeasure guidelines must be supported.

2.4.4.4 A take response exam is a special case of a follow up involving determining the outcome (take response) of a smallpox vaccination (or possibly other currently unidentified treatments). The capture of the exam outcome (major, equivocal or not available), take reader, take location, and adverse event information are required. If a take response cannot be collected, a reason for the lack of take availability should be captured.

2.4.4.5 Recording of information on the success of a treatment such as immunity to a disease as a result of a vaccination will be required for some countermeasures.

2.4.4.6 The linking of CRA patient treatment data with any corresponding reports in an active surveillance system should be supported.

2.4.4.7 The linking of CRA patient treatment data with any corresponding adverse events recorded in an adverse event reporting system should be supported. An example of such a system is the Vaccine Adverse Event Reporting System (VAERS) at *http://www.vaers.org*.

2.4.5 Adverse Event

If an affected person suffers a negative reaction to administered vaccinations or prophylaxis, adverse event data may be collected to determine whether additional treatments are needed, whether there is an issue with a particular lot of a pharmaceutical, whether pharmaceuticals dispensed from a certain container (batch) show unusual trends, or whether a specific treatment facility or treatment administrator has a high number of adverse events.

2.4.5.1 Data should be collected to describe the characteristics of the reaction, the amount of time lapsed between the entity receiving the vaccination and the onset of symptoms, pharmaceutical lot and batch information, as well as treatment information (including the location and administrator).

2.4.6 Isolation and Restriction Monitoring

Isolation and restriction monitoring involves overseeing the movement of subjects involved in a public health event, whether voluntary or involuntary. This data is useful for public health officials who are tracking the progress and treatment of subjects who were exposed or potentially exposed to a public health event

2.4.6.1 Recording and tracking of isolation and restriction monitoring information must be supported.

2.4.6.2 A restriction monitoring or isolation authorization must be issued in order to restrict a patient.

2.4.6.2.a CRA must have the flexibility to support isolation and restriction monitoring authorization information that varies based on the type of restriction imposed. Isolation and restriction monitoring requirements may include: a unique restriction authorization identifier, the campaign under which the restriction is authorized, the agent, the level of the authorizing authority (federal, state, local), the court order number, the name of the person who signed the court order, the type of restriction order (group or individual), the nature of the restriction (voluntary or mandatory), and the organization and staff member responsible for administering the restriction monitoring authorization.

2.4.6.2.b If the order is for a group of people, a description of the group is required.

2.4.6.2.c If the order is for an individual, information useful to identify or locate the person may be captured.

2.4.6.2.d Isolation and restriction monitoring data should be communicated to the restriction monitoring site in order to monitor the case's health status.

2.4.6.3 Each patient isolation or restriction monitoring event must be tied to the patient, campaign and authorization involved.

2.4.6.3.a Patient demographics must be collected for the restricted patient. See section *2.4.1 Patient Demographic Data* for more information.

2.4.6.3.b CRA must have the flexibility to support isolation and restriction monitoring information that varies based on the type of restriction imposed. Patient isolation and restriction monitoring information may include: a unique isolation or restriction event identifier, the patient, the attending physician, the isolation or restriction monitoring order, contact information (address and telephone numbers) for the restriction location (an organization previously identified as participating in the campaign as a restriction location, or a private residence, such as the patient's home), contact information for a relative or friend of the patient, the date range, and the facility and staff member responsible for monitoring the patient under restriction.

2.4.6.4 Monitoring of isolated or restricted patients is to be supported by triggering and capturing the results of activities such as daily telephone calls and restriction site visits.

2.4.6.4.a Based on the restriction imposed, monitoring information may include: a unique monitoring encounter identifier, the patient, the patient isolation or restriction event, temperature and symptom details, date and time of monitoring encounter, staff member who conducted the monitoring, number of attempts to contact the patient, the type of encounter (visit or telephone), whether the patient is complying with the restriction order, person spoken to if monitoring occurred by phone call, and a discharge date, reason and staff member authorizing the discharge.

2.4.6.4.b Symptom tracking and/or surveillance is required as part of an isolation or restriction monitoring event. The symptoms tracked will be from a limited list of symptoms, generally defined by a standards development organization (SDO).

2.4.6.4.c When monitoring occurs by telephone, the identity of the person contacted (the patient, a relative or a healthcare worker at the restriction site) should be captured.

2.5 REPORTING

2.5.1 Reporting categorized by treating organization, by referring organization, and by prepared countermeasure container must be available.

2.5.2 Reports showing detailed inventory information and calculation of pharmaceutical usage are required.

2.5.3 Daily detailed reports must be provided for use in proofing data entry of all types of patient information.

2.5.4 It must be possible to generate date-driven contact lists of patients in need of follow up.

2.5.5 Lists of patients by their referring organizations should be produced for use in building and managing response teams. There should be at least two such reports: one to identify all persons referred for treatment and to indicate their treatment statuses, and one to identify "protected" individuals able to serve on response teams.

2.5.6 Aggregate reports are required for each campaign to show patient counts such as number of patients treated, number of patients not treated, number of patients for whom the treatment did not have the desired outcome (e.g., an equivocal take for a smallpox vaccination), and number of patients complying with treatment.

2.5.7 Sufficient data must be provided to national partners to allow the creation of national reports of aggregate information (including mapping) to be used to track campaign progress. For campaigns with a response team component, national reports may also be produced to evaluate overall preparedness. (See *2.6 Systems Integration and Data Exchange* section below for more information.)

2.5.8 It must be possible to generate ad hoc reports from the stored CRA data.

2.6 SYSTEM INTEGRATION AND DATA EXCHANGE

Systems integration requirements specific to systems supporting CRA are included in the section below and describe the types of data that CRA should be able to send and receive. This section is limited to describing the types of data exchange that CRA must support; not the requirements for transporting the data. Secure data transport requirements that span PHIN functional areas are separately defined and should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.6.1 Bi-directional, secure exchange of data with partner organizations is required to support public health investigations across all levels of public health. Some of the system integration and data exchange requirements described in this section have been identified as key performance measures. These measures should be reviewed in the *PHIN Key Performance Measures* document. (*www.cdc.gov/phin/KPM.pdf*)

2.6.2 CRA information collected from multiple sites or systems is to be consolidated prior to exporting it to partner organizations.

2.6.3 CRA must be able to receive, parse and process data messages for "countermeasures that are requested", as well as to receive information regarding follow-up activities for treated subjects. This capability is only necessary when subjects identified for treatment or receiving follow-up, are managed in a system separate from the system that supports CRA. This functional requirement is identified as a key performance measure for assessing preparedness. PHIN *Key Performance Measures* are described in the document. (*www.cdc.gov/phin/KPM.pdf*)

2.6.4 CRA must be able to create and send data messages for individual and aggregated "countermeasures that have been administered". This functional requirement is identified as a key performance measure for assessing preparedness. PHIN *Key Performance Measures* are described in the document (*www.cdc.gov/phin/KPM.pdf*).

2.6.4.1 Sufficient data will be supplied to national partners to conduct statistical analysis including, but not limited to, treatment safety and efficacy, trends in adverse events, compliance, and preparedness level.

2.6.4.2 The ability to identify safety and efficacy issues with a countermeasure or the campaign staff at a particular treatment facility can lead to notification of all concerned parties that corrective action may be required, such as re-training of staff and/or recall of patients for additional treatment.

2.6.5 CRA must also be able to receive, parse and process data messages for individual and aggregate "countermeasures that have been administered". This functional requirement is identified as a key performance measure for assessing preparedness. PHIN *Key Performance Measures* are described in the document (*www.cdc.gov/phin/KPM.pdf*).

2.6.6 CRA should be able to create and electronically exchange individual and aggregate reports on adverse events. This functional requirement is identified as a key

performance measure for assessing preparedness. PHIN *Key Performance Measures* are described in the document. (*www.cdc.gov/phin/KPM.pdf*)

2.6.7 Active surveillance is CRA should be able to create and electronically exchange individual and aggregate reports on active surveillance. This functional requirement is identified as a key performance measure for assessing preparedness. PHIN *Key Performance Measures* are described in the document. (*www.cdc.gov/phin/KPM.pdf*)

2.6.8 The ability to receive data such as pharmaceutical information, campaign setup information, and vocabulary from authorized partner organizations, such as the CDC, is recommended.

2.7 VOCABULARY STANDARDS

It is recommended that standards be used across CRA systems; however, vocabulary standards must be used when exchanging data. Vocabulary requirements specific to systems supporting CRA are included in the section below. Terminology requirements that span PHIN functional areas are separately defined and should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.7.1 Systems supporting CRA functionality should follow defined data standards including but not limited to standards defined by the healthcare industry, national and international standards organizations (FIPS, ISO, etc), and the public health community.

2.8 OPERATIONS

Operational requirements, such as system backup policies and procedures, continuity of operations, system monitoring, and employee training ensure that public health partners can effectively support activities in CRA and other PHIN functional areas. Operational requirements that span PHIN functional areas should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.9 SYSTEM SECURITY AND AVAILABILITY

Systems supporting CRA must be protected from sabotage or other system corruption. Security requirements specific to systems supporting CRA are included in the section below. Security requirements that span PHIN functional areas are separately defined and should be reviewed at in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.9.1 A user's access to data will be limited by defined "filters" including but not limited to campaign, organization, and user functionality. For example:

2.9.1.1 A user may be able to view the treatment data of the Smallpox Preparedness Program but may not be able to view the treatment data of the Anthrax Outbreak, 2001.

2.9.1.2 A data entry user for treatment facility A cannot view the data of treatment facility B.

2.9.1.3 A follow up user may be able to see the patient's name and contact information but may not be able to see the patient's social security number, driver's license number, or demographic data (race, ethnicity, etc.).

2.10 PRIVACY

Privacy requirements ensure that sensitive information is not accessibly to unauthorized uses. Privacy requirements are broadly defined because they span all PHIN functional areas. These requirements should be reviewed at in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

3 PROCESS FLOWS

3.1 OVERVIEW

3.1.1 Workflow

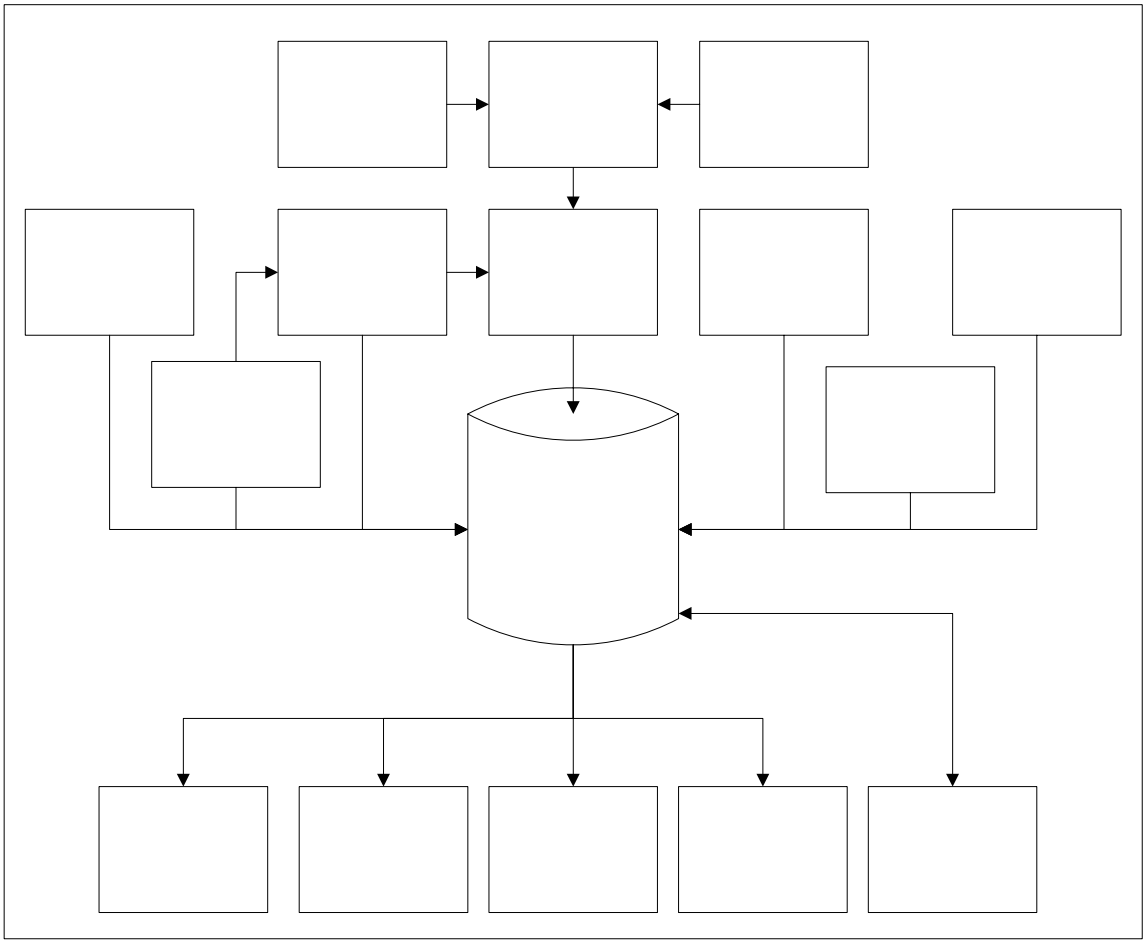

Figure 3-1: Process Flow Overview

This diagram illustrates the processes necessary to meet the requirements of a CRA system. Some of these processes may be abbreviated or not executed in the event of a large-scale public health emergency.

Campaign Setup

3.1 Campaign Setup: A CRA campaign may be initiated for pre-event preparedness or in response to a specific public health event. The setup process includes identifying agents, countermeasures, populations to be treated and jurisdictions participating, and specifying start and end dates. If an infectious disease is involved, restriction monitoring rules may be needed.

3.2 Identification of Eligible Candidates (Referral Only): For campaigns where referral is required, pre-treatment screening is performed by referring organizations such as hospitals and includes identifying and educating potential candidates. Coordination of eligible candidate lists with the jurisdiction and the coordination of schedules between the referring organization and the treating facility are included. Pre-treatment screening may also be conducted by outbreak management teams to identify people who should receive treatment due to exposure.

3.3 Identification of Exposed Individuals (Post-Event Only): When a public health event has occurred, potentially exposed people will be instructed to report to treatment facilities to receive the appropriate countermeasures. Instruction may be delivered by outbreak management teams, the media, or some other means. The entire population of an area may be considered exposed, or a subset of the entire population may be identified.

3.4 Patient Screening and Consent: Patient screening is performed at the treatment facility, and includes completion and review of a Patient Medical History and Consent Form, reinforcement of adverse events education, answering patient questions, and obtaining patient consent, as appropriate. People who fail screening may be referred for alternate countermeasures.

3.5 Treatment Administration: Treatment administration applies to consenting patients. It includes completion and processing of patient forms, patient treatment, education of patients (on compliance, take response reading, wound care, adverse events), and data entry.

3.6 Patient Follow Up: Patient follow up requirements vary with the countermeasure. Possible follow up activities include scheduling a re-treatment, recording information on compliance with the treatment regimen, and tracking any developed symptoms or adverse events.

3.7 Take Response Recording: Some treatments, such as the smallpox vaccine, require an evaluation to determine whether the desired outcome has resulted. Such an evaluation is a specific type of patient follow up. Patients should be evaluated and the results of the evaluation should be recorded.

3.8 Isolation and Restriction Monitoring: If the illness involved in a public health event may be transmitted by casual contact with a sick individual, isolation or restriction monitoring may be necessary. Information about the restriction includes the isolation or restriction order, the location, the medical personnel involved and the start and end dates. Restricted patients are monitored for symptoms and compliance.

3.9 Inventory Tracking: Quantities, expiration dates and reductions in inventory should be tracked to determine the amount of inventory available for use and to report on usage. Lot numbers must be recorded in order to ensure that the proper lot numbers are being used in recording the information about the use of prepared countermeasures. In

addition, many pharmaceuticals must be tightly controlled; therefore, the movement of the pharmaceutical inventory within the jurisdiction may require tracking.

The inventory tracking process may also involve working with or linking to the partner-defined stockpile system or a Strategic National Stockpile (SNS) data file to capture information about pharmaceuticals that are delivered to a public health recipient. Similar information should be made available for pharmaceuticals received from other sources.

3.10 Countermeasure Preparation: A facility, often the treatment facility, prepares countermeasures for dispensing to patients. The preparation may include such acts as re-packaging the pharmaceutical into individual patient-distributable amounts, mixing pharmaceuticals together into a single vial, or identifying a multi-use container. Information to identify the exact sources (lot numbers) and preparation date of a prepared countermeasure container must be stored in a CRA system.

3.11 Report Generation: Facility reports include detailed treatment administration and follow up activity, as well as aggregate counts. Public health reports include campaign summaries and other reports to assist in management of a campaign. For campaigns with response team components, there are public health reports to assist referring organizations in identifying potential response team members.

3.12 Active Surveillance: Active surveillance information about patients whose treatments have been recorded might be captured by external systems. The treatment identifier will be used to tie the patient to the active surveillance information.

3.13 VAERS Adverse Event Reporting: It is expected that the Vaccine Adverse Event Reporting System (VAERS) will be used to record adverse events. The VAERS form will include a field to record the treatment identifier of the patient treatment suspected as the trigger of the adverse event.

3.14 Statistical Reports: Statistical reports will be generated from CRA data and made available to grantee jurisdictions for download.

3.15 External Systems: External systems will engage in bi-directional secure data exchange with systems containing CRA data. Examples of data exchanges include receiving individual or aggregate lists of patients requiring treatment from an outbreak management system and sending treatment data to the outbreak management system, receiving "set-up" data such as campaign information, pharmaceutical lot numbers, and vocabulary, and sending patient treatment data to the CDC for use in evaluating pharmaceutical safety and efficacy, campaign progress, preparedness, or other analytical activities.

3.2 REPORT GENERATION

3.2.1 Workflow

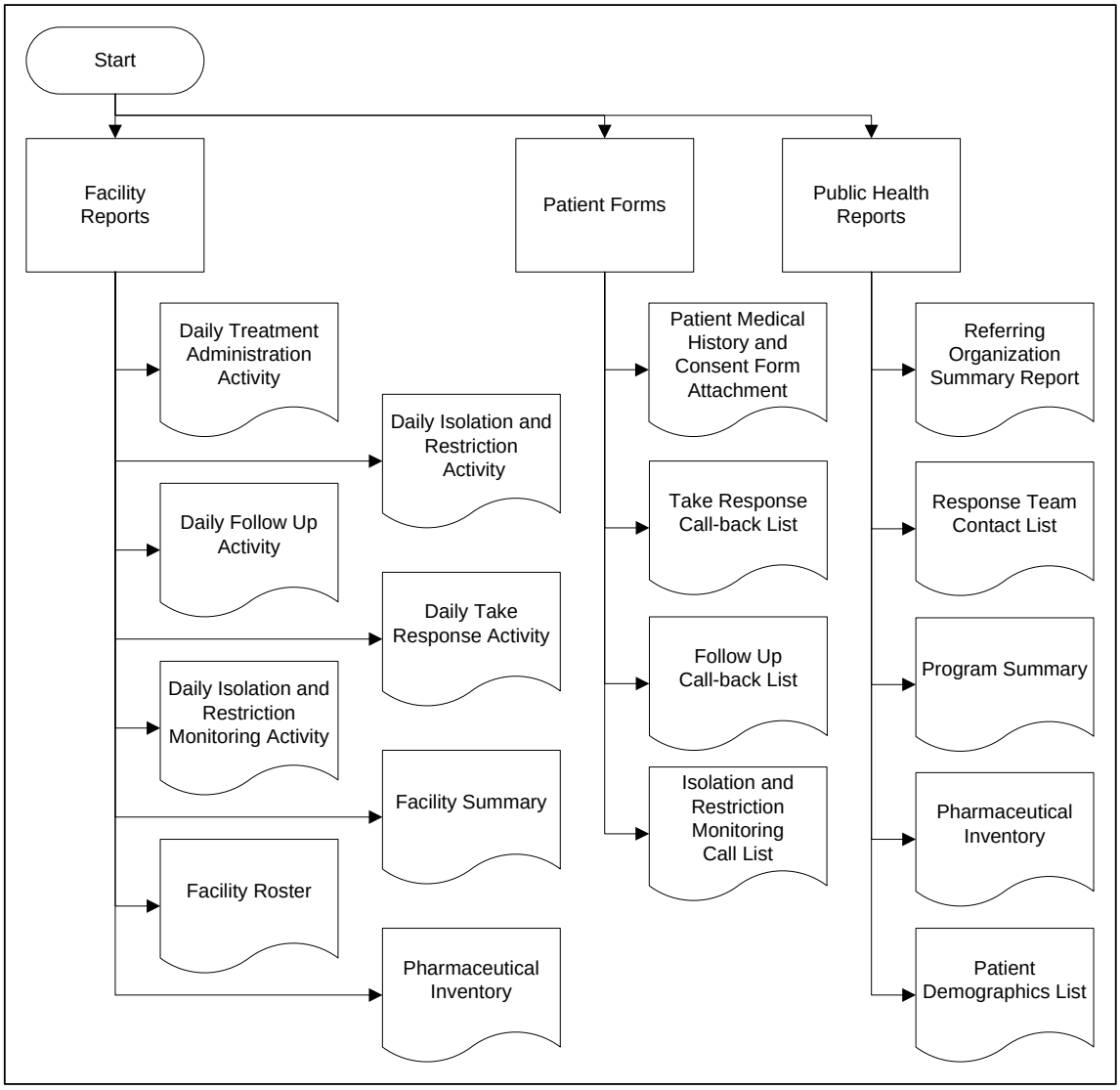

Figure 3-2: Generate Reports

3.2.2 Description

3.2.2.1 Facility Activity Reports

The facility that administers the countermeasures is responsible for generating facility reports; any system implemented by the facility or the jurisdiction should be able to provide the information described below.

3.2.2.1.a Daily Treatment Administration Activity

This report is a complete record of all treatments provided to patients at the facility 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 facility's treatment activity.

3.2.2.1.b Daily Isolation and Restriction Activity

This is a suggested new report which will contain a complete record of all isolations and restrictions declared by the facility 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 facility's isolation and restriction activity.

3.2.2.1.c Daily Follow up Activity

This report is a complete record of all follow up information reported to the facility 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 facility's follow up activity.

3.2.2.1.d Daily Take Response Activity

This report is a complete record of all take response readings performed at the facility 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 facility's take response activity.

3.2.2.1.e Daily Isolation and Restriction Monitoring Activity

This is a suggested new report which will contain a complete record of all isolation and restriction monitoring information reported to the facility 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 facility's isolation or restriction monitoring activity.

3.2.2.1.f Facility Summary

This report is a summary report for a facility. This report includes but is not limited to counts of the total number of treatments, the total number of take response readings, and the number patients having takes at each take response level (major and equivocal).

3.2.2.1.g Facility Roster

This report provides a list of patients who have been treated by a facility for a date range. This report is intended to assist a facility with tracking a patient's progress through the CRA process.

3.2.2.1.h Facility Pharmaceutical Inventory

This is a suggested new report providing information about countermeasures in use or stored at the facility. It should list all prepared countermeasure containers and pharmaceuticals not yet prepared for use.

3.2.2.2 Patient Forms

Patient forms contain patient-specific information. They are used by the facility to record treatment, compliance and take response information. The completed forms are sent to data entry for input to the system supporting CRA functionality.

3.2.2.2.a Patient Medical History and Consent Form Attachment

The Patient Medical History and Consent Form is a part of the patient package at each facility. The facility's system should either support printing a Patient Medical History and Consent Form attachment that is pre-populated with the information that identifies a prepared countermeasure container, or the identifying information should be manually

included on the medical history and consent form for each patient receiving the treatment. This identifying information includes: manufacturers and lot numbers of all pharmaceuticals included in the countermeasure, date of preparation for use (date of reconstitution for a lyophilized vaccine, first use date of a multi-use countermeasure,…), and the name of the facility that prepared the countermeasure for use.

Note: This report is integral to the facility flow and is covered in detail under a separate process flow.

3.2.2.2.b Take Response Call-back List

The Take Response Call-back List provides a list of vaccinees who should 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.

Note: This report is integral to the facility flow and is covered in detail under a separate process flow.

3.2.2.2.c Follow Up Call-back List

The Follow Up Call-back List provides a list of patients who should be called to check on their progress after treatment. This report is sorted by number of days since treatment, descending. This report will also have space to capture the data from the patient in preparation for data entry.

Note: This report is integral to the facility flow and is covered in detail under a separate process flow.

3.2.2.2.d Isolation and Restriction Monitoring Call List

The Isolation and Restriction Monitoring Call List provides a list of patients who should be contacted to check on their isolation or restriction progress. This report is sorted by number of days since most recent contact, descending. This report will also have space to capture the data from the patient in preparation for data entry.

Note: This report is integral to the facility flow and is covered in detail under a separate process flow.

3.2.2.3 Public Health Reports

The jurisdictions will generate these reports.

3.2.2.3.a Referring Organization Summary Report

The Referring Organization Summary Report is a pre-event report. It provides a list of patients referred by an organization with treatment event and, if available, take response or follow up information. This report is intended to assist a referring organization in tracking the progress of their referred patients through the CRA process.

3.2.2.3.b Response Team Contact List

This report is a list of people who are protected. Protection criteria vary based on the agent for which the countermeasure was administered. This report is intended to provide a list of protected people for building the response teams in the event of an outbreak or other public health emergency. (Patients are considered protected from smallpox if they have had a major take on their initial vaccination or revaccination or if they have had (1) a vaccination prior to the vaccination campaign, and (2) two vaccinations during the campaign both with equivocal take responses.)

3.2.2.3.c Campaign Summary

The Campaign Summary displays various counts for a specific jurisdiction and campaign. It can be executed at the jurisdiction level or at a subordinate jurisdiction level if organizations are assigned to subordinate jurisdictions. Information includes number of patients treated, number of patients considered protected, and compliance and take response level counts.

3.2.2.3.d Pharmaceutical Inventory Report

This is a suggested new report providing information about pharmaceuticals and their quantities and locations within the jurisdiction.

3.2.2.3.e Patient Demographics Report

This is a suggested new report providing information to be used to identify duplicate patient records.

3.3 ACTIVE SURVEILLANCE

3.3.1 Workflow

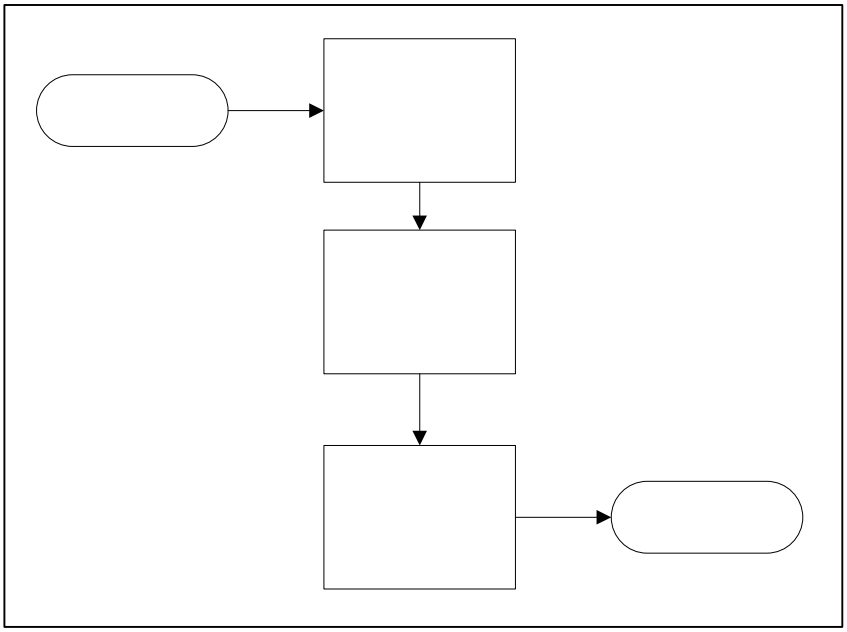

Figure 3-3: Active Surveillance

3.3.2 Description

3.3.2.1 An active surveillance team member contacts a patient and interviews the patient.

3.3.2.2 The interview results are collected electronically and provided to the CDC. The reporting of the results must adhere to the format and technology for data exchange provided by the CDC.

3.3.2.3 Active surveillance includes information about contraindications, risk factors, and health problems for patients and patient contacts.

3.3.2.4 The active surveillance record must include the patient's treatment identifier.

3.3.2.5 The CDC will link the active surveillance information to the corresponding CRA treatment information using the treatment identifier.

3.3.2.6 This activity may be optional, depending upon the countermeasure campaign that is being administered.

3.4 VAERS ADVERSE EVENT REPORTING

3.4.1 Workflow

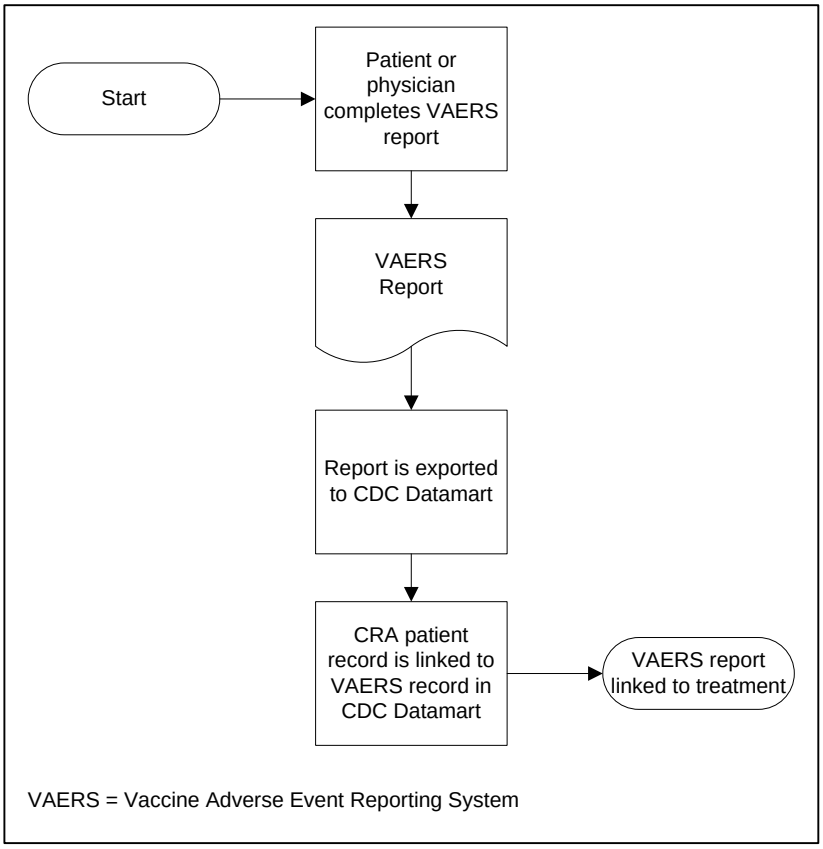

Figure 3-4: VAERS Adverse Event Reporting

3.4.2 Description

3.4.2.1 The patient or physician will create a vaccine adverse events report in the Vaccine Adverse Event Reporting System (VAERS).

3.4.2.2 The patient's treatment identifier will be included on the report.

3.4.2.3 VAERS reports are uploaded to the CDC on a daily basis.

3.4.2.4 The CDC will link the VAERS report to the corresponding CRA treatment information using the treatment identifier.