

Session 9.F: Investigation of Agent Specific Data Collection Requirements to Support Countermeasure and Response Administration

Presented by:
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Agenda

- Introductions
- Part 1: Countermeasure and Response Administration System Overview
- Part 2: Types of Information
- Part 3: Data Elements - Are We on Track?
- Conclusions



Introductions

- Victoria (Vicki) Kipreos, PMP
 - ◆ Lead IT Specialist, CDC/IRMO
 - ◆ Certified Project Manager with 17 years experience in healthcare and financial software development
 - ◆ Program Lead of the Emergency Preparedness Systems Group
 - ◆ Lead for Informatics support of CDC DEOC
 - ◆ Positioned with the CDC since Oct., 2001



Introductions

- Joseph (Joe) Baweja, III
 - ◆ Project Manager for Pre-Event Vaccination System (PVS)
 - ◆ Project Manager for Countermeasure and Response Administration System
 - ◆ Over 5 years of software project management experience
 - ◆ Over 10 years of full life cycle software development experience



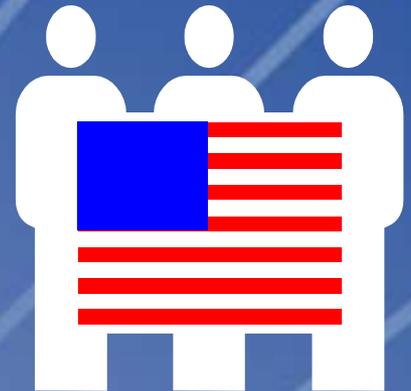
Introductions

- Betty H. Baker
 - ◆ Business Analyst, Northrop Grumman/IT
 - ◆ Information technology professional with 26 years experience in software design and development
 - ◆ Lead business analyst for Countermeasure and Response Administration System
 - ◆ Joined Pre-Event Vaccination System (PVS) development team in October of 2002



Part 1: Countermeasure and Response Administration System Overview

- Purpose of Countermeasure and Response Administration System
 - ◆ 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



Part 1: Countermeasure and Response Administration System Overview

- Countermeasures are administered under a Program
 - ◆ In preparation for a public health emergency (pre-event)
 - ◆ In response to a public health emergency (post-event)
- A program is for one or more Agents
- A program uses one or more Countermeasures
- A program is for one or more specific Populations



Part 1: Countermeasure and Response Administration System Overview

- Category A Agents
 - ◆ Anthrax
 - ◆ Botulism
 - ◆ Plague
 - ◆ Smallpox
 - ◆ Tularemia
 - ◆ Viral Hemorrhagic Fever



Part 1: Countermeasure and Response Administration System Overview

- Pharmaceutical Countermeasures
 - ◆ Vaccines
 - ◆ Antibiotics
 - ◆ Anti-viral drugs
 - ◆ Other drugs
- Non-pharmaceutical Countermeasures
 - ◆ Quarantine
 - ◆ Isolation
 - ◆ Patient follow up

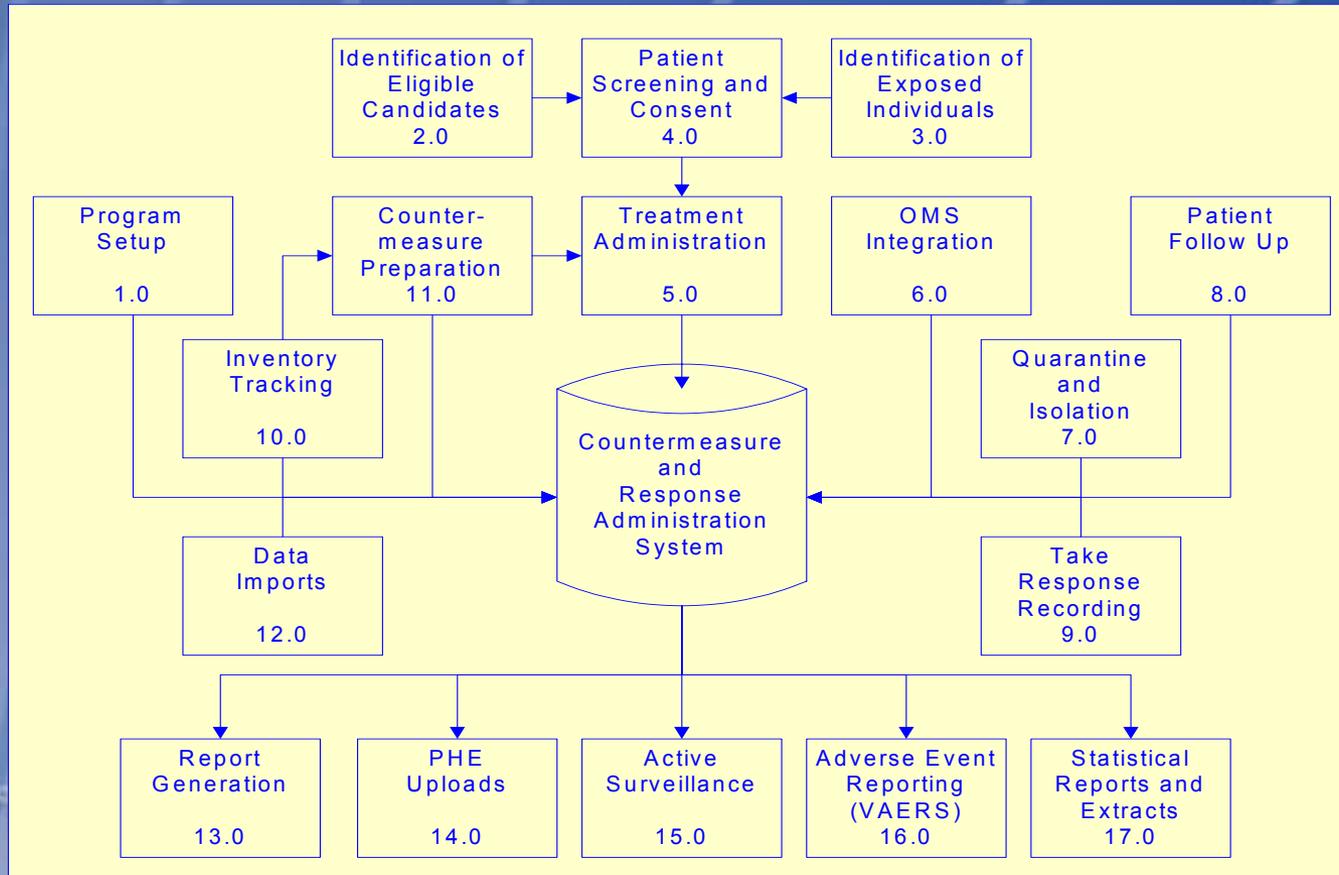


Part 1: Countermeasure and Response Administration System Overview

- Populations
 - ◆ Public Health Officials
 - ◆ Healthcare Workers
 - ◆ First Responders (Fire, Police, EMT)
 - ◆ Identified Exposed Individuals
 - ◆ General Public
 - ◆ Laboratorians



Part 1: Countermeasure and Response Administration System Overview



Part 2: Types of Information

- Patient information
 - ◆ Demographics
 - ◆ Vaccination history
 - ◆ Treatment
 - ◆ Quarantine
 - ◆ Isolation
 - ◆ Follow up



Part 2: Types of Information

- Countermeasure information
 - ◆ Pharmaceuticals
 - ◆ Inventory
 - ◆ Prepared countermeasure containers



Part 2: Types of Information

- Patient Information
 - ◆ Patient demographic data
 - ★ Patients are common to all programs
 - ★ The same patient may participate in multiple programs
 - ◆ Vaccination History Data
 - ★ Information about vaccinations the patient may have received external to any Countermeasure and Response Administration program
 - ★ Specific to vaccinations only
 - ◆ Treatment data
 - ★ Treatment events within a program during which patients receive pharmaceuticals
 - ★ Patient may receive multiple treatments during a program
 - ★ Patient may receive either an immediate treatment from medical personnel or pharmaceuticals to be self-administered over time



Part 2: Types of Information

■ Patient Information

◆ Quarantine

- ★ 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

- ★ Separation of ill persons with contagious disease
- ★ Usually in a healthcare setting

◆ Follow Up

- ★ Response of patients to countermeasures after countermeasures have been administered



Part 2: Types of Information

■ Countermeasure Information

◆ Pharmaceutical

- ★ Information about pharmaceuticals that are to be used in the treatment of patients
- ★ Data requirements may vary on the nature of the pharmaceutical (pill, liquid, aerosol, injection, etc.)

◆ Inventory

- ★ Information about pharmaceutical shipments
 - Between SNS or other suppliers and PHE's
 - Between PHE's and treatment facilities

◆ Prepared Countermeasure

- ★ Information to identify the exact sources (lot numbers, facility, preparation date) of a prepared countermeasure container such as a vaccine vial
- ★ Preparation may include re-packaging, reconstitution, opening for first use



Part 3: Data Elements - Are We on Track?

- What is in the Countermeasure and Response Administration System?
 - ◆ Includes all original PVS data elements
 - ◆ Expanded to cover multiple agents, countermeasures and populations
 - ◆ Includes an inventory component



Will it meet YOUR needs?



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Part 3: Data Elements - Are We on Track?

- Common Data
 - ◆ Collected for all instances of the type of information
- Specialized Data
 - ◆ Collected only for some subset of programs, countermeasures, agents, patient populations, pharmaceuticals, etc.



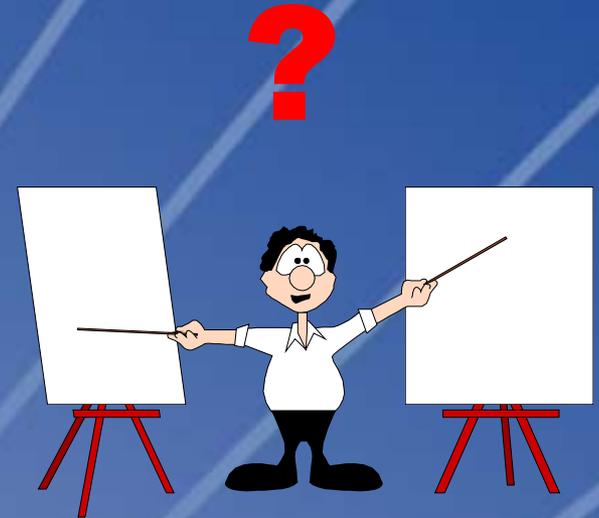
Part 3: Data Elements - Are We on Track?

- Patient Demographic Data
 - ◆ Common
 - ★ Patient Identification Number (PIN)
 - ★ Name
 - ★ Age (birthday or birth year)
 - ★ Gender
 - ★ External identifiers (ssn, drivers license, passport)
 - ★ Address (street, city, state, zip, country)
 - ★ County
 - ★ Contact information (phone numbers, email)
 - ★ Race/Ethnicity
 - ◆ Specialized
 - ★ Weight – for treatment of children
 - ★ Occupation – for response teams
 - ★ Skills – for response teams
 - ★ OMS Case or Contact ID



Part 3: Data Elements - Are We on Track?

- Patient Demographic Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there problems with any of these elements?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?



What do YOU think?



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Part 3: Data Elements - Are We on Track?

■ Vaccination History Data

◆ Common

- ★ History identifier

- ★ Patient

- ★ Countermeasure

- ★ Number of previous vaccinations

- ★ Date of most recent vaccination (Childhood, adulthood, year, exact date – external to CAS)

- ★ Date authority (documented or self-recall)

- ★ Adverse reaction information

◆ Specialized

- ★ Vaccination successful

- ★ Vaccination scar

- ★ Vaccinee status (primary, revaccinee)



Part 3: Data Elements - Are We on Track?

- Vaccination History Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about agent-specialized data?



What do YOU think?



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Part 3: Data Elements - Are We on Track?

■ Treatment Data

◆ Common

- ★ Treatment identifier
- ★ Patient
- ★ Program
- ★ Treatment facility name
- ★ Treatment date
- ★ Countermeasure
- ★ Dispensing container info (manufacturer, lot #, container)
- ★ Treatment administrator

◆ Specialized

- ★ Package information (number and dosage of pills)
- ★ Dosage information (frequency and number of pills per dose)
- ★ Referring organization
- ★ Dilution strength
- ★ Inoculation site



Part 3: Data Elements - Are We on Track?

- Treatment Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about specialized data?
 - ★ Agent
 - ★ Countermeasure
 - ★ Population



What do YOU think?



Part 3: Data Elements - Are We on Track?

■ Quarantine Data

◆ Common

- ★ Quarantine identifier
- ★ Patient
- ★ Program
- ★ Quarantine evaluator
- ★ Start and end dates
- ★ Quarantine site (Address and Phone #)
- ★ Quarantining authority

◆ Specialized

- ★ Quarantine Level
- ★ Quarantined area (jurisdiction, community, building, etc.)



Part 3: Data Elements - Are We on Track?

- Quarantine Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about agent-specialized data?



What do YOU think?



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Part 3: Data Elements - Are We on Track?

- Isolation Data
 - ◆ Common
 - ★ Isolation identifier
 - ★ Patient
 - ★ Program
 - ★ Isolation evaluator
 - ★ Start and end dates
 - ★ Isolation Site (Address and Phone #)
 - ◆ Specialized
 - ★ Isolation Level
 - ★ Infection Control Measures Needed (e.g., Airborne, Contact)



Part 3: Data Elements - Are We on Track?

- Isolation Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about agent-specialized data?



What do YOU think?



Part 3: Data Elements - Are We on Track?

■ Follow Up Data

◆ Common

- ★ Follow up identifier
- ★ Event (which patient treatment, quarantine, or isolation)
- ★ Follow up facility
- ★ Follow up date
- ★ Follow up monitor
- ★ Comment

◆ Specialized

- ★ Symptom monitoring (temperature, rash - smallpox quarantine)
- ★ Take response reading (smallpox vaccination)
- ★ Compliance with treatment regimen
- ★ Reason for non-compliance
- ★ Adverse event



Part 3: Data Elements - Are We on Track?

- Follow Up Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about specialized data?
 - ★ Agent
 - ★ Countermeasure
 - ★ Population



What do YOU think?



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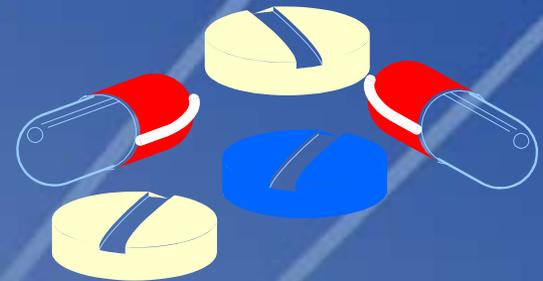


Part 3: Data Elements - Are We on Track?

■ Pharmaceutical Data

◆ Common

- ★ Pharmaceutical Identifier
- ★ Countermeasure
- ★ Manufacturer
- ★ Brand name
- ★ Lot number
- ★ Manufacture date
- ★ Shelf life (unopened and opened)
- ★ Expiration date

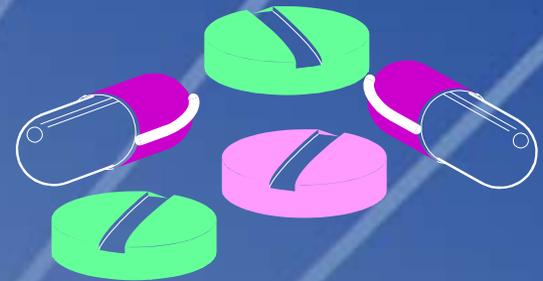


Part 3: Data Elements - Are We on Track?

■ Pharmaceutical Data

◆ Specialized

- ★ Number of patients that can be treated per container
- ★ Unit of Use (amount to be dispensed to one patient)
- ★ Dose strength, quantity, directions (2 100 mg tablets every 12 hours with food)
- ★ Pharmaceutical usage (vaccine, prophylaxis, mass therapy, ...)
- ★ Preferred/alternative/licensed/IND pharmaceutical
- ★ Applicable population group



Part 3: Data Elements - Are We on Track?

- Pharmaceutical Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about specialized data?
 - ★ Agent
 - ★ Countermeasure
 - ★ Population
 - ★ Pharmaceutical differences



What do YOU think?



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Part 3: Data Elements - Are We on Track?

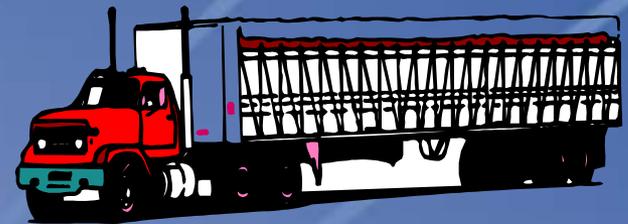
■ Inventory

◆ Common

- ★ Shipment identifier
- ★ Sending organization
- ★ Receiving organization
- ★ Pharmaceutical
- ★ Lot number
- ★ Quantity
- ★ Send or receive date

◆ Specialized

- ★ ???



Part 3: Data Elements - Are We on Track?

- Inventory Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about specific pharmaceutical data?



What do YOU think?



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Part 3: Data Elements - Are We on Track?

- Prepared Countermeasure Container Data
 - ◆ Common
 - ★ Dispensing container identifier
 - ★ Countermeasure
 - ★ Preparation facility
 - ★ Preparation date
 - ★ Manufacturer(s) and Lot number(s)
 - ★ Number of treatments
 - ◆ Specialized
 - ★ Protocol
 - ★ Dilution strength
 - ★ Current location of container



Part 3: Data Elements - Are We on Track?

- Prepared Countermeasure Container Data
 - ◆ Are these elements useful to you at the state or local level?
 - ◆ Are there any elements missing?
 - ◆ What else do you require?
 - ◆ What about specialized data?
 - ★ Agent
 - ★ Countermeasure
 - ★ Population
 - ★ ???



What do YOU think?



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Conclusions



Thank you!

- ◆ Your input is appreciated
- ◆ Your suggestions will be integrated into the previously identified requirements for the Countermeasure and Response Administration System



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