PHIN Preparedness

COUNTERMEASURE/RESPONSE ADMINISTRATION

FUNCTIONAL REQUIREMENTS

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1 INTRODUCTION

This document describes functional requirements and general workflows for systems implemented to manage specific actions taken to prepare for or respond to health events, collectively known as Countermeasure/Response Administration (CRA). Countermeasures include vaccination and other types of drug prophylaxis, as well as non-drug actions such as patient follow up activities and isolation and quarantine 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/Response Administration system and should in no way preclude a system from incorporating additional functionality beyond what has been covered in this document.

2 COUNTERMEASURE/RESPONSE ADMINISTRATION FUNCTIONAL REQUIREMENTS

The following requirements describe baseline functionality for any system(s) implemented to manage countermeasure/response administration data.

2.1 System Architecture: Broad system-level needs, such as flexible configuration, should be addressed by systems supporting CRA.

2.2 Campaigns: A CRA campaign is a set of specific actions taken over a definable period of time to provide protection for a potential health event or to contain and respond to a known health event. 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.

2.3 Organizations: Organizations may participate in CRA campaigns in one or more roles, such as that of state, metropolitan or local health department, administering facility, take response location, pharmaceutical distribution center, countermeasure preparation site, isolation or quarantine location, and referring organization. Example referring organizations are hospitals, police and fire departments, private doctors, and outbreak management teams.

2.4 Countermeasures: Countermeasures include pharmaceuticals such as vaccines, antibiotics, anti-virals, and other drugs, as well as medical supplies such as respirators and IV sets. Countermeasures also include actions such as follow up activities and isolation and quarantine monitoring.

2.5 Allocation and Tracking: Countermeasures in limited supply must be allocated to prioritize coverage of at-risk populations. The ordering, distribution and usage of limited supply countermeasures may require tracking at multiple levels of public health and coordination between multiple levels of public health.

2.6 Patients: The primary purpose of systems supporting CRA is to track the patients who received countermeasures and information about the countermeasures they received during CRA campaigns. The information collected might be used to conduct statistical analysis of the progress and efficacy of a campaign, identify patients who should be contacted because they have received a countermeasure 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 countermeasure administration counts. Additionally, managing CRA information includes tracking patient isolation and quarantine, and adverse events identified during active and passive surveillance.

2.7 Analysis, Visualization and Report Generation: 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.

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

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

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

2.11 System Security and Availability: Security of systems supporting CRA includes the protection of data from corruption and access by unauthorized individuals, as well as the protection of the actual systems supporting CRA from sabotage or other failure. A plan must be established for continuing campaign activities when systems supporting CRA are unavailable.

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

2.1   SYSTEM ARCHITECTURE

2.1.1   Systems supporting CRA must offer configuration flexibility to capture information unique to each particular campaign.

   2.1.1.1   Systems supporting CRA must have the flexibility to specify countermeasure data elements as required or optional based on the characteristics of the campaign under which a countermeasure is being delivered.

   2.1.1.2   Systems supporting CRA must have the flexibility to collect protocol specific information when the specific protocol for a campaign or a drug requires that additional information be collected. Examples are location on the subject's body where the vaccination was administered, exact weight and age at administration for children receiving the countermeasure, risk factors, contraindications (e.g., allergy to latex or eggs, age restrictions).

2.1.2   Systems supporting CRA must support structured data entry for common forms and fields to ensure data integrity, validity, and standardization. A standardized data structure ensures that data mapping of common elements will only be necessary one time, rather than for each campaign.

2.1.3   Systems supporting CRA should ideally support multiple, quickly deployable options (e.g., disconnected tablets and web based) to support automated data collection at remote sites (e.g., ad-hoc clinics, emergency points of distribution).

    2.1.3.1   Systems supporting CRA should provide the ability for computers in disconnected mode to reconnect to a server to share CRA data among other computers that operate in disconnected mode.

    2.1.3.2   CRA data should be synchronized so that all instances of CRA applications working from the same server are able to share and use the same data.

2.1.4   Systems supporting CRA should be able to electronically record and store data using remote devices that may be uploaded to an aggregating system.

2.1.5   Systems supporting CRA should be capable of using configurable, domain-specific vocabulary.

2.2   CAMPAIGNS

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

    2.2.1.1   Campaign information must include: a unique campaign identifier, the campaign name, agent(s) involved, start and end dates, a campaign type (e.g., preparedness, response), potential countermeasure(s), and jurisdiction(s) participating.

    2.2.1.2   Campaign information should include: the sponsoring entity (i.e., the party initiating or managing the campaign) and population(s) to receive countermeasures (e.g., first responders, exposed individuals, the general population, population risk groups).

    2.2.1.3   Campaign-specific information should also be stored, such as whether the campaign requires integration with outbreak monitoring capabilities, medical history collection, or response team building.

2.2.2   Systems supporting CRA must be able to support multiple concurrent campaigns.

2.2.3   Systems supporting CRA must be able to support merging multiple campaigns into one.

2.2.4   Systems supporting CRA must be able to support splitting a campaign into multiple campaigns

2.2.5   Systems supporting CRA must be able to support linking campaigns.

2.2.6   Linking CRA campaign data with corresponding campaign data in other systems (e.g., outbreak management systems) must be supported.

2.2.7   Systems supporting CRA should allow for collection of additional data elements 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.

2.2.8   Systems supporting CRA must have the flexibility to specify campaign data elements as required or optional based on the characteristics of the campaign.

2.2.8.1   It must be possible to redefine the set of required data to support the collection of a reduced amount of information, such as when the campaign involves a mass exposure.

2.2.8.2   It must be possible to redefine the set of required data to support the collection of an increased amount of information, such as when the campaign involves an investigational new drug (IND).

2.2.8.3   It must be possible to collect information about contraindications and risk factors during a campaign, and to flag a patient as needing a heightened level of monitoring. This may be needed when the pharmaceutical countermeasure is given despite the risk of side effects because the countermeasure poses less risk to the patient than the health event itself.

2.3   ORGANIZATIONS

2.3.1   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.

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

2.3.1.2   All organizations with roles in CRA campaigns must be entered into a local instance of a public health directory.

2.3.1.2.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 (e.g., state agency, local agency, hospital).

2.3.1.2.b   Authorized individuals must be able to add organizations "on the fly" to a local instance of a public health directory during entry of data that is linked to an organization.

2.3.2   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 (e.g., administering facility, take response location, pharmaceutical distribution center, isolation or quarantine location, referring organization) and any referring organization categories within a campaign (e.g., healthcare response team, public health response team) are required.

2.3.3   Every recorded countermeasure administration, patient follow up, take response reading, isolation or quarantine, 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 *2.6.3 Current Countermeasure Administration Data* of this document for more information.

2.3.4   Information about all individuals with roles in support of CRA campaigns must be captured.

    2.3.4.1   Every staff member must be assigned an identifier that is unique within the jurisdiction.

    2.3.4.2   All staff members with roles in CRA campaigns must be entered into a local instance of a public health directory.

        2.3.4.2.a   Staff data includes: a jurisdictionally unique identifier, the individual's name and a staff-known identification number (such as an American medical Association number, employee number, or other jurisdiction or organization-assigned number).

        2.3.4.2.b   Authorized individuals must be able to add staff members "on the fly" to a local instance of a public health directory during entry of data that is linked to a staff member.

    2.3.4.3   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: countermeasure administrator (e.g., vaccinator, other drug administrator), and patient follow up personnel.

2.3.5   The organization must be able to trace the electronic records of staff members to the actual people they represent.

2.3.6   Every record of a countermeasure administration, patient follow up, take response reading, isolation or quarantine 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 *2.6.3 Current Countermeasure Administration Data* of this document for more information.

2.4   COUNTERMEASURES

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

2.4.2   Pharmaceutical inventory should be captured to identify and respond to issues with availability of pharmaceuticals and to track the distribution and use of controlled substances.

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

    2.4.2.2   Inventory information may include: the generic name, the brand name, quantity, manufacture date, unopened shelf life, re-packaged shelf life, shipped date, received date, and current location.

    2.4.2.3   Inventory information may include: deactivation or destroyed status, date of deactivation or destruction, and reason.

2.4.3   Integration with pharmaceutical stockpiles should be supported.

2.4.3.1   Integration should support tracking the lot number, manufacturer, and other countermeasure/response administration-related information.

2.4.3.2   Systems supporting CRA should be able to determine the quantity allocated by the stockpile.

2.4.3.3   Systems supporting CRA should be able to report to the stockpile the quantity of the allocated countermeasure administered.

2.4.4   Validation of lot numbers must be used when recording countermeasure usage to ensure consistency and reduce the possibility of incorrect lot numbers.

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

2.4.5.1   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, staff member who performed the re-packaging or alteration, resulting amount of substance in the container, pharmaceutical name(s), lot number(s) and manufacturer(s), and maximum number of patient countermeasures that can be delivered from the container.

2.4.5.2   Support for the sharing of prepared countermeasure containers by multiple administering facilities is required.

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

2.4.5.4   If a prepared countermeasure container is destroyed, the reason for and date of destruction should be captured.

2.4.6   Every patient encounter 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 *2.6.3 Current Countermeasure Administration Data* of this document for more information.

2.5   ALLOCATION AND TRACKING

Pharmaceuticals in limited supply must be allocated to prioritize coverage to at-risk populations. The ordering, distribution and usage of limited supply pharmaceuticals may require tracking at multiple levels of public health and coordination between multiple levels of public health.

2.5.1   Systems supporting CRA must be able to manage allocation and tracking of countermeasures from a central location, whether it is national, territorial, state or local.

2.5.2   Systems supporting CRA must be able to track and allocate countermeasures based on available quantities or apportionments.

    2.5.2.1   The location and amount of the specific countermeasure within a jurisdiction should be recorded as contributing to the available quantities.

    2.5.2.2   Information about any pre-booked orders of the product must be available.

2.5.3   Systems supporting CRA must be able to base allocations upon assessment of high priority populations and usage guidelines for formulations matched to risk populations.

    2.5.3.1   The quantity requested to provide coverage should be recorded and used in determining apportionments.

2.5.4   Systems supporting CRA must support order placement, fulfillment, and status.

2.5.5   Systems supporting CRA must be able to convert order size (e.g., dosage) to packaging.

2.5.6   Systems supporting CRA must be able to reduce allocations to a jurisdiction based on amounts ordered.

2.5.7   Systems supporting CRA must be able to reallocate based on changes to requested allocations.

2.6 PATIENTS

2.6.1 Patient Demographic Data

    2.6.1.1   Demographic information about all patients who received countermeasures in a CRA campaign must be collected.

        2.6.1.1.a Each patient must be identified by a patient identifier that is unique within the jurisdiction.

        2.6.1.1.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 of residence, and occupation.

        2.6.1.1.c Demographic data may include: contact information (name, addresses such as residence and transitional, home and work phone numbers, fax number, and other pertinent communication paths (e.g., cell phone, pager, e-mail), date of birth, zip code, county and country of residence, state where employed, ethnicity, and race.

        2.6.1.1.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.

        2.6.1.1.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.

2.6.1.1.f Systems supporting CRA should provide the ability to capture patient identification and demographic data for each encounter (e.g., countermeasure administration, follow up) during a campaign. Edits to these data may only be made in association with continued follow up of the encounter.

2.6.1.2 Systems supporting CRA must be able to provide a means for locating and contacting patients who do not return for follow up visits, who must be monitored for compliance, or who might have received a countermeasure for which an issue has been discovered.

2.6.1.3 Systems supporting CRA must have the flexibility to specify demographic data elements as required or optional based on the characteristics of the campaign under which a countermeasure is being delivered.

2.6.1.4 Every patient should be represented only once in systems supporting CRA.

2.6.1.4.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.

2.6.1.4.b Matching functions must be provided to match patient records based on meaningful identifiers to reduce duplication of patient data.

2.6.1.4.c To accurately represent the level of preparedness, it must be possible to verify that responders are represented only once in systems supporting CRA and to validate all their level of protection based upon the vaccinations and prophylaxis that they have received.

2.6.1.5 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 systems supporting CRA. This link is necessary to support public health investigations, including exposure contact investigation, and to communicate with patients who need to receive countermeasures or who require post-administration follow up, including safety and efficacy follow up.

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

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

2.6.2 Historical Data

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

2.6.2.2   Systems supporting CRA must have the flexibility to specify historical data elements as required or optional based on the characteristics of the campaign or the countermeasure involved. For example, the data may be used in statistical analysis to determine whether a previously received countermeasure has an impact on the result of the countermeasure currently being administered.

2.6.2.3   Historical information collected must include a history identifier that is unique within the jurisdiction, the patient involved, and the campaign during which the history was collected.

2.6.2.4   In addition to the general historical information, medical history data may include the date, the result (e.g., take response, outcome), and the occurrence of adverse events.

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

    2.6.2.4.b   In addition to specific responses to medical history questions, aggregate information such as the total number of previous administrations will be captured (e.g., total doses of a vaccine administered to a person).

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

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

2.6.3   Current Countermeasure Administration Data

2.6.3.1   Entry and tracking of current countermeasure administration data must be provided.

2.6.3.2   Every countermeasure administration record must be assigned at least one unique identifier, such as the Patient Vaccination Number (PVN) used to identify vaccination events in the National Smallpox Preparedness Program.

    2.6.3.2.a   The identifier for the countermeasure administration record must be unique within the jurisdiction.

2.6.3.3   Every countermeasure administration record is to be linked to the campaign under which it was administered.

2.6.3.4   Each countermeasure administration record must be linked to the original patient record.

2.6.3.5   Countermeasure administration data must include: the actual dosage, the date of administration, the administering facility, the state where administered, the person who ordered the countermeasure, and the person who administered the countermeasure.

2.6.3.5.a The referring organization for patients referred for countermeasure administration as preparation for serving on a response team must be captured.

2.6.3.5.b The body site where the countermeasure was administered should be captured.

2.6.3.5.c Each patient encounter will be linked to all the specific prepared countermeasure containers (e.g., specific vaccine vials) from which the countermeasure was dispensed to the patient. Through the prepared countermeasure container, the countermeasure can be traced to all pharmaceutical lots used.

2.6.3.6 Systems supporting CRA must be able to capture the administration of more than one countermeasure during a patient encounter; for example, the administration of both antibiotic prophylaxis and vaccination to a patient exposed to inhalational anthrax.

2.6.3.7 Systems supporting CRA must support recording the administration of single and multiple doses of a countermeasure, and combinations of pharmaceuticals that may be dispensed as a countermeasure.

2.6.3.8 Each countermeasure administration record will be traceable to the specific facility and administrator involved in the administration of the countermeasure.

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

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

2.6.3.11 The acceptance of potentially incomplete patient and patient countermeasure information from external sources such as systems used to manage outbreak data must be supported. This might consist of an electronic request to administer a countermeasure to a patient or an electronic record of a countermeasure that has already been administered.

2.6.3.12 The participation of a patient in more than one campaign must be supported. For example, systems supporting CRA 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.

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

2.6.4   Patient Follow Up

2.6.4.1   Systems supporting CRA must provide the capability to conduct and record the results of patient follow up

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

    2.6.4.1.b   The follow up event may address administration of an additional countermeasure, response to medications, symptom tracking for adverse events, compliance monitoring and other activities such as reading and recording a take response to a vaccination.

2.6.4.2   Systems supporting CRA must have the flexibility to support follow up information that varies based on the type of countermeasure administered.

2.6.4.3   Each patient follow up record will be linked to the corresponding countermeasure administration record.

2.6.4.4   Follow up information must include a follow up event identifier that is unique within the jurisdiction.

2.6.4.5   Follow up information may include: the corresponding patient encounter, 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.

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

2.6.4.6   Systems supporting CRA must be able to capture information on the success (e.g., take response) or failure (e.g., lack of take response) of a countermeasure administration, as this information will be required for some types of countermeasures.

2.6.4.7   A take response exam is a special type of follow up involving determining the outcome (e.g., take response) of a smallpox vaccination (or possibly other currently unidentified countermeasures).

    2.6.4.7.a   The capture of the exam outcome (e.g., major, equivocal, not available), take reader, take location, and adverse event information are required.

    2.6.4.7.b   If a take response cannot be collected, a reason for the lack of take availability should be captured.

2.6.4.8   The linking of CRA patient countermeasure administration data with any corresponding cases in a surveillance system should be supported.

2.6.4.9   Systems supporting CRA should provide for the linking of CRA patient countermeasure administration data with any corresponding adverse events in an adverse event reporting system. An example of such a system is the Vaccine Adverse Event Reporting System (VAERS), available at *www.vaers.org*.

2.6.5   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 countermeasures are needed, whether there is an issue with a particular lot of a pharmaceutical, whether pharmaceuticals dispensed from a certain container or batch show unusual trends, or whether a specific facility or administrator has a high number of adverse events.

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

2.6.6   Isolation and Quarantine

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

2.6.6.1   Recording and tracking of isolation and quarantine information must be supported.

2.6.6.2   Systems supporting CRA must be able support quarantine or isolation authorizations that are issued to restrict a patient's movement.

2.6.6.2.a   Systems supporting CRA must have the flexibility to support authorization information that varies based on the type of isolation or quarantine imposed. Examples of authorization information include: the campaign under which the isolation or quarantine is authorized, the agent, the level of the authorizing authority (e.g., federal, state, local), the court order number, the name of the person who signed the court order, the type of order (e.g., group, individual), the nature of the restriction (e.g., voluntary, mandatory), the type of restriction (e.g., work, food, shelter in place), and the organization and staff member responsible for administering the authorization.

2.6.6.2.b   Each quarantine or isolation authorization must be assigned an identifier that is unique within the jurisdiction.

2.6.6.2.c   If the order is for a group of people, a description of the group is required.

2.6.6.2.d If the order is for an individual, information useful to identify or locate the person should be captured.

2.6.6.2.e Isolation and quarantine data should be communicated to the monitoring site to monitor the case's location, health status, and compliance with the order.

2.6.6.3 Each patient isolation or quarantine event must be tied to the patient, campaign and authorization involved.

2.6.6.3.a Patient demographics must be collected for the restricted patient. See section *2.6.1 Patient Demographic Data* of this document for more information.

2.6.6.3.b Systems supporting CRA must have the flexibility to support event information that varies based on the type of isolation or quarantine imposed. Examples of event information include: a unique event identifier, the patient, the attending physician, the isolation or quarantine authorization, contact information (e.g., address and telephone numbers) for the isolation or quarantine location (e.g., organization previously identified as participating in the campaign as an isolation or quarantine location, patient's private residence), contact information for a relative or friend of the patient, the start and stop date, and the facility and staff member responsible for monitoring the patient.

2.6.6.3.c Each quarantine or isolation event must be assigned an identifier that is unique within the jurisdiction.

2.6.6.4 Monitoring of isolated or quarantined patients is to be supported by triggering and capturing the results of investigator activities such as daily telephone calls and visits to the isolation or quarantine location.

2.6.6.4.a Based on the type of restriction imposed, monitoring information may include: the patient, the patient isolation or quarantine 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 (e.g., visit, telephone), whether the patient is complying with the quarantine order, person spoken to if monitoring occurred by phone call.

2.6.6.4.b When the restriction is ended, the discharge date, reason and staff member authorizing the discharge should be captured.

2.6.6.4.c Each isolation or quarantine monitoring event must be assigned an identifier that is unique within the jurisdiction.

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

2.6.6.4.e Possible cases identified as a part of symptom tracking and/or surveillance should be reported to systems managing contact exposure tracing.

2.6.6.4.f When monitoring occurs by telephone, the identity of the person contacted (e.g., patient, relative, healthcare worker at the quarantine site) should be captured.

2.7 ANALYSIS, VISUALIZATION AND REPORT GENERATION

2.7.1 Systems supporting CRA should allow for analytical searches based upon multiple criteria.

2.7.2 Systems supporting CRA should have the ability to product charts, maps and graphs that illustrate countermeasure and response data, including mapping patients by zip code or municipality.

2.7.3 Reporting categorized by administering or dispensing organization, by referring organization, and by prepared countermeasure container must be available.

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

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

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

2.7.7 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 countermeasures and to indicate their status, and one to identify "protected" individuals able to serve on response teams.

2.7.8 Systems supporting CRA should generate electronic data dictionaries for configurable data (or other user-defined data descriptions to assist with effective data exchange).

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

2.7.9.1 The aggregate reports should have multiple sorting and selection options; for example, time period, region, and administering or dispensing site.

2.7.10 For campaigns that specifically support tracking patients who did not receive countermeasures, aggregate reports are required to show patient counts such as number of patients who did not receive countermeasures.

2.7.11 Reports showing the projected number of patients to receive countermeasures by region or by administering site should be available.

2.7.12 Systems supporting CRA should have the ability to product pre-formatted queries and reports to allow faster and more accurate reporting, while still allowing the flexibility of ad-hoc reporting.

2.7.13 Data must be shared among state and local jurisdictions and national partners.

2.7.13.1 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 section *2.8 Systems Integration and Data Exchange* of this document for more information.

2.7.13.2 Jurisdictions must have the ability to receive and process aggregate data from national partners.

2.7.14 Post-campaign data should be aggregated into a centralized data store (e.g., data warehouse) designed specifically to support analysis of events over time.

2.7.14.1 Data should be accessible for use with commonly available analytical tools (e.g., SAS, SPSS, EPI-INFO, MS Access, MS Excel, Crystal Reports).

2.8   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 these systems should be able to send and receive. This section is limited to describing the types of data exchange that must be supported; not the requirements for transporting the data. Bi-directional, secure exchange of data with partner organizations supports public health investigations across all levels of public health. Message construction and parsing, and secure data transport requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.8.1 CRA information collected from multiple sites or systems must be consolidated prior to exchanging it with partner organizations.

2.8.2 Systems supporting CRA must be able to receive, parse and process messages for countermeasure administration requests. This requirement is identified as a key performance measure for assessing preparedness as described in *PHIN Preparedness Key Performance Measures*, available at *www.cdc.gov/phin*.

2.8.2.1 When patients identified for countermeasure administration or follow-up are managed separately from the system that supports CRA (such as a system that supports outbreak management), the system supporting CRA must be able to receive and acknowledge information regarding follow-up activities for those patients.

2.8.3 Systems supporting CRA should be able to create and send messages for countermeasure administration requests, in accordance with *PHIN Countermeasure Administration – Referral Message Implementation Guide*, available at *www.cdc.gov/phin*.

2.8.4   Systems supporting CRA must be able to exchange messages for countermeasures that have been administered. This requirement is identified as a key performance measure for assessing preparedness as described in PHIN *Preparedness Key Performance Measures*, available at *www.cdc.gov/phin*.

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

2.8.5   Systems supporting CRA must be able to notify all concerned parties that corrective action may be required, such as re-training of staff and/or recall of patients for additional countermeasures, when safety and efficacy issues with a countermeasure or the campaign staff at a particular administering facility are discovered. For more information, refer to *PHIN Preparedness Partner Communications and Alerting Functional Requirements*, available at *www.cdc.gov/phin*.

2.8.6   Systems supporting CRA must demonstrate the ability to exchange messages for adverse events identified during active surveillance. This requirement is identified as a key performance measure for assessing preparedness as described in *PHIN Preparedness Key Performance Measures*, available at *www.cdc.gov/phin*.

2.8.7   Systems supporting CRA must be able to exchange aggregated data. Examples of aggregated data to be supported are: patient counts such as number of patients who received countermeasures; number of patients for whom the countermeasure did not have the desired outcome (e.g., an equivocal take for a smallpox vaccination); and number of patients complying with prescribed countermeasures.

2.8.8   Systems supporting CRA should have the ability to receive data such as pharmaceutical information, campaign setup information, and vocabulary from authorized partner organizations, such as the CDC.

2.9   VOCABULARY STANDARDS

It is recommended that standards be used across systems supporting CRA; however, it is required that vocabulary standards 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 "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.9.1   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 (e.g., FIPS, ISO), and the public health community.

2.10 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 "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.10.1 Polices regarding data synchronization should be defined to support multiple deployment options as discussed in section *2.1 System Architecture* of this document.

2.10.2 Configuration management protocols and personnel should be identified to support multiple deployment options.

    2.10.2.1 Protocols and personnel should be identified to support the set-up and configuration of laptops and other field devices used in CRA campaigns.

    2.10.2.2 Processes and personnel should be identified to support the configuration of required and optional data elements based upon the agent, the countermeasure (e.g., licensed, investigational new drug), and the type of campaign (e.g., mass response, controlled pre-event response).

2.10.3 Policies and procedures should be in place for determining when follow up and isolation and quarantine monitoring should be done as a function of contact exposure tracing, rather than as a part of a focused countermeasure administration and response effort.

2.11 SYSTEM SECURITY AND AVAILABILITY

Systems and data supporting CRA must be protected from sabotage, corruption and unauthorized access, and must be available subsequent to a catastrophic event. Security requirements specific to systems supporting CRA are included in the section below. Security and Availability requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

    2.11.1.1 A user's access to data will be limited by defined "filters" including but not limited to campaign (e.g., user may view data about the National Smallpox preparedness program but not the Anthrax Outbreak of 2001), organization (e.g., data entry user for Facility A cannot view Facility B's data), and user functionality (e.g., follow up user is permitted to see only the patient's name and contact information).

2.12 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 "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.