PHIN Preparedness

(DRAFT for discussion)

COUNTERMEASURE AND RESPONSE ADMINISTRATION

FUNCTIONAL REQUIREMENTS

AND PROCESS FLOWS

Version 0.1 Draft

05/20/2004

VERSION HISTORY

Version #	Implemented By	Revision Date	Approved By	Approval Date	Reason
1	Betty H. Baker	04/08/2004	<name>	<mm/dd/yy>	Initial draft
2	Betty H. Baker	04/19/2004			Incorporate changes from reviewers
3	Betty H. Baker	04/28/2004			Replaced CAI with CAS where appropriate
4	Betty H. Baker	05/20/2004			Renamed Countermeasure and Response Administration System
5					

TABLE OF CONTENTS

TABLE OF FIGURES

1 INTRODUCTION

The Countermeasure and Response Administration (CRA) Initiative is intended to support the protection of the public in the event of acts of bio-terrorism or other public health threats by managing information about the administration of countermeasures under both pre-event and post-event conditions. Countermeasures include vaccination and other types of drug prophylaxis, as well as non-drug actions such as outbreak management, surveillance, patient follow up activities, isolation and quarantine. The recipients of the countermeasures may include the general public as well as identified individuals such as outbreak cases or contacts and potential response team members (both from public health and the private sector). A CRA program is conducted as a response to a specific preparedness campaign or public health emergency.

The guidelines in this document describe functional and informational requirements and process workflows for systems implemented to manage countermeasure and response administration. These guidelines provide the basis for data repositories and reporting systems that are needed by the Centers for Disease Control and Prevention (CDC) and their partner Public Health Entities (PHE), also known as Grantees, to support public health preparedness and response.

These guidelines provide minimum functional requirements for a CRA system and should in no way preclude a system from incorporating additional functionality beyond what has been covered in this document.

2 REQUIREMENTS

2.1 REQUIREMENT DESCRIPTION

A system implemented to comply with the CRA initiative should meet the following high-level requirements:

- Manage multiple concurrent CRA programs.
- Provide pre- and post-event treatments to patients.
- Record specific treatments provided to patients.
- Accept patient and treatment information from external sources such as the CDC Outbreak Management System (OMS).
- Verify compliance of patients with treatment protocols.
- Track quarantine and isolation information about patients.
- Provide adverse event tracking.
- Conduct active surveillance and record the result.
- Identify protected people able to serve on response teams in the occurrence of an event.
- Track the inventory of countermeasures available, including integration with pharmaceutical stockpiles.
- Support both investigational new drugs (IND) and licensed pharmaceuticals.

- Provide for electronic exchange of data with other systems, including imports and exports.

2.2 COUNTERMEASURE AND RESPONSE ADMINISTRATION PROGRAMS

- All countermeasures are administered under the auspices of a CRA program.
- Information about each program should be stored within the CRA system.
- Program information may include a program name, agent(s) involved, a sponsor, start and end dates, a program type (pre-event or post-event), OMS involvement (yes or no), response teams needed (yes or no), population to be treated, potential countermeasure(s), and jurisdictions participating.
- The characteristics of a program may affect the functional and data collection requirements for countermeasure and response administration.

2.3 ORGANIZATION DATA

- Organization data for organizations that participate in a CRA program should be stored in the CRA system. Organizations that participate may act in one or more of the following roles: State, Metropolitan or Local Health Department, Treatment Facility, Take Response Location, Compliance Monitoring Facility, Pharmaceutical Distribution Center, Countermeasure Preparation Site, Quarantine Location, and Referring Organization (hospitals and other organizations that have response teams such as police and fire departments, private doctors, outbreak management teams, etc.)
- Organization data includes: Organization name and address (including street address, city, state, county and zip code), contact name, phone number, fax number, type of organization (state agency, local agency, hospital, …), and referring organization categories.
- Information about individuals assigned to an organization in support of CRA programs should be captured. Examples are: contacts, treatment administrators (e.g., vaccinators and other drug administrators), compliance monitors, and take readers.
- The identified individuals will be linked to treatment events, compliance monitoring, or take readings in which they participate.
- A CRA system may support jurisdictional hierarchies by allowing PHE's to divide their jurisdictions into subordinate jurisdictions and assign their organizations to the subordinate jurisdictions.
- The PHE should be able to aggregate data by organization role (treatment facility, referring organization, etc.) to show, for example, the number of people that have been treated at each facility, the number of people that have been treated from each referring organization (possibly for the purpose of building response teams), and other statistical data that may indicate an issue with the countermeasure or the program staff at a particular treatment facility. (E.g., If there is a higher than expected rate of equivocal take responses for smallpox vaccinations at a given vaccination clinic, corrective action may be required.)

2.4 MANUFACTURER, LOT, AND PREPARED COUNTERMEASURE DATA

- Valid lot numbers for all pharmaceuticals should be stored in the CRA system.
- The pharmaceutical lots should be identified by their manufacturers.
- The lot numbers should appear in selection lists for use when recording the use of countermeasures. This will ensure consistency of lot numbers and reduce the possibility of incorrectly entered lot numbers.
- Information about specific containers of prepared countermeasures such as vaccine vials or large pill containers from which multiple patients may be treated should be stored.
- Information about a prepared countermeasure container includes: unique identifier of the container, countermeasure name, date of re-packaging or alteration (e. g., reconstitution, first usage), facility where re-packaging or alteration occurred, pharmaceutical lot number(s), and maximum number of patient treatments that can be delivered from the container.
- Prepared countermeasure containers may be shared by multiple treatment facilities within the same PHE.
- Each patient treatment event must be linked to the container used. This link between patient treatment and container may be used to trace issues to a pharmaceutical or potentially to the treatment facility or the prepared countermeasure container involved.
- The data will support reporting by prepared countermeasure container and may be used to calculate pharmaceutical usage.

2.5 PATIENT ADMINISTRATION DATA - UNIQUE IDENTIFICATION

2.5.1 Patient Demographic Data

- The patient demographic record must be uniquely identified to eliminate duplication of patients within the system.
- A CRA system must be able to store identifying information about patients.
- Identifying patient information is not required for all programs, but it is recommended.
- Identifying information may be required for patients treated under programs in which IND countermeasures are used.
- PHE's must be able to trace patient records within the CRA system to the actual people they represent, either manually or by the use of identifying information stored within the system.
- Patient demographic data includes: a unique patient identifier, contact information (name, address, phone number, fax number, other pertinent communication paths such as cell phone, pager, and email), date of birth, weight (for children), gender, state of residence, county of residence, zip code, ethnicity and race. Additional identifiers such as social security number, driver's license number, or passport number could be included to validate the uniqueness of the patient.

- The contact information may assist in locating a patient who does not return for a follow-up visit or who might have received a treatment for which an issue has been discovered.
- Contact information may also be used to track compliance with treatment.
- Contact information makes it possible to contact and recruit a "protected" patient to be on a response team in the event of an emergency.
- The system must be able to link CRA system patient records to corresponding case and contact records in OMS.
- For patients who may be assigned to a response team, occupation, expertise or role on a response team is collected.
- The collected information will be used at the PHE level to aggregate data and generate statistical reports for countermeasure and response administration activities and response team composition.

2.5.2 Current Treatment Data

- The CRA system must allow entry and tracking of the current treatment data.
- A treatment event should have a unique identifier. An example of a treatment identifier is the Patient Vaccination Number (PVN) used during the National Smallpox Preparedness Program.
- The CRA system must link each treatment record to the original patient record.
- Treatment data includes: the program under which the treatment is occurring, the countermeasure, the agent for which the countermeasure is being used, the date of the treatment, the treatment facility, and the person administering the treatment.
- A treatment may involve more than one countermeasure, such as vaccination and a course of antibiotics.
- If a patient has been referred for treatment as preparation for serving on a response team, the identity of the organization with the response team should be captured.
- Treatment records are linked to the specific prepared countermeasure container from which the treatment was dispensed to the patient, such as a specific vaccine vial. Through the prepared countermeasure container, the treatment can be traced to the lot number(s) of the pharmaceuticals used.
- The CRA system must be able to uniquely identify a treatment administrator for each treatment event. In the case where a take must be read, the take reader must be identified. The data must consist of a unique identifier for the PHE's name space; it may include a name. If a name is not used, the PHE must be able to use the unique identifier to identify the person who performed the action.
- The treatment information is used to track when the patient should return for a follow-up visit for an additional treatment or an evaluation, such as a smallpox take response reading.
- Statistical analysis for treatment efficacy and safety monitoring will be performed on the collected treatment information.

- Sufficient treatment information must be captured to identify all patients treated at a specific facility, by a specific person, or from a specific container if issues arise with the facility, the treatment administrator, the container, or the pharmaceutical lots in the container.
- The CRA system must be able to support limited treatment information including requests that specific patients be treated from external sources such as OMS.
- The treatment record should be linked to any adverse events recorded in the Vaccination Adverse Event Reporting System (VAERS), through the use of the unique treatment identifier.
- The CRA system must support multiple treatment events for a patient under a specific program. Additional treatments might be re-treatment with the same countermeasure, or administration of additional countermeasures. An example of multiple treatments is the use of both antibiotics and vaccination to treat a patient exposed to inhalational anthrax.
- The CRA system must support a patient participating in more than one program. For example, the system must be able to identify that a single person received a Smallpox vaccination during the Smallpox Preparedness Program and Anthrax prophylaxis during an Anthrax post-event campaign.

2.5.3 Quarantine and Isolation

- A CRA system must allow recording and tracking of quarantine and isolation information for a patient.
- Information to be recorded may include the countermeasure (quarantine or isolation), the location, the date range, and the quarantine or isolation level.

2.5.4 Patient Follow Up

- Some countermeasures may require a follow-up component such as compliance monitoring or a take reading.
- Follow up information must be linked to the corresponding treatment or quarantine event.
- Compliance monitoring information may include the type of event being monitored (treatment or quarantine), the event, compliance, reason for non-compliance or non-availability of information, adverse events or general comments, the identity of the compliance monitor, and the date the monitoring occurred.
- Take response reading is collected for smallpox vaccinations.
- Take reading information includes: take response (major, equivocal or not available), take reader, take location, and adverse events. If a take response cannot be collected, a reason for the lack of take availability may be captured.

2.5.5 External Treatment History Data

- The CRA system should support storing previous treatment records for treatments occurring external to the current program and not already captured within the CRA system.

- Treatment history data includes such information as date of treatment, take response/outcome, and the occurrence of adverse events.
- Date can be an actual date, a year, or a general value like childhood or adulthood.
- The data will be used to determine if previous treatments have an impact on the results of the current treatment. The data will also be used for statistical analysis.

2.5.6 Adverse Event Data

- Adverse events include any unexpected effects that may be attributed to the treatment event. These events differ by countermeasure and may include symptoms such as site specific skin findings, non-site specific skin findings, encephalitis, etc. In the case of vaccinations, these should be recorded in VAERS (http://www.vaers.org).
- It is requested that the VAERS record be identified with the unique CRA system treatment identifier of the treatment related to the adverse event.
- Adverse events data may be used to determine appropriate additional treatment for a patient.
- Adverse events data may also be used for statistical analysis to determine if there is an issue with a particular lot of a pharmaceutical, if pharmaceuticals dispensed from a certain container show unusual trends, or if a specific treatment facility has a high number of adverse events.

2.6 PATIENT RECORD MATCHING/DUPLICATE PATIENT RECORD MINIMIZATION

- The CRA system should support the ability to match patient records based on meaningful identifiers.
- Matching will reduce duplication of patient data in the system.
- Each patient should be assigned a unique Patient Identification Number (PIN).
- Unique identification of patient records will support contact tracing if an adverse reaction occurs. In addition, unique identification of patients will ensure that treatment totals are calculated correctly and response team compositions are derived correctly.

2.7 RECORD SEARCH AND RETRIEVAL

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

2.8 REPORT GENERATION

- The CRA system must support the ability to generate detailed and aggregate reports.

- Detailed patient reports may be used for quality assurance of data entry.
- Reports by PHE may be used to show preparedness across the PHE's jurisdiction as well as program progress.
- Reports by referring organization may be used to show response team composition within the referring organization.
- Aggregate reports for each program a PHE is participating in may be produced to show patient counts such as number of patients treated, number of patients not treated, number of patients with 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.
- National reports will generally consist of aggregate information (including mapping) and will be used to validate overall program progress. For programs with a response team component, national reports may also be produced to evaluate overall preparedness.

2.9 CENTRAL RECORDS REPOSITORY

- A CRA system must have a centralized repository to hold the treatment data described in this document.
- The CRA system should incorporate a backup process that may be used in the event that the system is temporarily unavailable (for example, paper forms).
- The central repository will store the data against which reports will be run at the detail and aggregate level.
- The centralized repository will maintain the data links that support retrieving patient and treatment records, and linking them to the pre-dispensing container of the prepared countermeasure used.
- The repository will be used to validate preparedness in the event that response is required to contain a public health emergency.

2.10 SUPPORT FOR DATA EXPORT

- The CRA system must support the ability to produce a data export in the prescribed format(s).
- Export functionality is required to exchange data with other authorized organizations such as the CDC.
- The current prescribed format for data exchange is an XML schema. The XML schema is detailed in a separate document that describes the data types, format, and data linking requirements.
- More than one data export format will be supported. HL& Version 3 messaging will be one such format.
- If information is collected at multiple sites within a PHE's jurisdiction, it must be consolidated prior to export to the CDC.
- PHE's that do not develop their own Systems must be able to receive extracts of the data they enter into the CRA system provided by the CDC.

- Non-identified patient data will be used by the CDC to conduct statistical analysis including, but not limited to, trends in adverse events, compliance, and preparedness level.

2.11 SUPPORT FOR DATA IMPORT

- The CRA system must support the ability to receive data imports in a prescribed format.
- Import functionality is required to receive data from other authorized organizations such as the CDC and the Strategic National Stockpile (SNS).
- The prescribed format has not been finalized; however, this format will be compliant with the Public Health Information Network (PHIN) and may include HL7 Version 3 messages.

3 PROCESS FLOWS

3.1 OVERVIEW

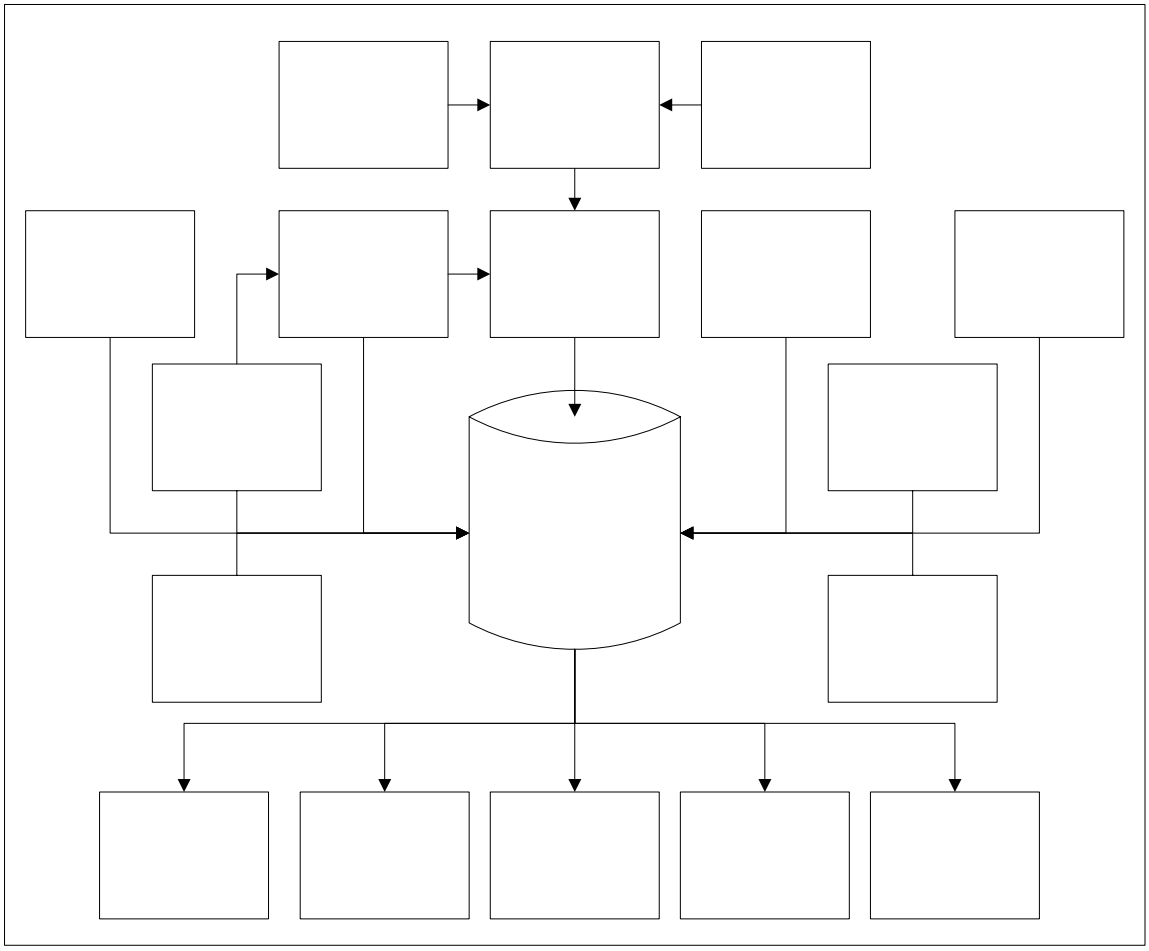

Figure 3-1: Process Flow Overview

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.

3.1.1 1.0 Program Setup

A countermeasure and response administration program 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, quarantine and isolation rules are needed.

3.1.2 2.0 Identification of Eligible Candidates (Referral Only)

For programs 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 PHE and the coordination of schedules between the referring organization and the treating facility are included.

3.1.3 3.0 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.

3.1.4 4.0 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.

3.1.5 5.0 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.

3.1.6 6.0 OMS Integration

Outbreak management teams collect information about cases and contacts, including limited patient treatment information. Integration with an Outbreak Management System (OMS) includes accepting the limited patient treatment information into the CRA system.

3.1.7 7.0 Quarantine and Isolation

If the illness involved in a public health event may be transmitted by casual contact with a sick individual, quarantine or isolation may be necessary. Information about the quarantine or isolation includes the quarantine level, the location and the start and end dates.

3.1.8 8.0 Patient Follow Up

Patient follow up requirements vary with the countermeasure. Possible follow up activities include scheduling a re-treatment, monitoring quarantined and isolated patients, recording information on compliance with the treatment regimen, and tracking any developed symptoms or adverse events.

3.1.9 9.0 Take Response Recording

Some treatments, such as the smallpox vaccine, require an evaluation to determine whether or not 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.

3.1.10 10.0 Inventory Tracking

The Strategic National Stockpile (SNS) provides such information as manufacturer, national drug code (NDC), lot number, expiration date, and quantity when pharmaceuticals are delivered to a public health recipient. 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. Quantities, expiration dates and reductions in inventory should be tracked to determine the amount of inventory available for use and to report on usage.

In addition, many pharmaceuticals must be tightly controlled. Movement of the pharmaceutical inventory within the PHE may require tracking.

3.1.11 11.0 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 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 the system.

3.1.12 12.0 Data Imports

For PHE's with their own Systems, an import of data may be provided. This import may include "set-up" data such as program information, pharmaceutical lot numbers, and vocabulary. The PHE's system is expected to be able to receive and utilize the data.

3.1.13 13.0 Report Generation

Facility reports include detailed treatment administration and compliance activity, as well as aggregate counts. Public health reports include program summaries and other reports to assist in management of a program. For programs with response team components, there are public health reports to assist referring organizations in identifying potential response team members.

3.1.14 14.0 PHE Uploads

For PHE's with their own Systems, an export of data must be produced to be uploaded to the CDC for use in pharmaceutical safety monitoring, program progress and monitoring, response team identification and other analytical activities. While the data may be non-identified, some programs may require identified data.

3.1.15 15.0 Active Surveillance

The application will be able to capture active surveillance information about patients whose treatments have been recorded. The treatment identifier will be used to tie the patient to the active surveillance information.

3.1.16 16.0 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.

3.1.17 17.0 Statistical Reports and Extracts

Statistical reports will be generated from CRA system non-identified data and made available to PHE's for download. Additionally, those PHE's who use the CDC CRA system web application will be able to download extracts of all of their patient data.

3.2 1.0 PROGRAM SETUP

3.2.1 Workflow

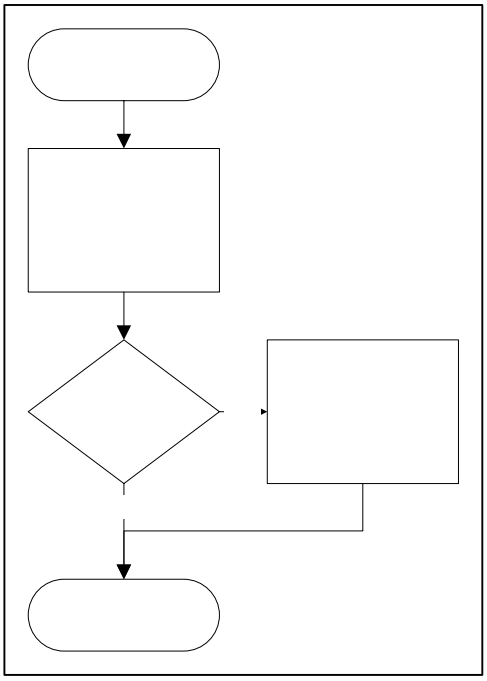

Figure 3-2: Program Setup

3.2.2 Description

- A countermeasure and response administration program is declared by the CDC.
- Program characteristics include the type of program (pre-event preparedness, post-even exposure, etc.), agents, countermeasures, time frame and population to be treated (general public, first responders, etc.), and jurisdictions participating.
- Characteristics of a program may determine the treatment protocols and data collection requirements.
- Not all the characteristics of a program may be known at the outset of an event.
- Quarantine and isolation rules may be declared for infectious disease outbreaks.

3.3 2.0 IDENTIFICATION OF ELIGIBLE CANDIDATES (REFERRAL ONLY)

3.3.1 Workflow

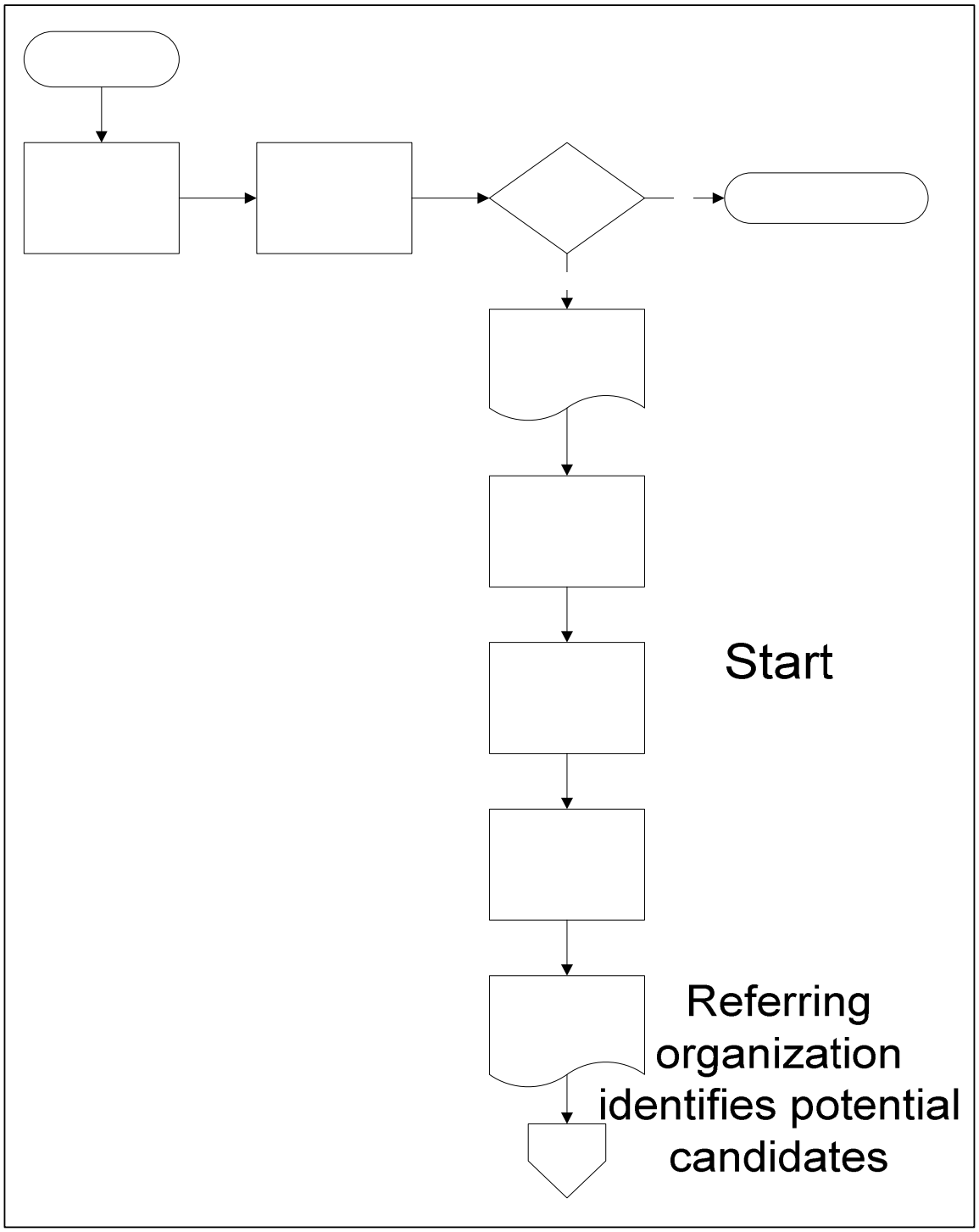

Figure 3-3: Identification of Candidates

3.3.2 Description

- The identification of eligible candidates is for programs where referrals are required only.
- Referring organizations will identify possible candidates.
- Referring organizations will educate and pre-screen identified candidates on benefits, risks, contraindications, and procedures for the countermeasure to be administered.
- Candidates may need to consult with their personal physicians and/or receive tests to rule out contraindications.
- Candidates who pass pre-screening and volunteer for treatment will be placed on the eligible candidate list for the referring organization.
- Referring organizations will send their eligible candidate lists to the PHE.
- The PHE will receive, organize, and manage lists from multiple referring organizations, determine which treatment facility each referring organization should use, and provide the treatment facilities with referring organization eligible candidate lists.
- The PHE will also be responsible for informing the referring organizations of the treatment facilities with which they should coordinate scheduling.
- Each referring organization will coordinate scheduling with its assigned facilities. The referring organization will be responsible for informing eligible candidates of the facility, date, and time to report for treatment.
- The eligible candidate list will hold the name and contact information of individuals at the referring organization who are able to resolve any eligibility or scheduling issues that may exist when the patient arrives at the treatment facility.

3.4 3.0 IDENTIFICATION OF EXPOSED INDIVIDUALS (POST-EVENT ONLY)

3.4.1 Workflow

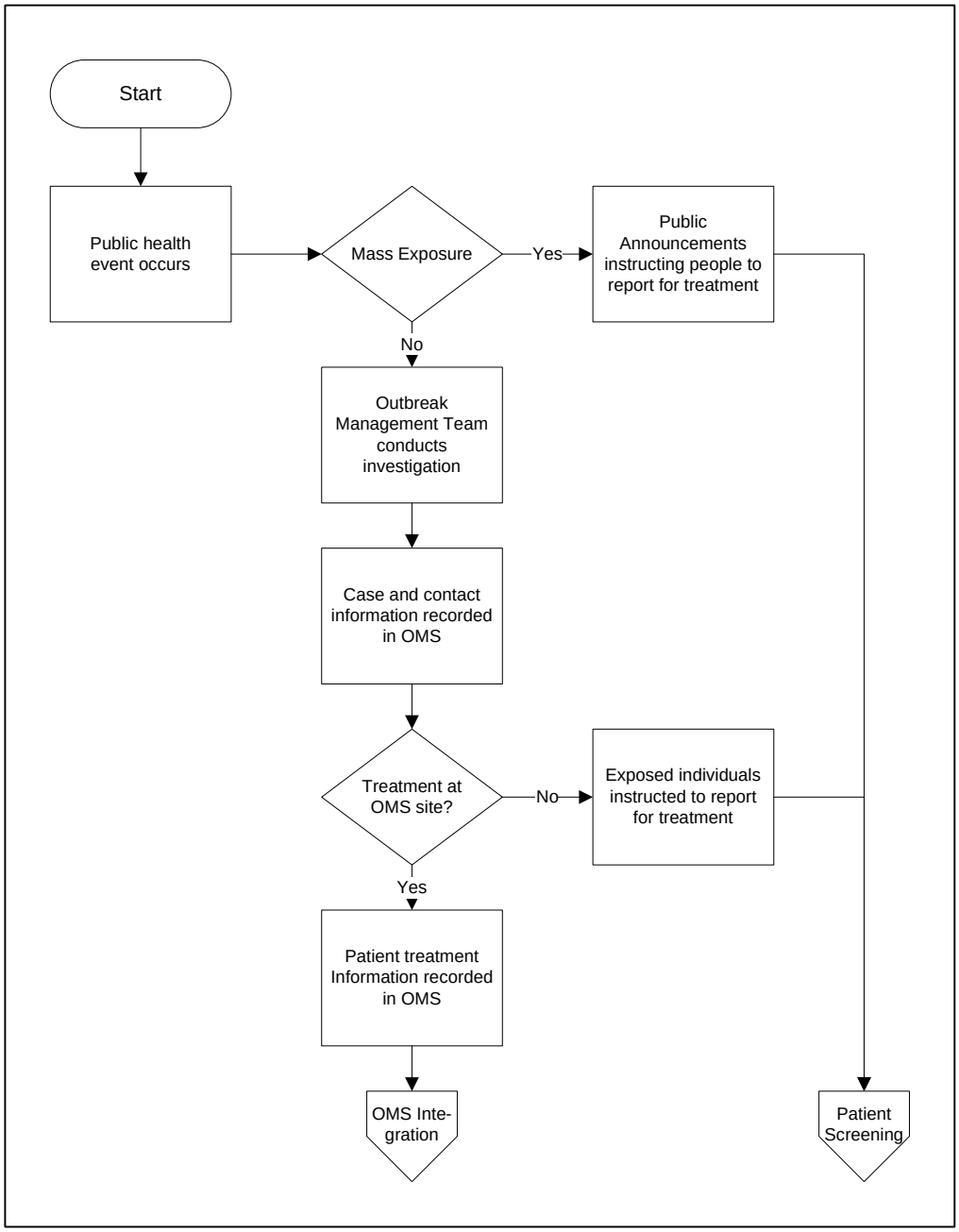

Figure 3-4: Identification of Exposed Individuals

3.4.2 Description

- The scope of a public health event determines the method of identifying exposed individuals.
- In the event of a mass exposure, all people in the event area are considered to be exposed and are instructed to report to treatment facilities.

- An outbreak management system (OMS) is used to record case and contact information for limited exposure events.
- Cases and contacts with data recorded in OMS may be sent to CRA treatment facilities for treatment.
- People sent to CRA treatment facilities by OMS teams should bring documentation of their OMS records including case or contact identifier. Additionally, the CRA system might receive electronic records from the OMS system.
- OMS may capture limited patient treatment information for those patients treated at the investigation site. This limited information is to be made available to the CRA system for inclusion with CRA system data. The integration of OMS data with CRA system data allows the use of the CRA system to conduct any follow-up activities such as compliance monitoring with treated patients.

3.5 4.0 PATIENT SCREENING AND CONSENT

3.5.1 Workflow

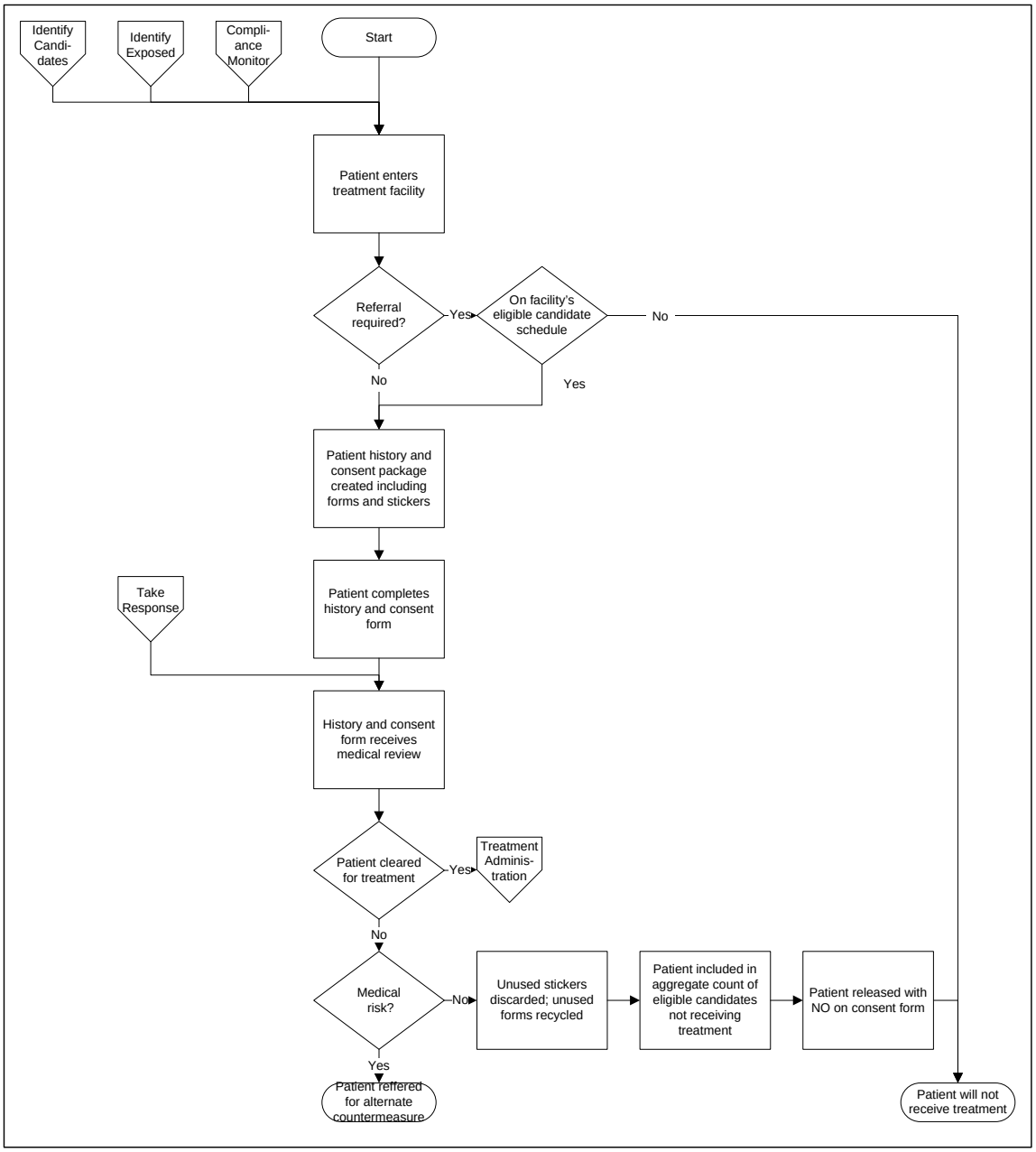

Figure 3-5: Patient Screening

3.5.2 Description

- Patient arrives at facility.
  - For a program requiring referral, the patient should have an appointment and have been identified as eligible by a referring organization.
    - Facility checks patients who arrive against the eligible list from the PHE for the specified appointment date.

        - Patients who are not on the list may be investigated with the referring organization. If they are not eligible, they will be sent home. No paperwork will be recorded for these individuals.
    - For post-event programs, or for other programs set up to treat the general public, the patient may not have an appointment or a referral.
        - Patients who are identified as cases or contacts within OMS should have case or contact identifiers.
- Patients will be provided with and asked to review educational materials concerning health risk and treatment benefits, risks, contraindications, and procedures.
- Patients who are on the list will have a package of forms and information created that may consist of:
    - Patient Medical History and Consent Form
    - Treatment Card
- The Patient Medical History and Consent Form consists of appropriate pages from this list:
    - Patient Demographic and Vaccination History page
    - Patient Medical History pages
    - Medical Consent page
    - Treatment Administration page
- Each treatment event will be assigned a unique identifier. This may be done by the use of sets of pre-printed stickers, such as the sets of Patient Vaccination Number (PVN) stickers used in the National Smallpox Preparedness Program. The treatment identifier is given to the patient and facilitates any post-treatment communication with healthcare providers, related systems such as VAERS and Active Surveillance, and other parties.
- Each page of the Patient Medical History and Consent Form will be labeled with the treatment event identifier. One sticker (or equivalent) will be placed on each page of the Patient Medical History and Consent Form. Any extra stickers will be reserved with the package.
- The treatment administration page of the Patient Medical History and Consent Form must include the name of the treatment facility and identification information about the treatment administered (manufacturer(s), lot number(s), preparing facility, reconstitution date for lyophilized vaccines, first use date for multi-use vial(s), and prepared countermeasure container identifier(s) such as vaccine batch number). This information is required for each patient that receives a treatment and should be either pre-printed or manually recorded on the form.
- The patient will complete the Patient Medical History and Consent Form and review the informational materials.
- A screener will reiterate the education provided as a part of pre-treatment screening, review the patient's medical history, and determine the appropriate treatment and whether or not the patient is cleared to receive the treatment.
- If cleared and willing to receive the treatment, the patient will sign the Patient Medical History and Consent Form. The patient is now a consenting patient.
- Patients who do not receive treatment due to contra-indications or refusal may receive other countermeasures, including alternative treatments, observation, quarantine and isolation. Those patients who pose no risk to others may be released.

- For any patient not receiving any countermeasure, any extra identifying stickers will be discarded and the patient's Patient Medical History and Consent Form will be placed in the appropriate resolution stack (no-consent due to contraindications, or no-consent due to not willing). All resolution stacks will be tallied at the end of the day and their counts entered as aggregate figures in the system.

3.6 5.0 TREATMENT ADMINISTRATION

3.6.1 Workflow

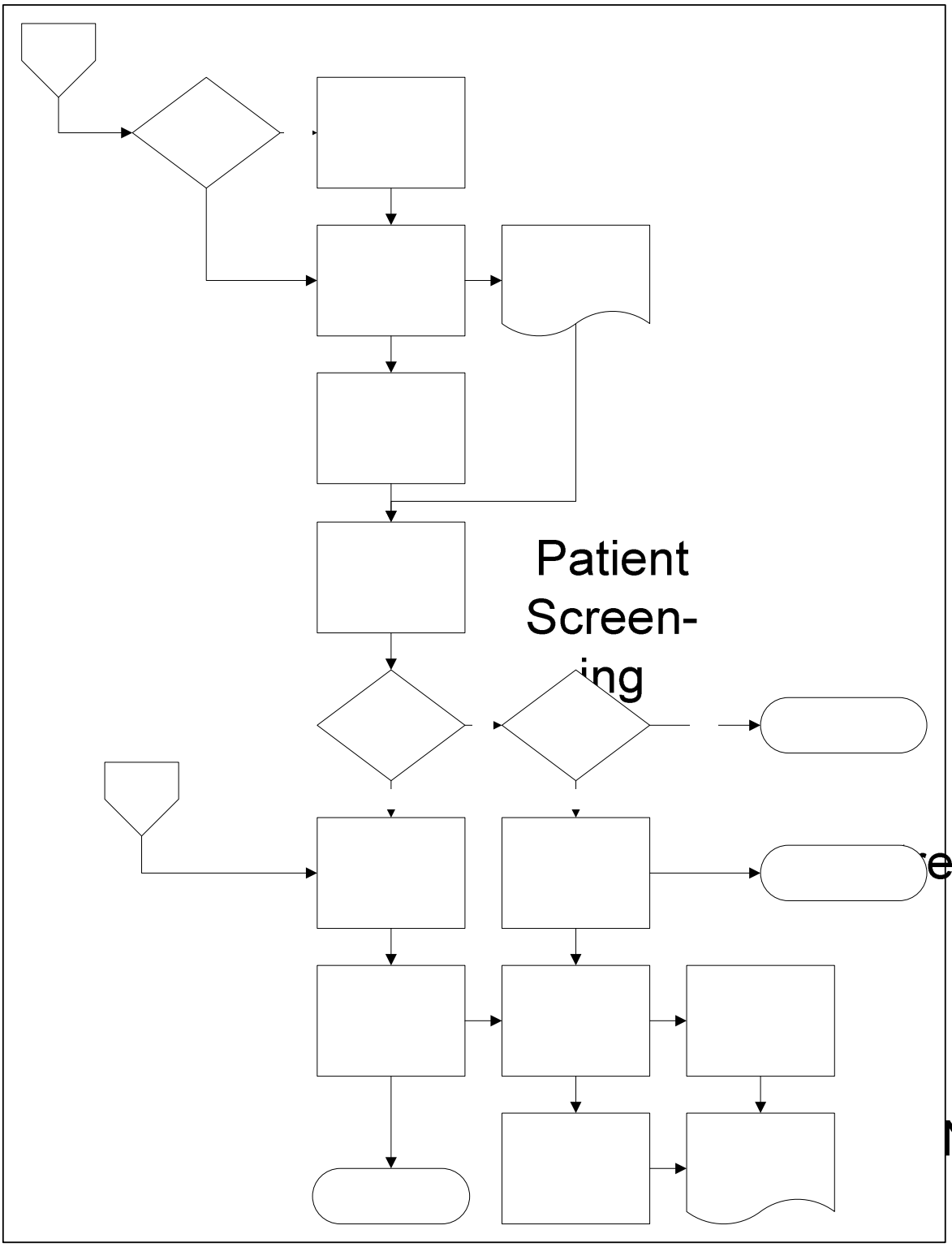

Figure 3-6: Treatment Administration

3.6.2 Description

- Patients who have been cleared and have consented to a treatment for which a treatment card is required will complete the demographics on the treatment card. The unique treatment identifier will be placed on the treatment card.
- The completed patient packages will be delivered to the treatment administrator.
- The treatment administrator will call patients based on the package queue, verify their information, and verify the consent signatures.
- Patients who opt out at this time will be indicated as such on their Patient Medical History and Consent Form, and their packages will be separated for later aggregation. Depending on the program, the patient may be referred for other countermeasures including alternative treatments, observation, quarantine and isolation.
- Treatment event information will be added to the appropriate section of the Patient Medical History and Consent Form. This information includes the treatment date, the treatment administered, the agent for which the patient is being treated, the program, the treatment administrator identifier (number and/or name), and other information about the treatment, including pharmaceutical dosage information.
- Specific information about the prepared countermeasure container used in the treatment must be recorded. It may be either manually entered on the form or supplied via a pre-printed prepared countermeasure attachment.
- If a treatment card is required, it will be completed and delivered to the patient.
- Patients will receive education on compliance, site care, potential adverse events, and reporting of an adverse event. If a follow-up visit is needed, the treatment facility may choose to schedule patients to return for their follow-up visits at this time.
- When a pre-determined number of treatments have been completed, the demographic and treatment administration pages of the Patient Medical History and Consent Form will be given to data entry to be entered into the system.
- Data entry will enter available patient demographics, treatment history, and treatment event information into the system. They will then return the Patient Medical History and Consent Forms to the treatment administrator to be re-filed into the patient packages.
- Aggregates will be entered into the system by Data Entry at the end of each day.

Please Note: This is a general treatment facility flow that does not attempt to include implementation details that the facility may choose to put into practice to maximize efficiency or improve education. Examples include batching of patients for education and throughput, intake greeters, fast-track treatment path for patients with no contraindications, and frequently asked questions list in send home package.

3.7 6.0 OMS INTEGRATION

3.7.1 Workflow

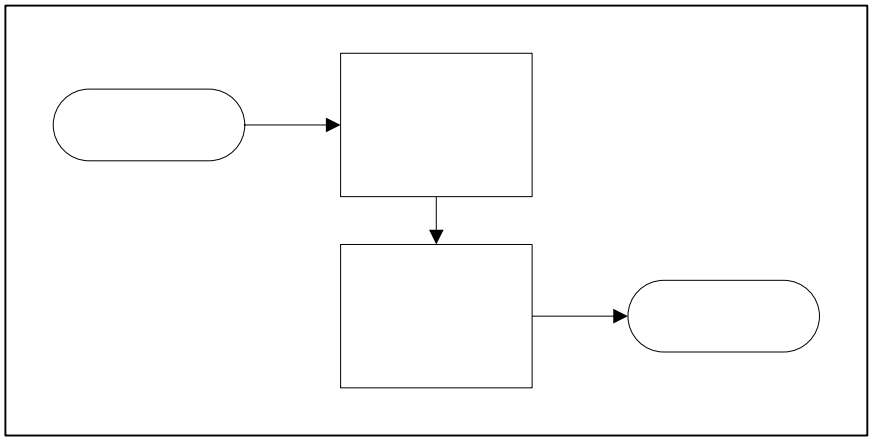

Figure 3-7: OMS Integration

3.7.2 Description

- The outbreak management team captures limited patient treatment information in OMS.
- An electronic file of the limited data will be provided to the CRA system.
- A process will be run to import the OMS data into the CRA system.
- The limited nature of the OMS data will not prevent its import into the CRA system.
- The data from OMS will be used in the same manner as data recorded directly into the CRA system for pharmaceutical safety and patient compliance monitoring, pharmaceutical usage tracking, statistical reporting and other CRA system processes.

3.8 7.0 QUARANTINE AND ISOLATION

3.8.1 Workflow

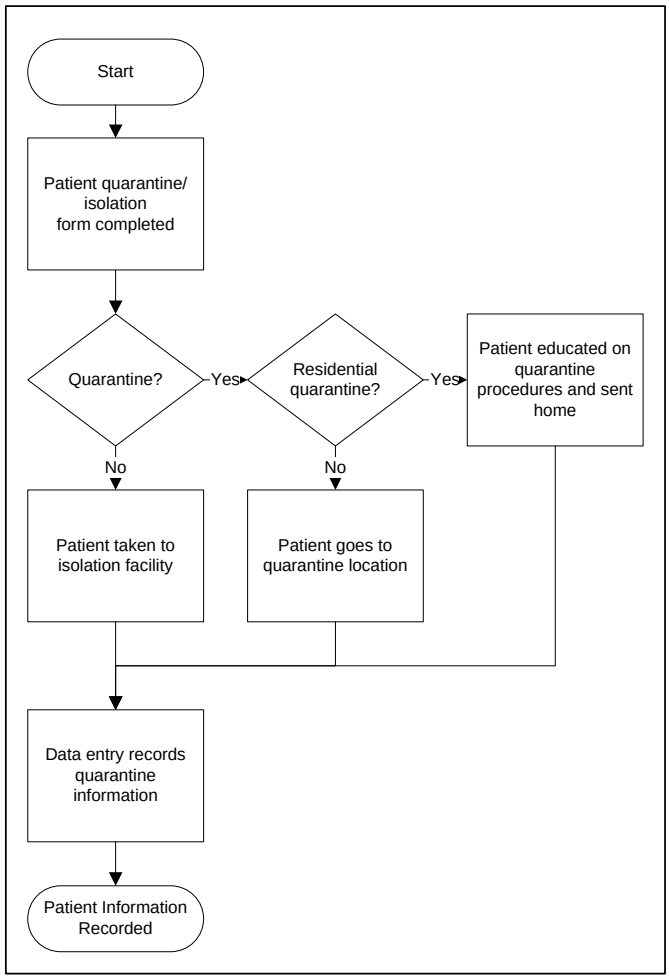

Figure 3-8: Quarantine and Isolation

3.8.2 Description

- Quarantine or isolation is to be used when disease may be transmitted to an otherwise healthy individual by casual contact with a sick individual.
- Quarantine is the restriction of persons who are not ill, but are presumed to have been exposed; used for primary and secondary contacts (usually in home or designated facility).
- Isolation is separation of ill persons with contagious disease (usually in a hospital setting).
- Quarantine and isolation will be declared as acceptable countermeasures for programs with agents whose resulting diseases warrant them.
- Medical personnel should complete a Patient Quarantine/Isolation form for each quarantined or isolated patient detailing the terms of the quarantine or isolation.

- Quarantine/isolation data should include a unique identifier for the quarantine/isolation event, the event type (quarantine or isolation), the quarantine or isolation level, the location, and the dates.
- Collected quarantine/isolation data will be recorded in the CRA system.
- Compliance monitoring should be conducted on all quarantined and isolated patients.
- Quarantined and isolated patients may receive additional treatments following the Treatment Administration workflow as documented above.

3.9 8.0 COMPLIANCE MONITORING

3.9.1 Workflow

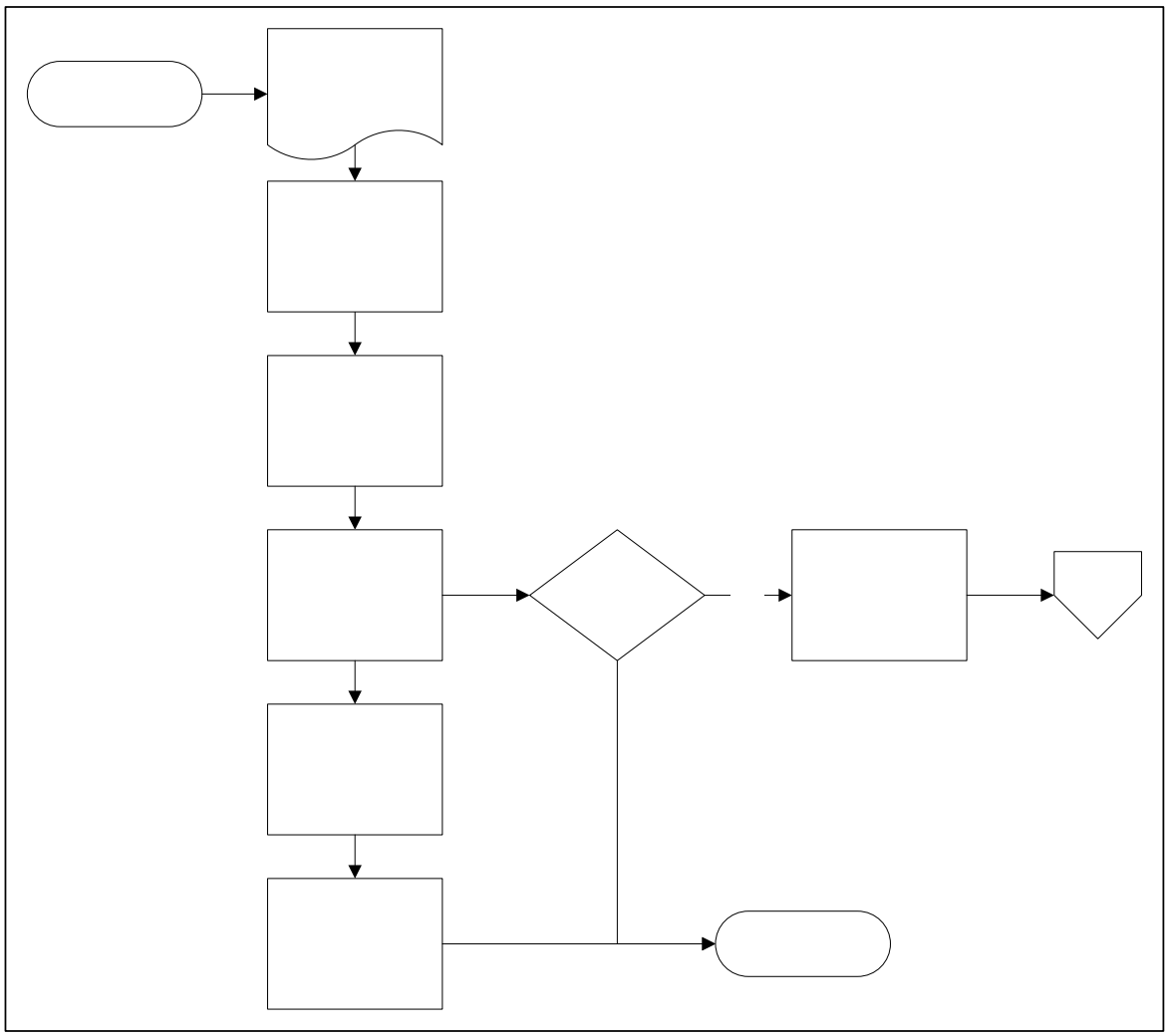

Figure 3-9: Compliance Monitoring

3.9.2 Description

- A CRA system must be capable of generating a report listing patients whose compliance should be monitored.

Start

- Each individual who appears on the list will be contacted and questioned to determine compliance with the treatment regimen or quarantine rules.
- Compliance information will be recorded in the system.
- If a follow-up visit is required, as is the case with multiple-dose vaccinations, the patient is scheduled or requested to return to the treatment facility for the follow-up.
- If the facility scheduled the follow-up appointment when the previous treatment occurred, then the call will serve as a reminder for the patient to return for the follow-up.
- The selection of patients to be included in a run of the report must take into account the variation of the dosing schedule based on the treatment and the program.

3.10 9.0 TAKE RESPONSE RECORDING

3.10.1 Workflow

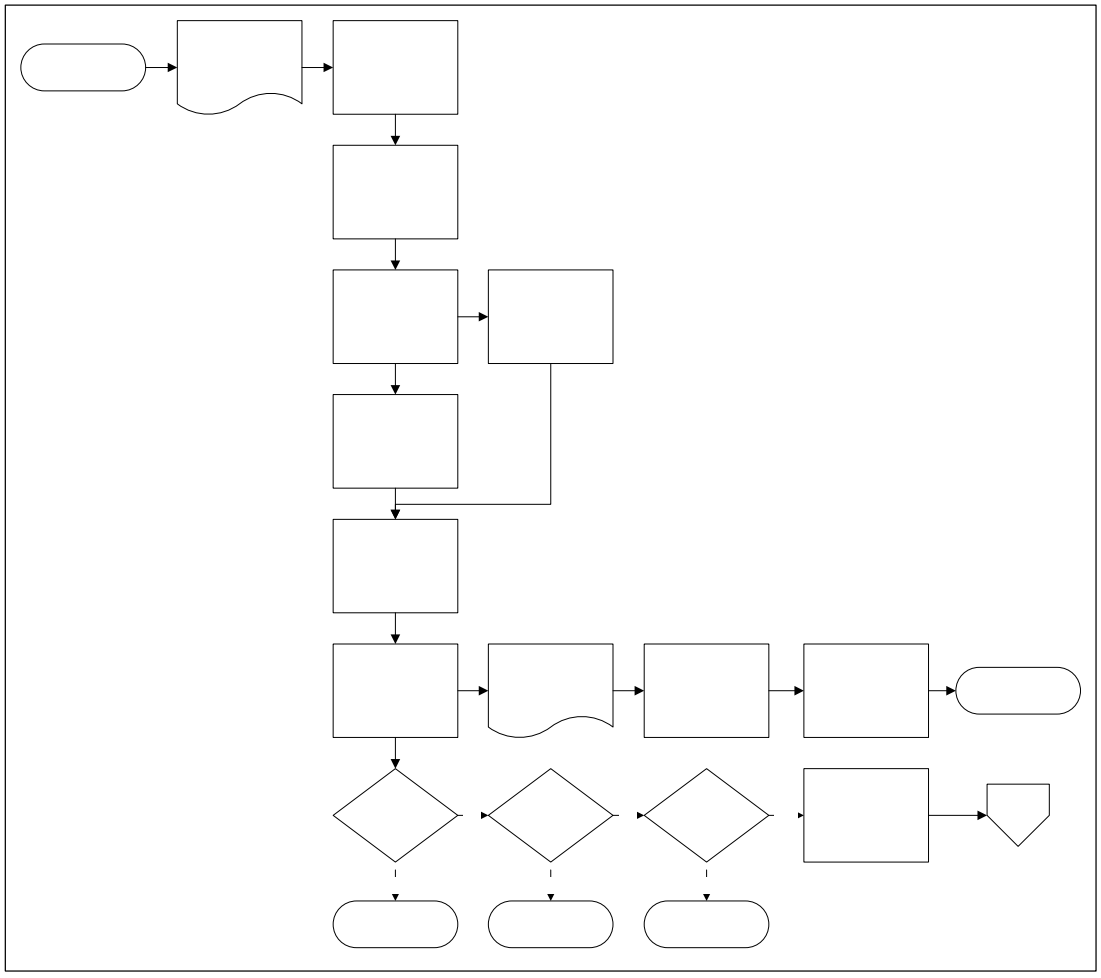

Figure 3-10: Take Response Recording

3.10.2 Description

- Take response recording is a specific type of compliance monitoring which occurs as part of a smallpox vaccination program. Take response recording may also be required for countermeasures that are developed in the future.
- A Take Response Callback List will be generated to list patients who should return for take response reading.
- Each individual on the list will be called and scheduled or requested to return to the treatment facility for the take response reading.
    - A treatment may have a "window of opportunity" during which the efficacy of the treatment may be evaluated. For example, if the treatment is a smallpox vaccination, the take response reading should occur on the 6^{th} to 8^{th} day following vaccination.
    - If the treatment facility scheduled the take reading appointment when the vaccination was given, then the call will serve as a reminder for the patient to return to have the take response read.
- The patient arrives at the take response location and is examined.
- The specific take response outcome varies with the countermeasure, the agent or the program. For example, the following applies for smallpox vaccinations received as part of the National Smallpox Preparedness Program:
    - If the take is major, the patient is considered immune.
    - If it is a first vaccination and the take is equivocal, the patient is given the option of being re-vaccinated.
    - If it is a re-vaccination and the take is equivocal, the patient is referred to a physician.
- The result of the examination is recorded on the Patient Medical History and Consent Form and the treatment card. Alternatively, the take reading information may be recorded on the Take Response Callback List for later transfer to the Patient Medical History and Consent Form.
- Data entry records the result of the examination in the system.

3.11 10.0 INVENTORY TRACKING

3.11.1 Workflow

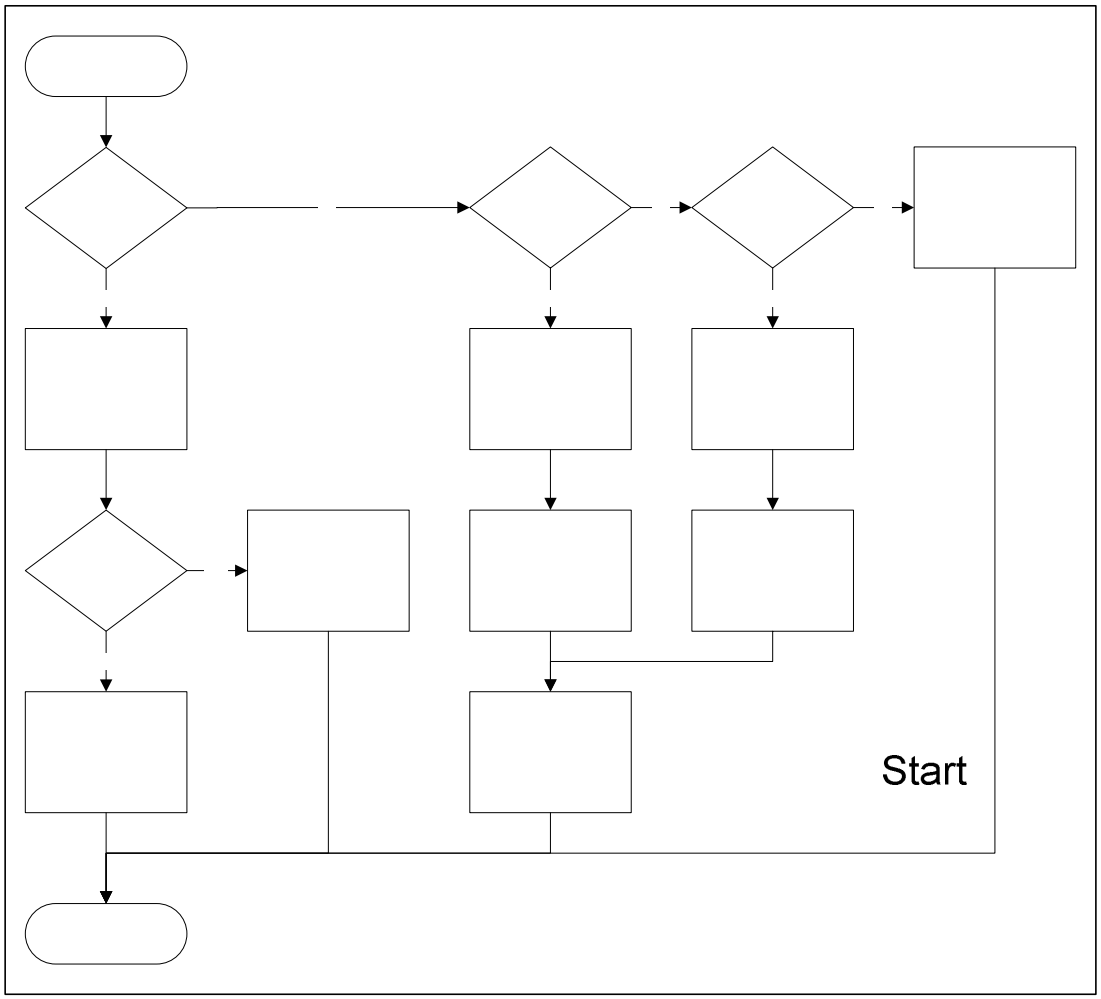

Figure 3-11: Inventory Tracking

3.11.2 Description

- Inventory tracking includes receipt of shipments of pharmaceuticals and distribution of the pharmaceuticals to administration facilities or to other locations.
- Shipments to a distribution facility may be from the Strategic National Stockpile or from other sources.
- Documentation about the contents of a shipment must accompany the shipment. For each bulk pharmaceutical package in the shipment, information such as the following should be provided: countermeasure name, manufacturer name, lot number, quantity, dosage, and expiration date.
- When a shipment is received at the distribution facility, the contents are compared with the accompanying documentation.
- The information from the shipment documentation is to be recorded in the CRA system. If the documentation is in electronic form, a data import process will be used to import the data directly into the CRA system.

- The importance of verifying and capturing the shipment contents information upon receipt is to ensure the availability of the correct information about the pharmaceuticals used when treatments are recorded in the system.
- Pharmaceuticals may leave the distribution center either to be distributed to administration facilities or to be removed from usage.
- Removal from usage should result if the pharmaceutical is approaching its expiration date or has been identified as not useable.
- When pharmaceuticals leave the distribution center, the quantities and destination of the shipment should be recorded and the inventory should be reduced in the system.

3.12 11.0 COUNTERMEASURE PREPARATION

3.12.1 Workflow

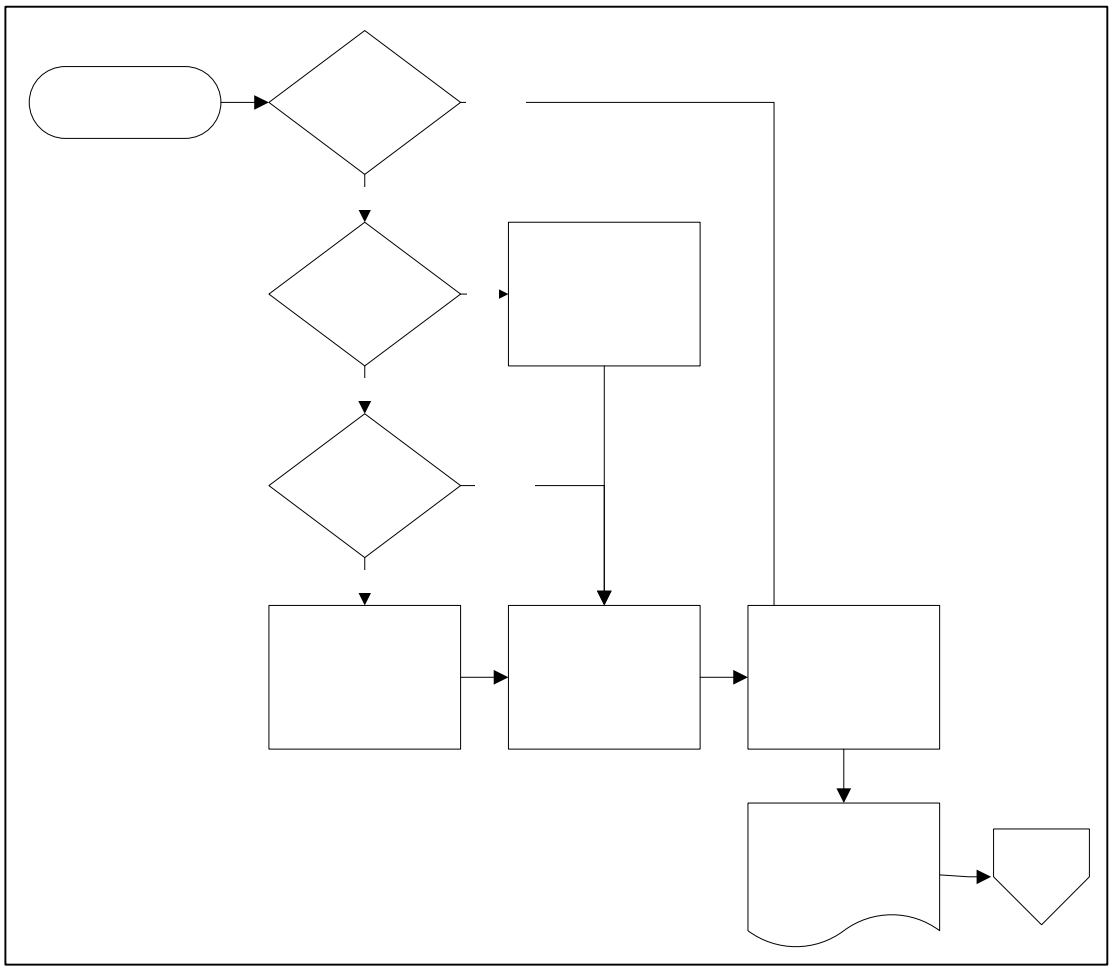

Figure 3-12: Countermeasure Preparation

3.12.2 Description

- The purpose of countermeasure preparation is to make the countermeasure available for administration and to provide a means to tie treatments to the

manufacturer(s), lot(s), and multi-use container from which the countermeasure was administered.

- Each countermeasure will have preparation protocols as part of the product information. In the case of the smallpox vaccine, a vaccine batch is created by using the products provided in one vaccine kit shipped from the Strategic National Stockpile to make one vial of vaccine; therefore, a vaccine batch is equivalent to a vial of vaccine, or one multi-use dispensing container.
- Countermeasure preparation involves identifying the first use of a multi-use container, potentially re-packaging or reconstituting the pharmaceutical, and entering information about the prepared countermeasure container into the system.
- A prepared countermeasure container is identified by manufacturers and lot numbers of its components, preparing facility, and date/time (hours and minutes) it was prepared for first use.
- The facility's system should be able to hold the above identifying information as well as a unique identifier that is specific to the container. This will allow traceability back to a container to support usage tracking and research of issues that may be container specific, and to increase efficiency in the process.
- At the beginning of the day, either a new container is prepared, or previously prepared containers are identified for use during that day.
- It is possible that multiple containers will have been identified for use for the same day; this possibility should be supported by the system used at the facility and considered in the facility's process flow.
- Prepared countermeasure containers may be shared by multiple facilities within a PHE's jurisdiction. The movement of these containers may require tracking.
- If possible, the system should produce a pre-printed Patient Medical History and Consent Form attachment for each multi-patient container identifying the container and listing all of the information for its contents.
- The pre-printed attachment will be attached to the Patient Medical History and Consent Form at the time of treatment to identify the exact prepared countermeasure container used.
- A sufficient number of copies of the Patient Medical History and Consent Form attachment commensurate with the number of treatments expected from the container should be produced.
- The prepared countermeasure container and the copies of the Patient Medical History and Consent Form attachment will be delivered to the treatment administrator.
- The treatment administrator will be responsible for attaching the correct Patient Medical History and Consent Form attachment to the Patient Medical History and Consent Form, and ensuring that the container used in the treatment matches the one identified on the attachment.
- If waste occurs, the facility must make sure that any extra forms are destroyed.

3.13 12.0 DATA IMPORTS

3.13.1 Workflow

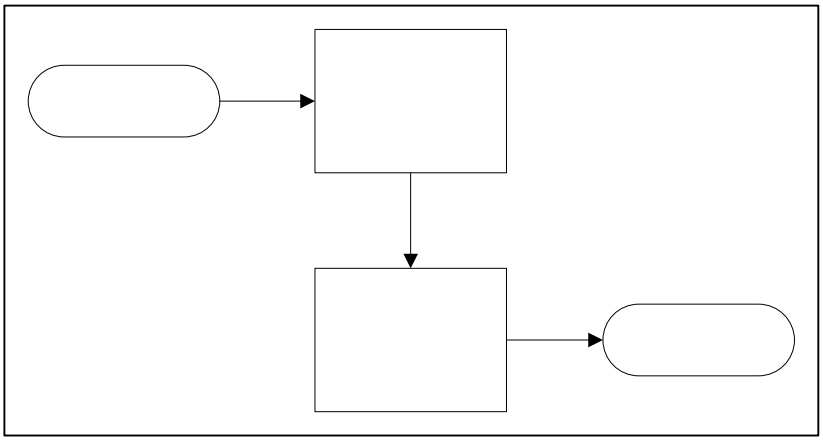

Figure 3-13: Data Imports

3.13.2 Description

- For PHE's with their own systems, an import of data may be provided.
- This import may include "set-up" data including program information, pharmaceutical information, vocabulary, and patient and treatment information collected by external systems such as OMS.
- The PHE's system is expected to be able to receive and utilize this data in their system.
- The format and content for the import data have not been determined at this time.

3.14 13.0 REPORT GENERATION

3.14.1 Workflow

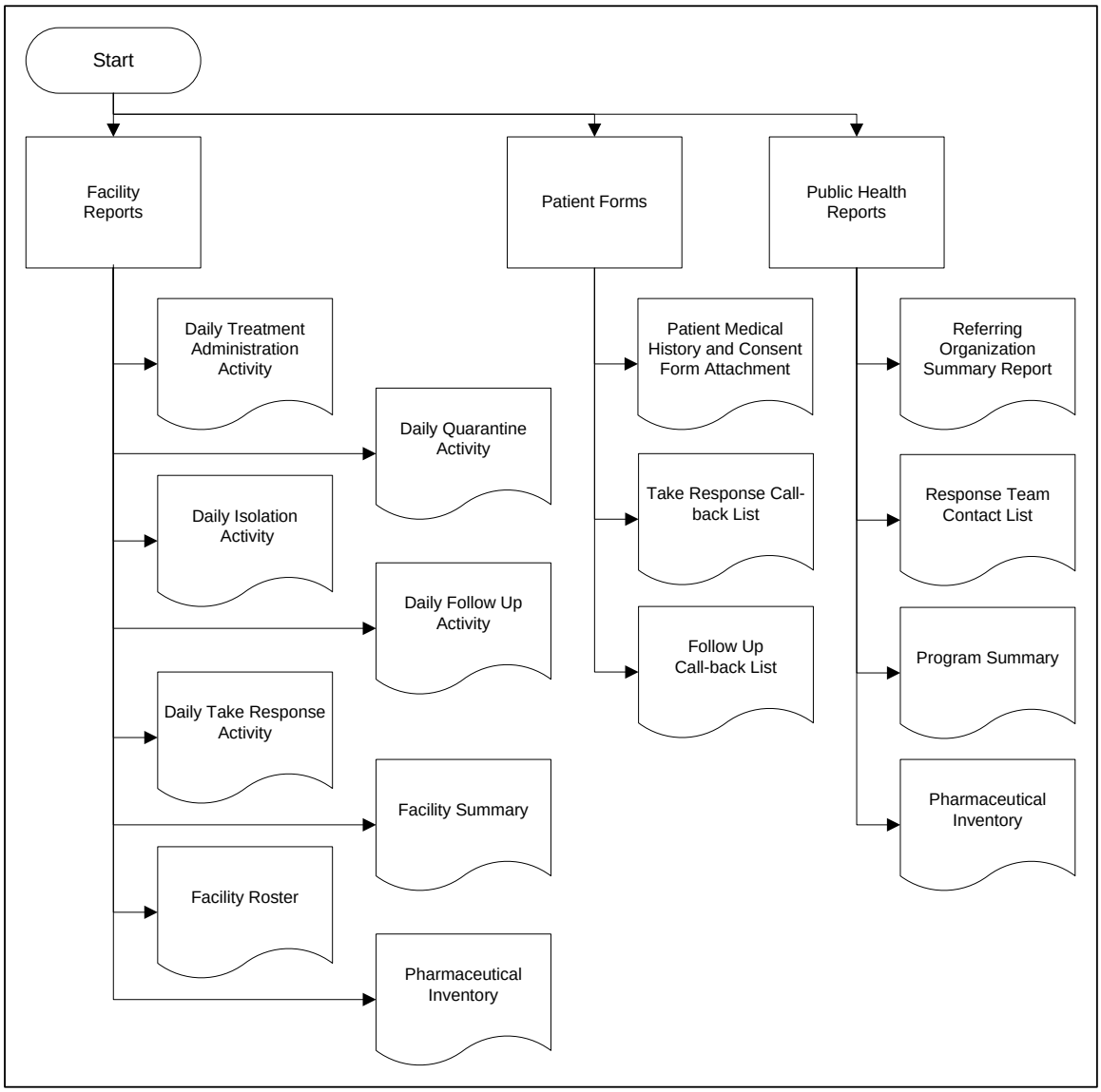

Figure 3-14: Generate Reports

3.14.2 Description

3.14.2.1 Facility Activity Reports

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

3.14.2.1.1 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.

3.14.2.1.2 Daily Quarantine Activity

This report is a complete record of all quarantines declared 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 quarantine activity.

3.14.2.1.3 Daily Isolation Activity

This report is a complete record of all isolations declared 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 activity.

3.14.2.1.4 Daily Compliance Activity

This report is a complete record of all compliance 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 compliance activity.

3.14.2.1.5 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.

3.14.2.1.6 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).

3.14.2.1.7 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 countermeasure and response administration process.

3.14.2.1.8 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.

3.14.2.2 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 CRA system.

3.14.2.2.1 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.

3.14.2.2.2 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.

3.14.2.2.3 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 countermeasure and response administration, 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.

3.14.2.3 Public Health Reports

The PHE will generate these reports.

3.14.2.3.1 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 compliance information. This report is intended to assist a referring organization in tracking the progress of their referred patients through the countermeasure and response administration process.

3.14.2.3.2 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.)

3.14.2.3.3 Program Summary

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

3.14.2.3.4 Pharmaceutical Inventory Report

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

3.15 14.0 PHE UPLOADS

3.15.1 Workflow

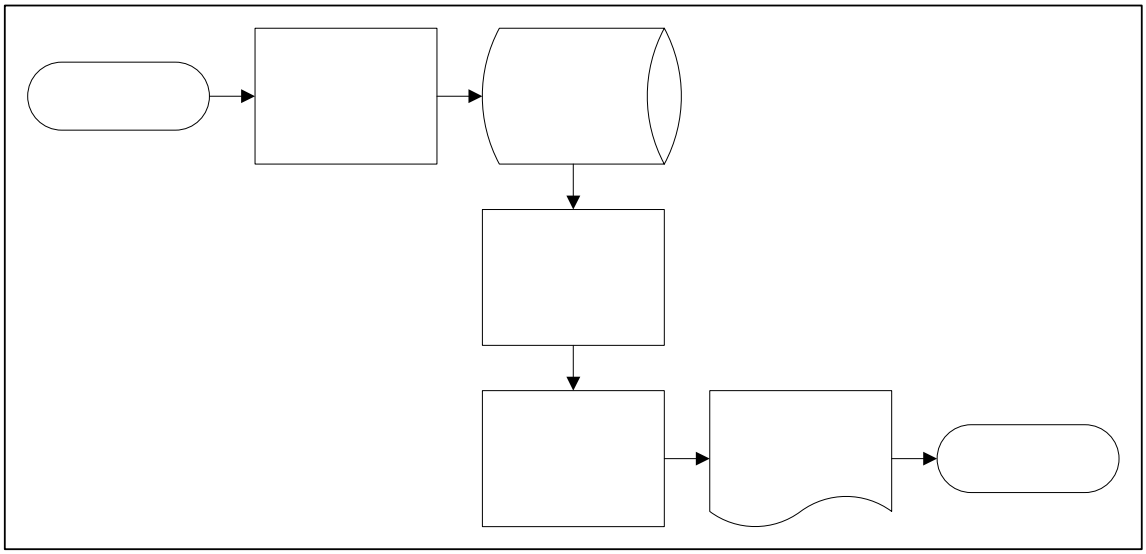

Figure 3-15: PHE Upload

3.15.2 Description

- The PHE's system should support generating an extract of countermeasure and response administration data.
- The extract must be uploaded to the CDC on a pre-determined regular schedule.
- The extract should be in XML and adhere to the format for data exchange provided by the CDC.
- The PHE will be responsible for uploading the extract to the CDC.
- Executing the upload process will require a digital certificate supplied by the CDC's Secure Data network group.
- The extract will include linked data in a nested format for program organizations (vaccination clinics and other treatment facilities, referring organizations, grantee organization, take response locations, etc.), aggregate data, patients, treatments administered, compliance information, take responses read, and prepared countermeasure information.

Start

- Any and all unique identifiers are included in the extracts and are crucial to uniquely identify the data collected from across the nation. This assimilated data set will be used to perform statistical analysis that provides the basis for drug safety monitoring, program progress, and other nationwide research by the CDC.

3.16 15.0 ACTIVE SURVEILLANCE

3.16.1 Workflow

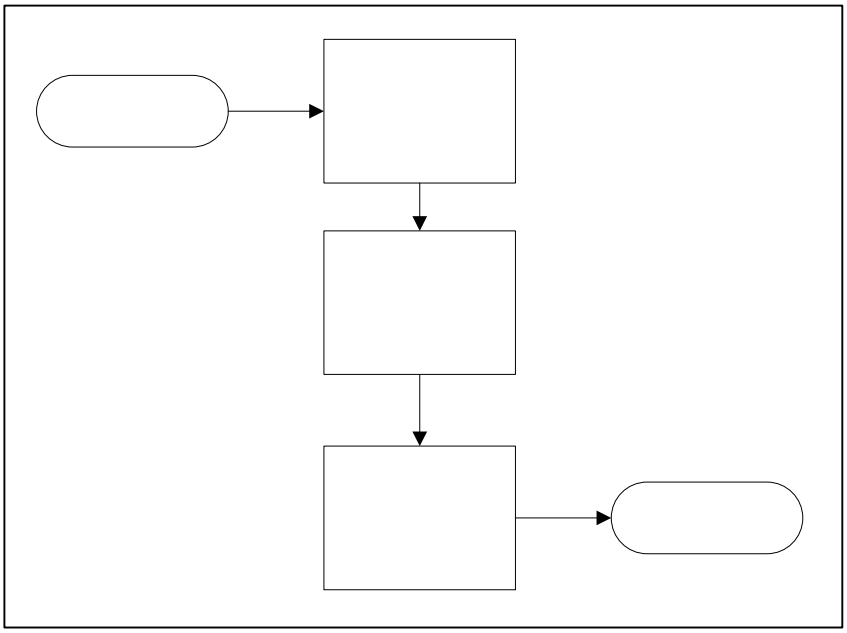

Figure 3-16: Active Surveillance

3.16.2 Description

- An active surveillance team member contacts a patient and interviews the patient.
- 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
- Active surveillance includes information about contraindications, risk factors, and health problems for patients and patient contacts.
- The active surveillance record must include the patient's treatment identifier.
- The CDC will link the active surveillance information to the countermeasure and response administration information using the treatment identifier.
- This activity may be optional, depending upon the countermeasure program that is being administered.

3.17 16.0 VAERS ADVERSE EVENT REPORTING

3.17.1 Workflow

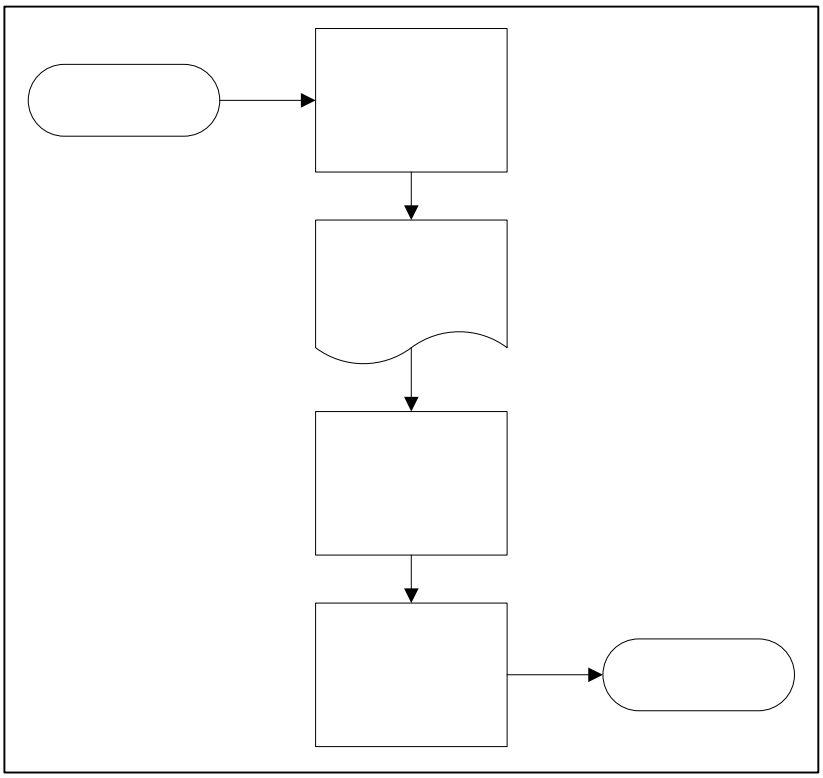

Figure 3-17: VAERS Adverse Event Reporting

3.17.2 Description

- The patient or physician will create a vaccine adverse events report in VAERS.
- The patient's treatment identifier will be included on the report.
- VAERS reports are uploaded to the CDC on a daily basis.
- The CDC will link the VAERS report to the countermeasure and response administration information sent to the CDC using the treatment identifier.

3.18 17.0 STATISTICAL REPORTS AND EXTRACTS

3.18.1 Workflow

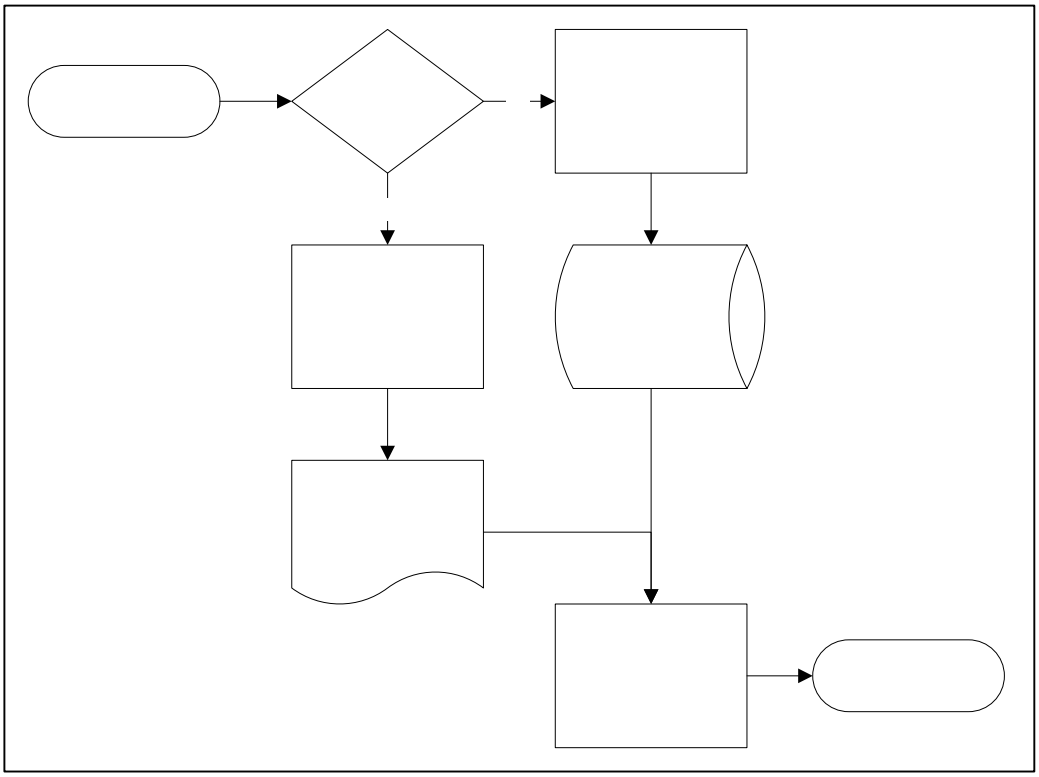

Figure 3-18: Statistical Reports and Extracts

3.18.2 Description

- The CDC, based on data provided by PHE's, will generate several reports to be used in monitoring the countermeasure and response administration program.
- Data from the CRA system, Outbreak Management, Active Surveillance and VAERS will be consolidated to produce some of the reports.
- Clarification request reports will identify records from the various data sources which do not comply with CDC validation criteria. Some of these validations will prevent records from being used in statistical reports, and others will not. Those with non-critical errors should still be examined, as they may represent data entry errors.
- State residency reports will present daily and cumulative totals of the number of individuals who have been treated in a state. They may include information about compliance or take response.
- Referring organization occupational summary reports will present information on the total number of patients treated by occupation for each referring organization within a state. These reports will be useful for estimating preparedness.
- State usage reports will provide information on the number of treatments of a countermeasure have been shipped and used based on CDC records, and estimates the number that remain available for use, either in "opened" or "unopened" containers. It also estimates the age of the remaining treatments in opened

containers. The information will be provided by treatment facility and by prepared countermeasure container, to facilitate follow-up on treatment issues by treatment administrators and by container.