Bioterrorism and Other
Public Health Emergencies
Tools and Models for Planning and Preparedness

# Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness

**Prepared for:**

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20805
www.ahrq.gov

**Contract No. 290-02-0013-3**

1. **Prepared by:**

Weill Medical College of Cornell University, Department of Public Health

Nathaniel Hupert, M.D., M.P.H.
Jason Cuomo, M.P.H.
Mark A. Callahan, M.D.
Alvin I. Mushlin, M.D., Sc.M.

Columbia University Mailman School of Public Health, Center for Public Health Preparedness

Stephen S. Morse, Ph.D.

AHRQ Pub No. 04-0044
August 2004

**Suggested Citation:**
Hupert N, Cuomo J, Callahan MA, Mushlin AI, Morse SS. Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness. Prepared by Weill Medical College of Cornell University, Department of Public Health under Contract No. 290-02-0013-3. AHRQ Pub No. 04-0044. Rockville, MD: Agency for Healthcare Research and Quality. August 2004.

Funding to support development of the dispensing clinic concept and related computer models, as well as preparation of this report, was provided by the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, under Contract No. 290-00-0013.

Testing of the dispensing clinic concept and prototype computer models (Operation TriPOD, New York City, 5/22/02) was funded by the U.S. Department of Homeland Security, Office for Domestic Preparedness.

# Contents

## Figures



## Appendixes

# Executive Summary

Recent intentional and natural disease outbreaks in the United States, such as the 2001 anthrax attacks and the 2003 influenza season, have focused increased attention on the ability of state and local public health authorities to provide affected individuals and communities with rapid, reliable access to prophylactic medications.[1-3] In light of the substantial health risks posed by anthrax, influenza, and other bacteria, spores, toxins, or viruses, the U.S. Federal government has called on all states to devise comprehensive mass prophylaxis plans to ensure that civilian populations have timely access to necessary antibiotics and/or vaccines in the event of future outbreaks.[4-6]

The last five years have seen a major expansion of Federal assets to assist local public health providers in the planning and execution of mass prophylaxis campaigns for bioterrorism and epidemic outbreak response, including development of the Strategic National Stockpile (SNS), improvement in public health laboratory capabilities, creation of a national Health Alert Network (HAN), and implementation of the Cities Readiness Initiative (CRI).[5, 7, 8] However, none of these assets is intended to replace local first response capabilities or the need for comprehensive local plans for extended mass prophylaxis campaigns in the setting of a bioterrorist attack or natural disease outbreak.[9-13]

State, county, and local health authorities have been charged with the development of these plans, with financial and technical support of the Department of Health and Human Services Office of Public Health Emergency Preparedness (OPHEP) as well as the Centers for Disease Control and Prevention (CDC). This Planning Guide, which complements the CDC's Strategic National Stockpile Guidebook (especially Chapter 11 on dispensing operations), is intended to assist public health and emergency management officials in this task.[5]

Section One of this Guide provides an overview of the five components of a mass prophylaxis response to epidemic outbreaks: surveillance, stockpiling, distribution, dispensing, and follow-up. The next two sections focus on planning and conducting dispensing operations using specially-designated dispensing clinics, here called Dispensing/Vaccination Centers (DVCs) but also known as Points of Dispensing (PODs). These concepts are then put to work in developing sample antibiotic dispensing and vaccination clinic plans that can be "run" using a separate customizable computer planning model, the Bioterrorism and Epidemic Outbreak Response Model (BERM), developed in conjunction with this planning guide. The last section describes the implementation of a comprehensive operational structure for dispensing/ vaccination clinics based on the National Incident Management System (NIMS).

This planning guide is intended for multiple audiences. Section One should be of interest both to officials tasked with developing local response plans and to members of government, industry, academia, the media, and non-governmental organizations (NGOs) who may play important roles in support of these emergency public health activities. Sections Two and Three should be of interest to public health and emergency management planners from the local to national level. Finally, the description of the DVC command structure in Section Four demonstrates the application of NIMS to this critical public health emergency response role and may help non-public health emergency response professionals successfully contribute to DVC operations and management.

# Section One: Overview of Mass Prophylaxis

## 1. Mass Prophylaxis in Context

### A. Components of Outbreak Response

Effective public health response to a bioterrorist attack or other disease outbreak hinges on the ability to recognize the outbreak, mobilize supplies of needed materials to affected populations in a timely manner, and provide ongoing medical care for affected individuals.[14, 15] There are five distinct components of this response:

**1. Surveillance**

Surveillance activities may range from use of passive systems for detecting specific pathogenic microbes in the environment to development of syndromic surveillance programs to mine existing emergency medicine, primary care, or pharmaceutical databases to rapidly identify unusual clusters of suspicious symptoms.[16-19] Determination of appropriate trigger or action levels in these surveillance systems is an ongoing challenge for medical and public health personnel that will not be considered here.[20]

**2. Supply and Stockpiling**

Response capacity to a large-scale bioterrorist attack may be limited by the ready availability of antibiotics and/or vaccines.[21] For this reason, the Federal government has created the Strategic National Stockpile (SNS), composed of a number of ready-to-deploy "Push Packs" containing medical supplies to treat thousands of patients affected by the highest-priority disease-causing agents (the CDC Category A agents), as well as pre-designated pharmaceutical supply caches and production arrangements that may be used for large-scale ongoing prophylaxis and/or vaccination campaigns (Vendor Managed Inventory, VMI).[5, 22] Some large municipalities and medical facilities across the country also have developed smaller stockpiles and secure supply chains for critical antibiotics and medical materiel for use in terrorism response.[23-27]

**3. Distribution**

In the context of a mass prophylaxis response to bioterrorism, distribution refers to the logistics of transporting materiel such as antibiotics and vaccines from stockpile locations (e.g., the airhead where the SNS has been deposited) to dispensing centers where they are given to affected populations.[22]

**4. Dispensing**

Dispensing operations are the final step in getting prophylactic medications and vaccines to affected populations.[28] Dispensing center functions (described more fully in Section Two) include mass triage, medical evaluation of symptomatic individuals, pharmacotherapeutic consultation for drug or dosage adjustment if needed, and provision of antibiotics or vaccination.[29] Additional functions may include data collection, patient briefings, mental health or pharmacist consultations, and emergency transportation for patients requiring medical care.

**5. Followup**

Followup may include monitoring patients for antibiotic effectiveness or vaccine immunoresponse, identifying patients who require dose modification, and arranging alternative treatment for patients who have adverse effects from the prophylactic treatment.[30] As demonstrated after the 2001 anthrax prophylaxis campaigns, follow-up data gathering is also essential for determining compliance with recommended treatment regimens.[31-33]

## B. Dispensing operations and the role of Dispensing/Vaccination Centers (DVCs)

Dispensing of antibiotics and/or vaccines is a cornerstone of any mass prophylaxis campaign against outbreaks of preventable disease.[12, 21, 34-43] Without the ability to safely dispense large volumes of medications or vaccines to community-based individuals, efforts to improve surveillance, stockpiling, or distribution capacity will not translate into improved public health response.[44] Conversely, dispensing operations are critically dependent on these surveillance, stockpiling, and distribution functions for defining the prophylaxis mission to be accomplished and for supplying the medical materiel necessary for its successful completion.

There are two conceptual approaches to mass prophylaxis: “push” and “pull”. The “push” approach, exemplified by the recent Memorandum of Agreement between the Department of Health and Human Services (DHHS) and the U.S. Postal Service, consists of bringing medicine directly to individuals or homes in an affected community.[45] The “pull” approach, in contrast, requires that individuals leave their homes or places of work in order to travel to specially designated centers where they can receive medications or vaccinations.[28, 39, 43] Each approach has strengths and weaknesses. The “push” approach may enable faster and more widespread coverage of an affected community, but it has little flexibility to handle medical evaluation for contraindications or dosage adjustment and may be infeasible for vaccination campaigns.[31] The “pull” approach may increase efficient use of scarce health care providers and resources, enable medical evaluation of potential victims, and provide opportunities for centralized data collection and law enforcement investigation (in the setting of a known or suspected bioterrorism event).[46, 47] However, these advantages must be weighed against the delays and logistical challenges of setting up sufficient dispensing centers to handle high patient volumes.[48, 49]

It is likely that in large-scale outbreak response, elements of both “push” and “pull” strategies will be utilized. For example, in addressing the needs of homebound or institutionalized individuals in a community, a “push” approach may be preferred to avoid complex transportation requirements in the midst of a public health crisis. Alternatively, even if a “push” approach is used to provide the majority of community residents with antibiotic prophylaxis, a small number of dispensing centers may be established to handle specific sub-populations (e.g., first responders and their families, tourists, etc.).[50]

As of this writing, "push" approaches to mass prophylaxis remain at an early planning stage. For that reason, this planning guide will focus on "pull" strategies using specialized dispensing centers. In local and national planning documents, these centers have been given a variety of names and acronyms. We use the term Dispensing/Vaccination Center (DVC), though a competing (and perfectly acceptable) alternative name is Point of Dispensing (POD).[5, 43] We have chosen not to use POD due to potential confusion with the term Point of Distribution, which refers to the local or regional site for unloading and breaking down antibiotic stockpiles shipped from the Strategic National Stockpile or other sources (this is also called the Receipt, Store, and Stage (RSS) site).

In the "pull" model of mass prophylaxis, the Dispensing/Vaccination Center is the principal operational unit of the dispensing function of community-wide disease outbreak response.[40] A DVC is a single dispensing site that can be free-standing or located in a pre-existing building such as a school. Any mass prophylaxis plan involving the use of DVCs must have at least these two components:

- A description of the command, operational, and logistical requirements for the deployment and operation of a single DVC

- A description of the command, operational, and logistical requirements for a scalable response involving multiple DVCs to achieve timely community mass prophylaxis.

Factors such as the size and nature of the release of disease-causing agents and the availability of local and Federal resources and personnel will determine whether the initial response to a bioterrorist attack or natural disease epidemic consists of the establishment of one, several, or many dozen DVCs. The stockpiling and distribution components of a public health emergency response plan need to be similarly scalable to maintain a reliable and adequate supply of antibiotics, vaccines, and other medical materiel to these DVCs.

CDC maintains the Strategic National Stockpile (SNS) and provides technical assistance on dispensing operations to local public health and emergency management planners throughout the United States. However, the SNS and its support staff do **not** constitute a stand-alone first response operation.[5] Similarly, the National Disaster Medical System (NDMS) has been established by the Department of Health and Human Services to provide rapid response capability for medical disasters throughout the United States, but this system as well is not designed to supplant comprehensive local planning and operations for mass prophylaxis campaigns.[51]

Instead, these Federal assets and resources are intended to build on the local and regional first response infrastructure (that is, personnel and planning, but <u>not</u> necessarily stockpiles) for carrying out mass prophylaxis. The basic rule of community-wide mass prophylaxis is:

***Every public health jurisdiction in the country has the responsibility to develop and maintain the capability to carry out first response and ongoing (Federally assisted) mass antibiotic dispensing and vaccination campaigns tailored to its local population.***

There are at least four separate reasons underlying this rule:

- Local mass prophylaxis activities (e.g., plan activation, DVC set-up, and possibly limited prophylaxis of select groups like hospital employees) will need to be underway prior to the arrival of any Federal assets.

- Federal or state assistance is very unlikely to include sufficient personnel to fully command or staff community-wide mass prophylaxis dispensing operations.

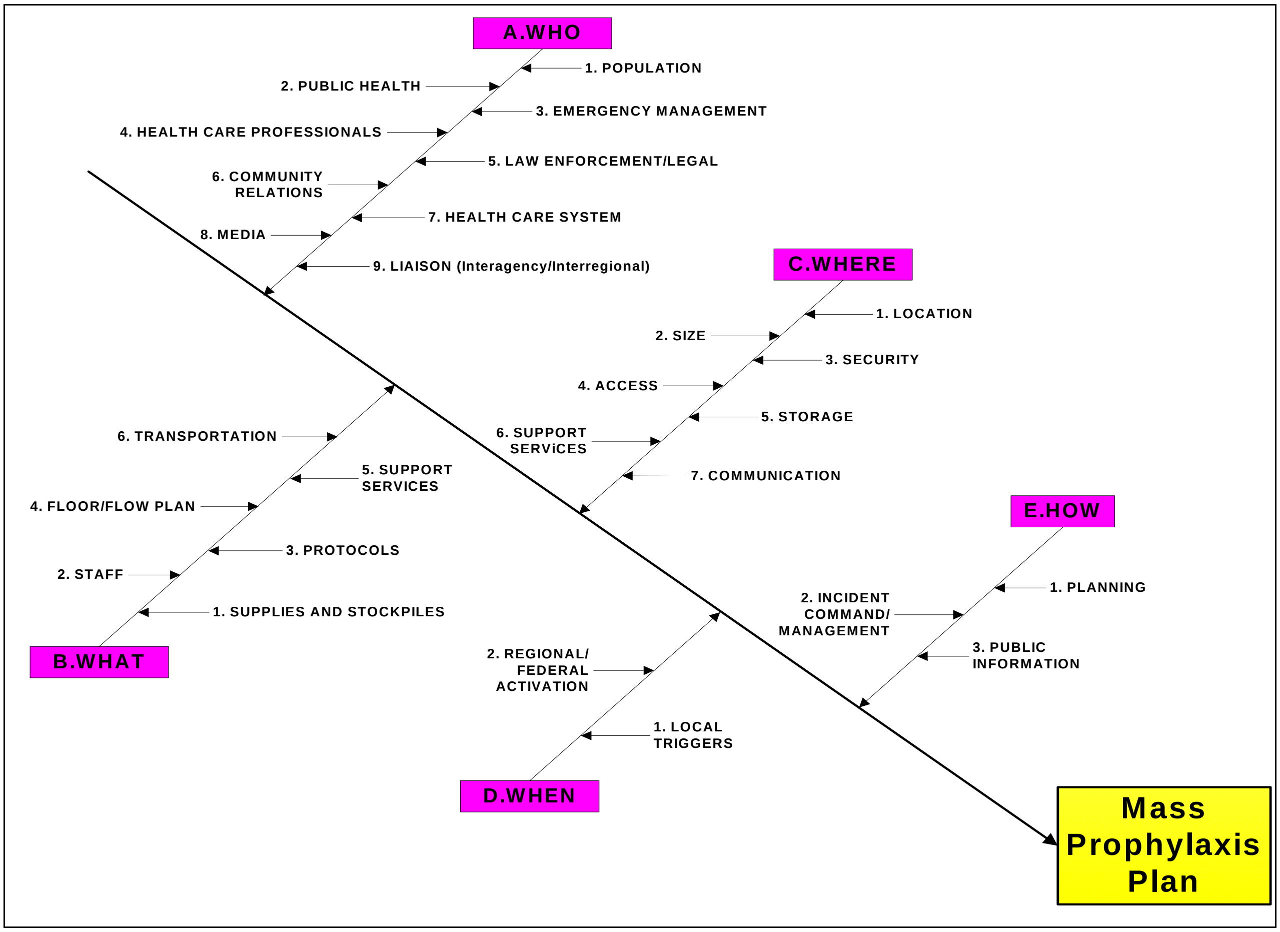
- DVC operation may likely remain under local control even after Federal and/or state assets are delivered.

- Dispensing and follow-up operations may continue after the departure of Federal or state assets.

# 2. Overview of Planning For Mass Prophylaxis Using DVCs

The purpose of this Chapter is to survey the major issues that factor into the creation of a successful mass prophylaxis plan. This information will provide readers with a general understanding of the complex issues involved in designing community-based dispensing operations. It also serves as a primer for Sections Two and Three, which are written for a more technical audience involved in development of local DVC plans. Figure 1 shows an outline of this Chapter:

**Figure 1: Elements of a Local Mass Prophylaxis Plan**




## A. Who Are The Stakeholders?

Many significant stakeholders should be included in planning for civilian bioterrorism response.[9] We focus here on the nine local stake-holding groups who are essential to the planning and operation of a mass prophylaxis plan in an emergency setting.

## 1. Population

Planning starts with an understanding of the covered community.[52, 53] Demographic, medical, and ethnographic information is critical to developing DVC floor plans (e.g., taking into account accessibility issues and typical family size), drug dosing schedules (e.g., age distribution), and information dissemination activities (e.g., translation services for non-English-speaking populations). Population density may be the chief determinant of choice of DVC sites (see Item C, below). Since DVC operation would require population-wide cooperation with directives to proceed to specific sites for triage and prophylaxis, community representatives should be involved at the earliest planning stages in order to increase the likelihood of community buy-in to DVC plans (See Number 6, below). Prophylaxis for home- or institution-bound individuals (e.g., nursing home residents, jail and prison inmates) requires specific additional planning that is not covered in these guidelines. The prophylaxis needs of these populations may be best addressed through pre-existing delivery systems (e.g., U.S. Postal Service, visiting nurse services, prison health systems) operating within a "push"-style mass prophylaxis framework but separately from community DVC activities.[45]

## 2. Public Health

The Federal government is working collaboratively with state and local public health officials to develop mass prophylaxis plans for bioterrorism response. The Strategic National Stockpile (SNS) Program was developed to assist states and communities in responding to public health emergencies. The SNS Program ensures the availability of medicines, antidotes, medical supplies, and medical equipment necessary for states and communities to counter the effects of biological pathogens and chemical nerve agents. The SNS Program stands ready for deployment and will arrive within twelve hours to any location across the nation to augment medical resources, treat symptomatic individuals, and provide prophylaxis therapy in support of efforts at the state and local level.

The Centers for Disease Control and Prevention's (CDC's) cooperative agreement on public health preparedness and response for bioterrorism provides funding to upgrade state and local public health jurisdictions' preparedness for and response to bioterrorism, other outbreaks of infectious disease, and other public health threats and emergencies. Funding through this cooperative agreement is also being used to implement the Cities Readiness Initiative (CRI), which will help save lives through timely delivery of medicines and medical supplies during a large-scale public health emergency. Twenty cities and the National Capital Region (District of Columbia) have been chosen to participate in this pilot program. These cities have been chosen based on their population and geographic location.

The CRI will provide direct assistance to cities to help them increase their abilities to receive and dispense medicine and medical supplies from the Strategic National Stockpile. As a result of this pilot program, plans from all levels of government (federal, state and local) will be unified to ensure a consistent, effective and timely response in the event of a large-scale public health emergency. CRI will help ensure that cities are able to use all the resources available to them for emergency response and preparedness efficiently and effectively.

Continued collaborations between the federal government and local and state public health officials are essential for developing mass prophylaxis plans for bioterrorism response. Public health practitioners bring a diverse skill set to mass prophylaxis and DVC planning, including expertise in epidemiology, health policy and law, health and risk communication, and diagnosis and treatment of medical and psychiatric disease.

### 3. Emergency Management

Emergency management officials bring expertise in emergency response and operational command structures to public health planning.[54] They also bring a broad perspective on incident management and have an understanding of existing infrastructure and resources in the community.[55] In addition, these professionals may have experience in directing interagency response operations.

### 4. Health Care Professionals

Health care professionals, including nurses, pharmacists, emergency service providers, and physicians, have detailed technical knowledge that can inform planning at numerous stages along the prophylaxis pathway (e.g., triage, materiel storage and packaging, medical evaluation, drug dosing).[11, 56-58] Additionally, since DVCs may be intended to supplant normal health care venues in the setting of a bioterrorist attack (at least initially during the prophylaxis stage), an important aspect of DVC planning involves determining the optimal role for community health professionals during the mass prophylaxis response.[59] If these professionals are expected to participate directly in triage, evaluation, and dispensing activities, planning should include development of educational material and in-service training sessions directed at health care providers. Even if community health professionals are not expected to have direct patient care responsibilities in DVC operations, their cooperation is essential for educating patients about mass prophylaxis, providing appropriate directions to prophylaxis sites during an event, and providing follow-up care after an attack.

### 5. Law Enforcement/Legal

A bioterrorist attack would be both a public health emergency and a crime, so law enforcement would have three distinct tasks in a mass prophylaxis response: maintaining the safety and security of both patients and medical stockpiles during the prophylaxis response, maintaining public order generally, and carrying out a criminal investigation of the attack.[46] These three tasks may need to occur simultaneously at each DVC, requiring extensive pre-planning and coordination between law enforcement and public health authorities to ensure proper resource allocation. Additionally, many aspects of DVC planning and operation will involve legal issues that should be carefully evaluated prior to any event (e.g., pharmaceutical dispensing waivers, memoranda of understanding, emergency declarations, etc.).[60]

### 6. Community Relations

Effective planning can make the public a valuable asset during disease outbreak response.[61] Mass prophylaxis would require the rapid and coordinated mobilization not only of persons living in affected communities but also of ancillary service staff (e.g., food preparation and janitorial personnel) to support DVC activities. Community outreach should:

- Identify key non-media points of information dissemination in the community (e.g., community centers, civic clubs).
- Assist emergency management professionals in creation of inventory lists of non-governmental resources that may be donated or lent in the event of an attack (e.g., volunteers, transportation vehicles, communication devices).
- Educate the public about the general features of a mass prophylaxis response to natural or intentional outbreaks of disease.
- Utilize the expertise and resources of established community-based organizations such as the American Red Cross.

### 7. Health Care System Representatives

Traditional health care facilities such as hospitals and medical clinics may not be optimal sites for DVC activities because of the need to maximize space in these facilities for the treatment of mass casualties.[55] Nevertheless, each DVC must have direct communication and transportation linkages with health care facilities capable of evaluating and treating both severe attack-related illnesses and adverse reactions to the antibiotics or vaccines administered in the DVCs.[23, 62] For that reason, representatives of local and regional health care delivery systems (hospitals, multi-specialty clinics, rehabilitation facilities, long-term care facilities) may provide important assistance with certain aspects of mass prophylaxis planning and should be included in the development of DVC plans.[63] Additionally, communities may want to prioritize prophylaxis of hospital staff and their family members in order to maintain maximum operating capacity in the early days of an attack.[64]

### 8. Media Representatives

Effective collaboration with local media is essential for community preparedness.[65] Harnessing multiple modalities for information dissemination (e.g., radio, television, Internet) in the early hours of a bioterrorist attack or other disease outbreak may greatly improve the chances of effective community mobilization.[4] This requires not only close collaboration between public health and emergency management officials and the media in the (pre-event) planning stages, but also the creation of ready-to-air response scripts for immediate distribution to media outlets.[53]

### 9. Liaison (interagency and inter-regional)

Mass prophylaxis will constitute one of many response activities initiated by local, regional, state, and Federal government agencies in the setting of a bioterrorist attack or major disease outbreak.[66] Interagency coordination in these activities will prevent unnecessary duplication or unexpected absence of services (e.g., in transportation and security details for DVCs), and inter-regional coordination will minimize competing claims for scarce resources (e.g., for SNS materiel in adjacent counties affected by an attack).[4, 67, 68]

## B. What Resources Are Required?

Each DVC site requires, at minimum, the following:

### 1. Supplies and Stockpiles

Setting up and operating a DVC requires a range of generic office and medical supplies in addition to specialized items like signage and medications. Over the last year, several U.S. communities have developed checklists and even pre-stocked trailers for rapid deployment of one or multiple DVCs.

Once requested, assets from the Strategic National Stockpile are likely to arrive in less time than it takes to set up a network of fully functional DVCs.[69] Each DVC must have a well-defined supply route linking it to the Receipt, Store, Stage (RSS) site for these SNS materials as well as to any local stockpiles. Most local stockpiles are pre-designated for use by local first responder, hospital, and emergency management personnel to ensure that they are ready to work with the public as soon as or before Federal assets arrive.

On-site stockpile management requires ability to ensure proper storage (e.g., coolers), inventory management, and security of supplies. If the DVC is dispensing antibiotics or vaccines under Investigational New Drug (IND) protocols, local staff may have to track patients to whom those supplies are distributed. However, recent legislative proposals call for the creation of Emergency Use Authorizations to facilitate rapid dispensing of "off-label" or investigational medicines and vaccines in the setting of mass prophylaxis (e.g., Project BioShield, press release at http://www.whitehouse.gov/news/releases/2003/02/20030203.html).

### 2. Staff

DVC staff fall into two categories: those engaged in direct patient interaction (or "core staff") and those providing support functions. (Details of the DVC core and support staff are covered in Section Two, Part 3.B, while DVC command structure is covered in Section Four.) Core staff may operate in one of three areas: medical (including triage, medical evaluation, and emergency medical service (EMS)), psychiatric (for acute and sub-acute evaluation and counseling), or pharmacotherapeutic (for dispensing and evaluation of patients with drug contraindications or other complicating factors). EMS staff may be needed to stabilize seriously ill patients who are direct casualties of an attack or outbreak, patients with exacerbations of chronic medical conditions like asthma or cardiac disease, or patients who experience severe adverse reactions to dispensed medicines or vaccines. These patients may require transfer to health care facilities, as described in Item 6, below. Support functions include DVC security, communications, custodial services, and site management.

### 3. Protocols

All DVC activities should be protocol-driven to the greatest extent possible to achieve maximum efficiency and standardization. At least four protocols are needed for DVC operation: **triage**, **medical evaluation**, **pharmacotherapeutic evaluation**, and **mental health evaluation**.[29, 56, 70-72] Of these, the first three may change depending on the attack agent(s), with corresponding changes in pharmacotherapeutic or vaccination response strategies. The last, focusing on assessment and management of anxiety, grief, and panic reactions, will be applicable to most, if not all, bioterrorism and epidemic outbreak scenarios.

### 4. Floor/Flow Plan

The DVC plan should include a basic floor plan and description of station-to-station patient flow under normal operation (e.g., precisely how patients are supposed to proceed from triage to dispensing). Optimally, all DVCs in a community should share the same basic layout, thereby streamlining related agency planning activities (e.g., law enforcement) and ensuring interoperability of staff between different DVCs. This will simplify training and improve the operational flexibility of staff. As detailed in Section Two of this guide, DVC planners will need to design patient flow patterns to minimize bottlenecks and optimize staff allocation.

### 5. Support Services

Since DVCs may be open 24 hours a day for many days in a row, planners need to consider support services for staff including food preparation, rest areas, toilet facilities, and counseling.[5] Additionally, toilet facilities should be identified for the public and staff both inside and outside each DVC. Since clinic operation will likely include a variety of minor medical procedures that may produce biohazardous waste (e.g., initiation of intravenous lines for patients requiring transport to health care facilities), clinic services should include medical waste disposal.

### 6. Transportation

Each DVC should have access to vehicles to transport casualties and patients with acute illnesses identified through the DVC triage process and for people who have immediate adverse reactions to the medications or vaccinations administered in the DVC. Transportation capability for transferring subacute patients to health care facilities (e.g., by municipal bus) may minimize crowding at the DVC site.

## C. Where Will It Take Place?

### 1. Location

Choice of DVC sites should be guided by knowledge of local population density and proposed location of stockpile staging and distribution sites (called the Receipt, Store, and Stage (RSS) or Point of Distribution (POD) sites). In the absence of complicating factors (e.g., environmental contamination preventing DVC set-up in a given locale), DVCs should be situated so as to minimize transportation required for both people and medical materiel. Ideally, these locations will be familiar to local populations and can be rapidly demobilized and returned to their original use after the event.[73] Locations that may have unintended stigma attached to them (e.g., STD treatment facilities) or that have special cultural significance (e.g., religious institutions) may pose challenges as sites for mass prophylaxis efforts. Contingency (secondary or tertiary) sites should be identified in the event of unavailability of primary sites.

**2. Size**

Optimal DVC size will vary, depending on a number of population-, outbreak-, and staff-related factors (see Section Two for detailed discussion of these factors and their impact on DVC design). To simplify selection of DVC sites, planners may begin by cataloging all sites that meet a set of requirements, such as a recognizable physical dimension (e.g., area of a basketball court).[38]

**3. Security**

DVC sites should have a both an outer and an inner perimeter that can prevent wholesale movement of crowds into the dispensing area. Additionally, the inner perimeter should have only a limited number of controlled entry and exit portals. DVC sites also must have internal storage and drug or vaccine preparation areas that can be secured during clinic operational hours (See also Section Two, 3.B.8).

**4. Access**

DVCs should be accessible by forms of transportation that are common to the community (e.g., automobile for rural and suburban settings, mass transportation for urban settings). When scouting for potential DVC sites, planners should consider handicapped accessibility issues to provide coverage for people with impaired mobility.

**5. Storage**

DVC sites should have facilities for controlled storage of antibiotics and vaccines, including electrical outlets for cold storage containers requiring external power supplies.[5] In addition, these sites should have separate areas for storage of medical supplies, communication equipment, and information dissemination material, which may require different levels of security.

**6. Facilities support**

Proposed DVC locations should have space for safe removal and temporary storage of medical waste, on-site potable water supply, electrical wiring capable of supporting multiple electrical and electronic appliances (e.g., coolers, computers), and restrooms. Food preparation facilities are not necessary, but additional securable space for this function is desirable in order to provide respite to staff.

In light of recent large-scale disruptions of electrical grids on both the east and west coasts of the United States and the possibility that future terrorist attacks may involve multiple (biological and non-biological) threats, it is critical to ensure that proposed dispensing sites have both backup power generation capacity and backup fuel delivery arrangements for those generators. This applies especially to DVCs that are intended for 24–hour operation.

**7. Communications**

DVC locations should have land-line phone capability to supplement cellular, radio, and satellite communications, which may be unavailable or overloaded during a terrorist event.[74] Additionally, preexisting video and audio equipment (e.g., school audio-visual equipment) may reduce logistical burdens when planning staff training and public briefings at the DVC sites.

## D. When Will It Be Needed?

**1. Local triggers**

Local public health and emergency management officials may initiate the rollout of full community-wide or more targeted mass prophylaxis plans using DVCs in response to local triggers such as the isolation of an unusual disease-causing organism in multiple patients (for example, in an outbreak of meningococcal meningitis).[16, 19] If SNS assets are not requested, initiation of a local DVC plan does not require specific state or Federal authorization. However, SNS requisition must follow the chain of command established by CDC. Furthermore, any event involving suspicion or confirmation of bioterrorism will trigger a Federal criminal investigation.[4] Local response capacity may be limited by the amount of local pharmaceutical supplies (e.g., of prophylaxis caches for hospital staff and their families in the setting of an infectious disease outbreak).

**2. Regional/Federal Activation**

Local DVC plans may be activated by regional, state, or Federal authorities in response either to perceived threats to public health or to actual release of pathogenic material.[75] While activation may be triggered at higher levels of government, DVC deployment and operation will remain under local control. Local planners need to establish clear procedures for confirmation of and response to such activations.

## E. How Will It Work?

**1. Planning**

Mass prophylaxis planning involves the identification of stakeholders, resources, sites, and triggers for DVC activation (items A-D above). DVC planners are responsible for developing complete operational plans for individual DVCs as well as plans to integrate multiple DVCs in a large-scale response (See Figure 2). The full spectrum of activities to achieve activation, maintenance, and demobilization of each DVC should be addressed. It is important that plans have inherent flexibility to adapt to unexpected changes in the unfolding events. Finally, these plans should incorporate an incident command system which in turn should be an extension of the community emergency management structure (for a description of incident command systems, see Section Four).

## 2. Incident Command/Management

DVC management and command structure should be addressed during the early stages of planning. An effective DVC command structure should have the following characteristics:

- Pre-defined roles and responsibilities for all staff
- Clear and uniform chain of command
- Scalability to meet the needs of an increasingly or decreasingly resource-intensive prophylaxis campaign
- Flexibility to respond to unanticipated variables
- Integration into the community's emergency management system or Central Command and Control function (e.g., as spelled out in the National Incident Management System[74])

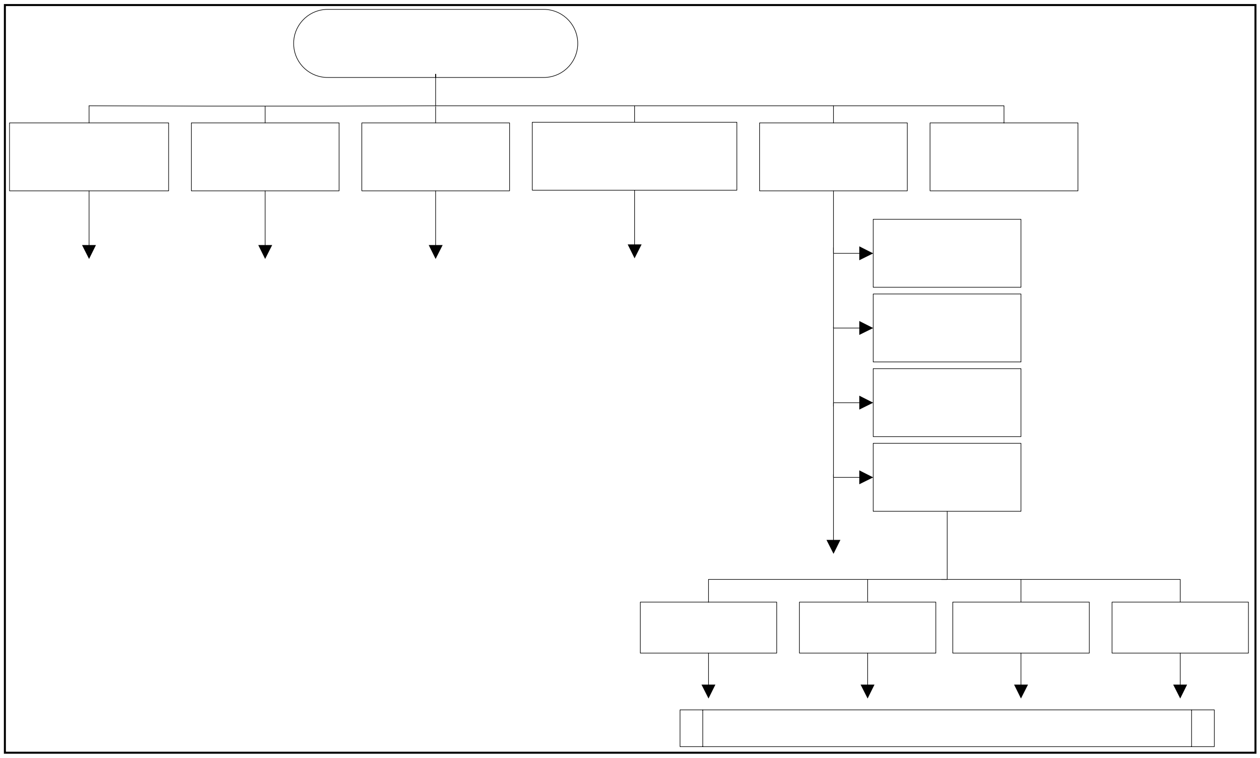
The Incident Command System (ICS) and Incident Management System (IMS) serve as widely-recognized and time-tested command systems upon which to base DVC management.[74, 76] Section Four of this guide presents a detailed IC/MS-based management outline for DVC operation that addresses these requirements.

## 3. Public Information

To promote community buy-in of a mass prophylaxis campaign, the public must be fully informed of the reasons for such a campaign as well as the community's role in ensuring its success.[65, 77, 78] The public should be made aware of key procedures and responsibilities for community bioterrorism response *prior to the initiation of a mass prophylaxis campaign.*[79]. This may include publicizing the ways in which the public would be assigned to DVCs (e.g., organized by zip code, last name, etc.), the expected DVC processes (e.g., education followed by prophylaxis), and post-DVC responsibilities (e.g., follow-up with a local health provider). Local print, radio, television, and Internet media representatives should be included in this planning process to develop uniform public messages. Finally, training materials for DVC staff and the general public should be developed early in the planning process in order to minimize DVC operational start-up time in the event of activation.

Many emergency management experts recommend against pre-publicizing the proposed locations of DVCs, since this information may change prior to or during a mass prophylaxis event, thus precipitating confusion. Emphasis instead should be placed on ensuring that planners have robust means of communicating exact clinic locations in an emergency setting.

**Figure 2: Schematic of the Command Structure of a Mass Prophylaxis Campaign**



# Section Two: Fundamentals of Dispensing/ Vaccination Clinic Design

Whenever possible, planners should develop a single generic DVC design (including floor plan and patient flow plan) for use throughout their community. Having a single master DVC plan will simplify training and improve interoperability of staff, increase the ability to forecast patient flow and therefore resupply needs, and maintain flexibility to uniformly alter all DVCs in response to unfolding events.

DVC design may range from very simple to extremely complex, depending on the nature of the event, requirements of the response, and time frame for action. This Section covers general DVC functions, important factors that affect the efficiency and accuracy of mass dispensing operations, and methods for estimating patient flow through a single DVC and network of DVCs. This planning guide may be used in conjunction with a computer-based interactive spreadsheet model (the Bioterrorism and Epidemic Outbreak Response Model, or BERM) that allows users to calculate the number of personnel required to operate DVCs using either an antibiotic dispensing or a vaccination design.[84] The model allows the user to study the relationship between various population- and attack-related variables and DVC staffing requirements.

## 3. DVC Concept of Operation

DVC operations may be divided into **core** and **support** (or "non-core") **functions**. Core functions include all processes that directly facilitate the dispensing of drugs and vaccines and almost always involve one-on-one interaction between staff and patients. Exceptions include distribution of forms and patient briefings, in which one staff member may interact with a large number of people at once. **Core stations** are sites within the DVC where core functions take place. Support functions include all the processes that take place in the DVC that are critical in supporting the core stations. These tasks range from medication or vaccine resupply to security to command and control. Core and support staff are equally important to the overall success of the DVC plan.

### A. Core Functions

Core functions are also called "Operations" when using Incident Management terminology.

**1. Greeting**

Greeters have the dual role of directing people into the DVC and also screening the crowd (visually and/or via direct questions) for obviously ill patients who require immediate medical evaluation (i.e., skip steps (b) and (c), below) or individuals at higher risk for exposure (i.e., if time and location of exposure is known).

## 2. Form Distribution

Most DVC plans will include some type of data collection using forms filled out by patients.[40, 56, 71, 80] These forms serve multiple purposes, including guiding triage (e.g., by asking all those who checked off a certain box or set of boxes to proceed to medical or mental health evaluation) and facilitating follow-up (e.g., by asking for contact information).

## 3. Triage

Triage involves using patient-completed forms (see (b), above) or protocol-based questions to identify people requiring medical evaluation and/or, depending on DVC design, mental health evaluation.[29, 70, 81, 82] People who screen negative at triage can proceed directly to the dispensing station. Since it is protocol driven, triage does not necessarily need to be performed by health care professionals.

## 4. Medical Evaluation

Acutely symptomatic individuals or those who have symptoms suggestive of illness due to the attack may require evaluation by health care professionals, preferably staff who are experienced in evaluation and stabilization of sick patients (e.g., paramedics and emergency department nurses as well as physicians).[43] Depending on time, resource availability, and linkages to health care facilities, medical treatment at DVCs may include initiation of antibiotics and other interventions prior to transport for seriously ill patients.

## 5. Transportation Assistance

Patients deemed seriously or critically ill will require assistance getting into vehicles (e.g., ambulances, buses, vans) that can provide transportation to tertiary care or other higher level care facilities. The extent and complexity of potential DVC-based treatments for these patients (e.g., whether to start intravenous antibiotics for a suspected anthrax victim) will depend on the estimated time needed for transfer from the DVC to the definitive care facility.[50]

## 6. Mental Health Evaluation

If mental health activities are located in the DVC, they may vary from simple evaluation and treatment of acute panic and stress reactions to more extensive counseling for grief and depressive symptoms in the aftermath of an attack.[72] The type, extent, and proper location of mental health evaluation in the DVC will vary based on details of the disease outbreak, time frame for response, space, and availability of trained mental health practitioners who can participate in DVC activities.[83] More elaborate DVC plans may call for separation of acute and non-acute mental health stations.

## 7. Briefing

Briefings may improve compliance with medical regimens, decrease mental stress due to the event, and in some cases may be required by regulation (e.g., with Investigational New Drug

(IND) protocols).[5] Additionally, briefings may provide information about referrals to off-site counseling. Briefings should take advantage of the standardization and flexibility provided by pre-taped video/audio presentations, although these require additional resources and technical support (e.g., translation into multiple languages). The size and number of briefing rooms and the duration of briefings may limit the maximum rate of patient flow through a DVC, as described below in Section 7.A.1.

### 8. Drug Triage (Pharmacotherapeutic Evaluation)

The purpose of drug triage is to rapidly identify people who require any drug regimen other than the standard drug type and dose (e.g., patients requiring a medication other than adult dose doxycycline for anthrax prophylaxis). Drug triage questions may be part of the written information form filled out at entry to the DVC (see (b), above) or asked of patients arriving in the dispensing area.[56, 71] Families with children may be identified at drug triage for further assistance to determine pediatric dosages.

### 9. Dispensing or Vaccination (Express vs. Assisted)

Patients may be directed to a single dispensing station that has staff available for pharmacotherapeutic consultation or, alternatively, to one of two dispensing areas designed to handle uncomplicated (“Express”) or complicated (“Assisted”) dispensing cases. Large DVCs with sufficient staff may achieve greater efficiency by establishing a separate dispensing line for people whose drug triage evaluation suggests the need for dose modification or an alternative drug. Assistance may include determining the correct type and dose of antibiotics for adults with reduced kidney function or medication allergies, or for children based on age, weight, and/or height as well as history of allergic reactions. Communities may opt to allow one person (e.g., the head of a household, the spouse or friend of someone who has a mobility impairment, etc.) to pick up medications for persons other than themselves; these cases may take additional time and should be directed to the “Assisted” dispensing area.

All DVC plans should include some mechanism for quality assurance, such as designating a pharmacist or other health care professional to monitor the accuracy with which antibiotics or vaccines are being dispensed.

### 10. Form Collection and Exit

Although patient information forms may have been used for triage purposes inside the DVC, exit staff may still be needed to check the accuracy of contact information as patients leave. Additionally, exit staff may be able to provide details of follow-up care, reinforce compliance messages, and even perform “spot check” for quality assurance (e.g., checking whether patients are receiving the correct medications).

## B. Support Functions

Support functions are also called "Logistics" when using Incident Management terminology.

### 1. Drug/Vaccine Inventory, Preparation, and/or Re-supply

CDC SNS supplies both unit-of-use antibiotic regimen bottles and bulk supply of antibiotics and vaccines that can be repackaged at central materiel distribution centers such as the Receipt, Store, and Stage (RSS) site. Inventory support staff at each DVC will be responsible for restocking dispensing stations with ready-to-use doses of ntibiotics and/or reconstituted vaccines. Re-supply staff should receive training in cold-chain techniques and proper use of mobile cold storage devices (e.g., Vaxicools).

### 2. Patient Traffic Directors

DVC sites and entry points must be externally identified using appropriate signage (e.g., using relevant languages in areas with non-English speaking populations). Inside the DVCs, personnel are needed to help direct patients from station to station and to assist in managing crowds when bottlenecks form.[40]

### 3. Data Entry

Data entry staff may be needed to transfer patient information from written forms to computerized databases to facilitate epidemiological investigation of the attack, assessment of the mass prophylaxis campaign, and follow-up care for treated patients.

### 4. Translation services

Planning for translation services includes ethnographic evaluation of covered populations and identification of personnel who will be available to provide appropriate translation services under crisis conditions.

### 5. Communications/Information Technology Support

Secure and reliable communication links inside each DVC, between different DVCs in a given community, and from DVCs to a central Command and Control center are critical to the successful implementation of any DVC plan. In addition, key DVC operations including inventory management and data entry may require computer support and secure Internet access for web-based services.

### 6. Food Service

Local factors will determine whether DVCs can support on-site food preparation and/or distribution for staff. If not, planners will need to find alternative means of providing meals, snacks, and beverages during DVC activations.

### 7. Facilities Maintenance

The need for facilities services will depend in part on the extent of on-site food service and/or preparation, but extends to maintenance of toilet facilities for both staff and patients, as well as facilities for and staff trained in proper disposal of contaminated medical waste.

### 8. Security

DVC security includes maintaining crowd control both outside and inside the DVC as well as securing medication stocks, confidential patient information, and communication and computer equipment inside the DVC. Additionally, security staff are needed to ensure the personal safety of DVC staff. While the past several years have seen increasing attention by the public health community to these security needs for mass prophylaxis campaigns, there is as yet no consensus on the number of individuals required to achieve these goals. One approximation (derived from live exercises at several U.S. sites with the SNS training package (the "TED") is that for every 4 to 5 core staff assigned to the DVC there should be approximately 1 security staff.

### 9. Managers

DVC managers are considered support staff because they do not have direct patient care responsibilities. However, the command staff may be thought of as a separate work group. Section Four of these Guidelines provides a description of a model command structure for DVC operations.

# 4. DVC Design and Patient Flow

This chapter reviews a number of possible clinic layouts (also called patient flow diagrams) to help local DVC planners develop a DVC-based mass prophylaxis plan that is appropriate for local needs, including population size, staff resources, and response time frame.

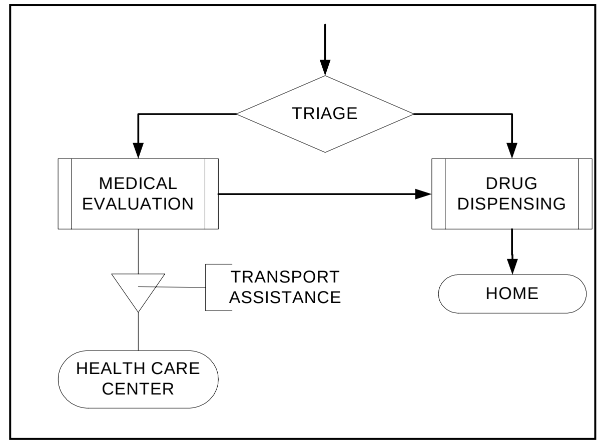
## A. Patient Flow Plans

One of the first tasks for mass prophylaxis planners is to determine which core stations will be included in the basic DVC plan for their community and what the physical arrangement of those stations will be in each DVC. The choice of core stations for a given DVC design depends on a number of factors, including the target patient flow rate (larger, more complex station arrangements will inevitably lead to slower patient throughput), the availability of personnel to adequately staff those stations, and the physical space for DVC activities. The patient flow diagrams shown below illustrate DVC designs of increasing complexity. Note that while increasing complexity generally requires increased staff and time, it does allow for valuable (and perhaps necessary) additional processes, such as data collection.

## 1. Diagram 1: Basic High Flow Model

Very high patient flow rates would require streamlining of many DVC functions in order to decrease the total processing time of the average patient to the minimum needed to accurately dispense medications and/or vaccines. The most basic "high-flow" DVC design is pictured at right. It consists of only four core stations (**triage**, **medical evaluation**, **transport assistance**, and **drug dispensing**). Note that this DVC does not include stations that may be required (e.g., briefings) or considered useful given the nature of the event (e.g., distribution and collection of data collection forms).

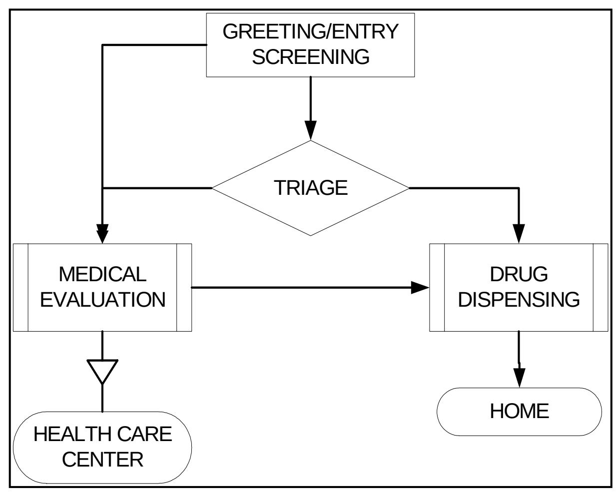
**Diagram 1**




## 2. Diagram 2: High-Flow with Entry Screening

This diagram shows the addition of a **greeting and screening** station to the basic four-component plan. This would facilitate rapid identification and isolation of symptomatic patients in the setting of an outbreak of a contagious illness or in the case of a rapidly fatal disease such as anthrax. This floor plan was used to attain patient flow rates of over 1,000 per hour in the high-flow antibiotic dispensing exercise called Operation TriPOD in New York City (May 22, 2002).

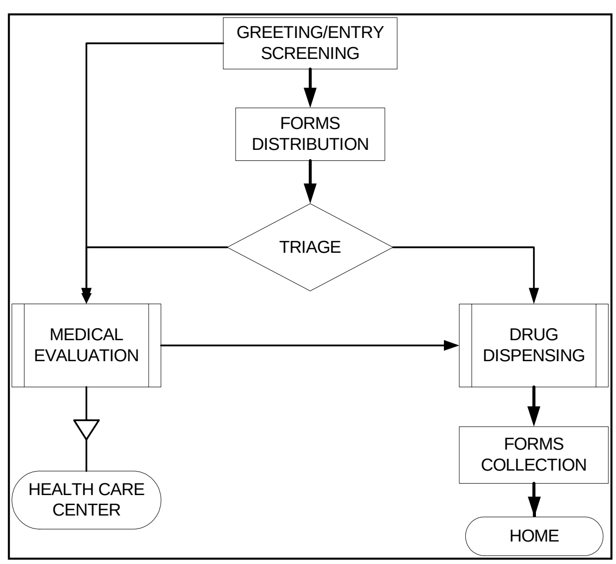
**Diagram 2**




## 3. Diagram 3: Form Distribution and Collection

This layout includes stations for **form distribution** prior to triage and **form collection** directly prior to exit. In addition to allowing data collection for epidemiological and medication follow-up purposes, patient forms may be designed to facilitate triage and medical evaluation. Forms with "check-off" boxes listing medical contraindications and potential drug interactions may eliminate the need for repetition at subsequent stations. Staff may annotate these forms as a convenient way of communicating with other

**Diagram 3**

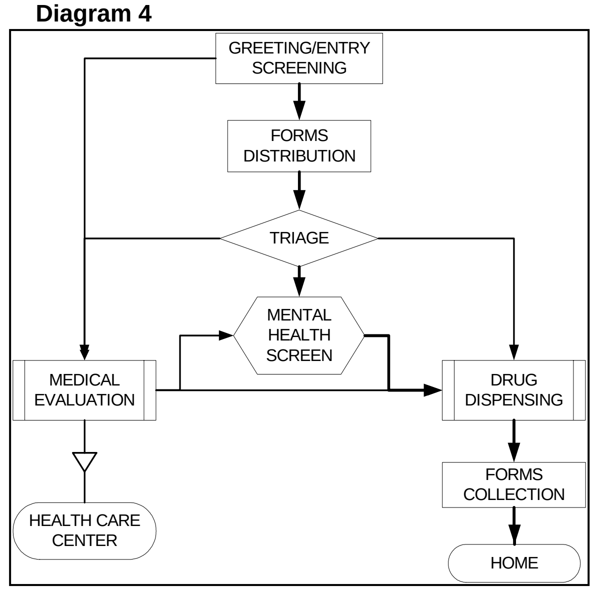


(downstream) DVC staff regarding patient management (e.g., a patient who checks off a potentially conflicting medication may have that box highlighted at triage in order to let the specialists in the medical evaluation station know why the patient had been sent over for further management).

### 4. Diagram 4: Mental Health Evaluation

This layout includes a **mental health evaluation** station located after triage and before drug dispensing. Patients with acute and/or debilitating symptoms of panic, fear, etc. in response to a large-scale disease outbreak or bioterrorism event may not be in a position to comprehend and follow even straightforward medical regimens. For this subset of patients, mental health crisis counseling may improve their ability to comprehend medical instructions and successfully utilize prophylactic medications.

Diagram 4

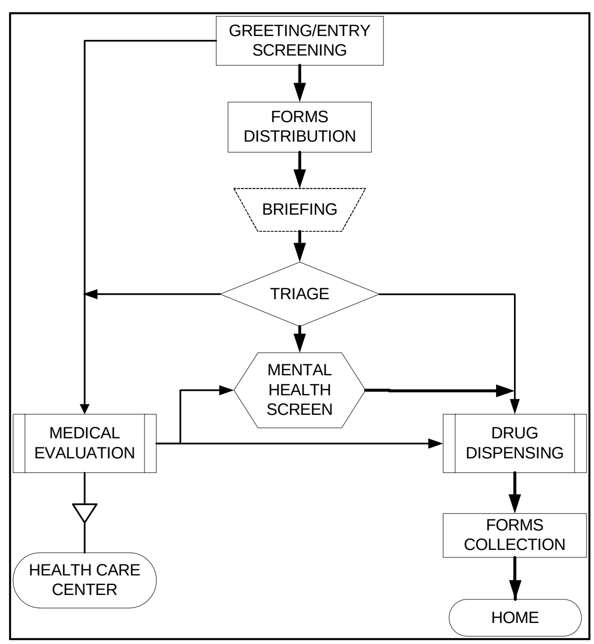



### 5. Diagrams 5A and 5B: Briefing

Here, **patient briefing** is included as a separate station within the DVC. Briefings may be mandated (e.g., in settings where informed consent is required for administration of an investigational drug) or deemed useful for improving patient adherence to medication regimens and/or for calming fears about a bioterrorist event.

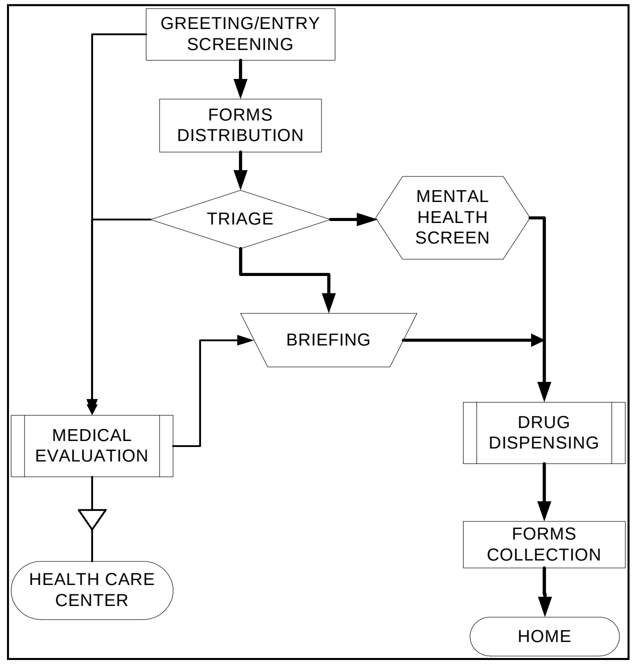
Briefing stations may be situated before or after triage, depending on a variety of factors such as the importance of rapidly identifying patients with symptoms suggestive of attack-related illness. If briefing is mandatory and the likelihood of symptomatic disease is low (e.g., in a pre-event mass vaccination campaign for smallpox), then the briefing station should be situated to capture a large proportion of patient flow (Diagram 5A).

Diagram 5A



Conversely, if early detection is a priority (e.g., as with inhalational anthrax, where on-site treatment of suspected cases may involve rapid administration of antibiotics), then briefing should be limited to patients who are asymptomatic or those whose symptoms have been fully evaluated and deemed not to require immediate intervention beyond routine prophylaxis (Diagram 5B).

**Diagram 5B**

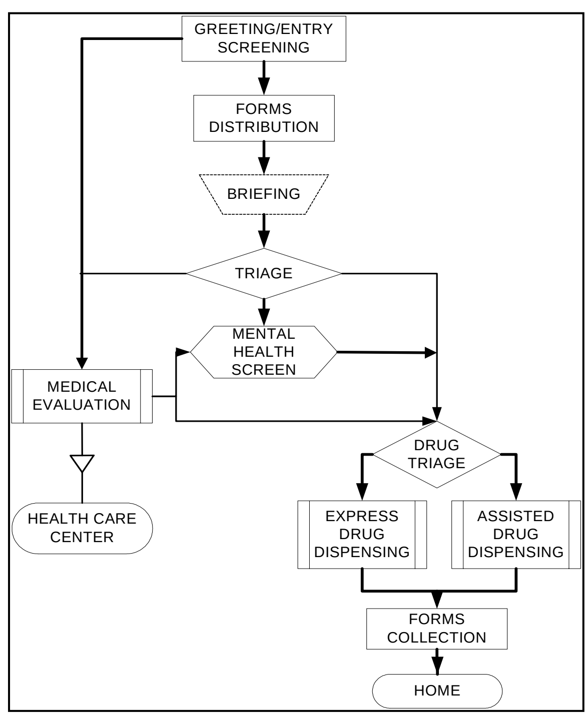



## 6. Diagrams 6A and 6B: Express Dispensing

The 2001 Capital region response to the anthrax attacks validated the notion of creating a **separate drug triage area** and "**express drug**" line to facilitate rapid dispensing of antibiotics to asymptomatic persons with no drug contraindications.[56, 71] The justification for adding this additional step to overall patient flow is that pre-identification of complicated cases (i.e., those requiring consultation with a pharmacist or physician prior to receiving medication) will speed overall processing time in the dispensing area by not clogging all dispensing points with potentially long delays. This will allow better utilization of specialist staff at designated "assisted drug dispensing" areas.

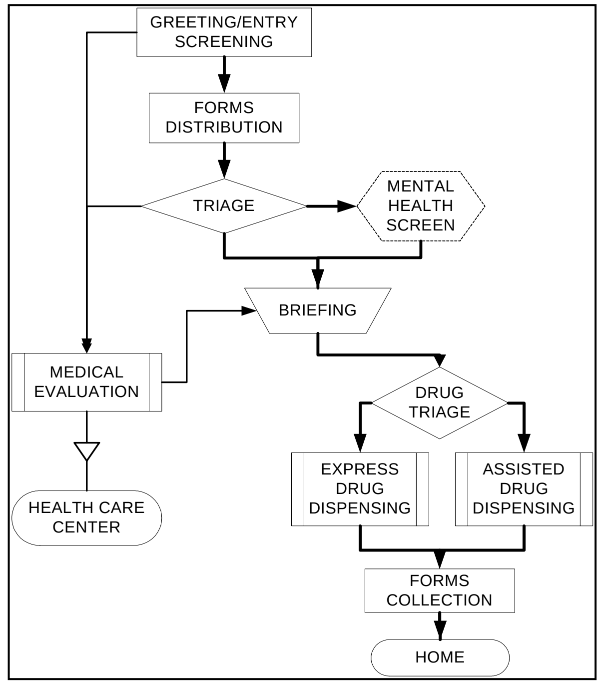
Diagrams 6A and 6B show that these changes in drug dispensing operations are

**Diagram 6A**



compatible with both DVC plans covered in Diagram 5. Drug triage may be facilitated by appropriately designed forms that allow easy identification of adult and pediatric patients whose age, medical conditions, or preexisting medications necessitate dose or drug adjustment. For example, check boxes may be aligned on the form to highlight positive responses upon quick (i.e., less than 10 second) visual scanning.

**Diagram 6B**




### 7. Summary of Patient Flow Diagrams

These plans show patient flow paths through a variety of DVC designs and illustrate the potential complexity and variability of DVC station layouts. While such plans may be adopted "as is," they are intended to serve more as a starting point for local planning than as final designs.

## B. Bottlenecks

In order to minimize bottlenecks in patient flow, a DVC should be designed with a floor plan that prioritizes the expected transit pattern of the following three patient groups:

- **Uncomplicated cases**: individuals who are asymptomatic and/or unexposed (e.g., in the case of smallpox) and have no pre-existing conditions requiring specialized dispensing/prophylaxis regimens

- **Specialized-care cases**: individuals with mild, non-outbreak related symptoms and/or pre-existing conditions or possible contraindications requiring specialized dispensing

- **Seriously ill individuals** identified upon entry, at triage, or at medical evaluation with disabling and/or life-threatening symptoms needing immediate medical attention and transportation to a health care facility

Since the majority of patients will most likely fall into the first group, even small errors in DVC layout for this group may adversely impact overall patient flow rate. In this case, a small delay may not necessarily affect outcomes for the individual patient, but it may affect the operating efficiency of the mass prophylaxis campaign as a whole. Specialized-care cases will constitute a smaller group but require increased time and/or resources. Small, infrequent delays will have less of an effect on DVC operating efficiency, but a constant delay eventually will lead to the formation of bottlenecks and may adversely affect clinic operations. Seriously ill individuals will constitute a small minority of patients processed by the DVC in all but the most dire of scenarios. Consequently, design flaws in medical evaluation and emergency transportation areas will not significantly affect overall DVC operating efficiency. However, these delays may adversely affect the care of individual patients. Ideally, the routing of patients from entry to exit should be as direct as possible for all three groups, with seriously ill individuals traveling the shortest distance from entry to transport.

## C. Making Things Flow: The Highway Traffic Analogy

Highway automobile traffic provides a useful analogy for understanding the factors that can interfere with efficient patient flow in the DVC. There are four basic causes of traffic jams: **merges** (e.g., of two lanes into one), **surges** (e.g., rush hour), **accidents** (which can block both the affected lane and adjacent ones due to spectators), and **tolls** or other features of the road that slow the speed of all cars (e.g., bridges).

**Merges** are easily managed at the DVC design stage: DVC stations and staffing should be arranged to avoid line merges, especially in areas seeing the majority of patient flow, since these will lead to backups and queues that may interfere with DVC support functions (e.g., re-supply). Backups due to **surges** in arrivals are more difficult to solve at the DVC design stage, since these may require shifting or adding staff or shortening processing times (e.g., shortening patient information briefings or forms) to handle increased patient flow. DVCs that are designed to process a certain patient volume without bottlenecks should therefore have a staff member assigned to monitor and report incoming patient flow in order to expedite these types of adjustments before DVC operations are affected by any sustained surge.

The DVC equivalent of a **traffic accident** could be a patient who is seriously ill on arrival and requires immediate assistance at the entrance to the DVC (thus blocking traffic) or any person or group who requires special assistance (e.g., a large family, a disruptive individual, etc.). Contingency plans to manage these and other unexpected events should be developed with the goal of identifying DVC locations and staff to isolate the affected individual(s) from the main flow of patients in order to minimize bottlenecks that compromise overall DVC efficiency.

The DVC analogy to the **toll booth** is the core station (e.g., triage, drug dispensing) that requires a certain processing time for each patient. The length of this processing "delay" will be determined by the length of the protocols and forms and by the waiting time at each station; for patient information stations, this delay is determined by the duration of briefings plus any question and answer period. Designers of briefing scripts and station protocols need to balance thoroughness with efficiency and economy in order to maintain smooth patient flow. Ideally, planners should also pre-designate ways in which these processes can be shortened if bottlenecks do occur and lines begin to form (e.g., pre-identifying portions of a briefing that can be eliminated or provided by alternate communications modalities like radio or television).

## D. Planning For Breakdowns: What to Do About Lines (Queues)?

Lines (technically called "queues") may form inside the DVC whenever the arrival rate exceeds the processing rate. In general, this may result from a "surge" in new arrivals (i.e., above the baseline for which staff has been allocated), from a decrease in staff below what is needed to process the baseline arrival rate, or from an increase in the time needed to process individuals in the DVC. This is so important and seemingly obvious that it bears repeating: bottlenecks and their resultant queues arise, in general, from only three causes:

- Too many patients
- Too few staff
- Too much to do.

DVC floor plans should take into account the possibility that queues will form at each station as part of the natural variation in arrivals, staffing, and processing times. The amount of space allocated for these queues cannot be accurately predicted prior to running of the DVC. One general rule of thumb is that for two stations with identical arrival rates but different processing times (and therefore different numbers of staff assigned for baseline operation), the removal of a staff member at the *quicker* station will lead to more rapid development of a queue than removal of a staff member at the *slower* station.

The reason for this is that each staff member at the quick station processes more individual patients per unit time than staff at the slow station. Thus the relative loss of each additional staff member from the quick station will have a greater impact on maximum queue size (though not necessarily on queue duration, if the problem is rectified by addition of a staff member to the station) than from a slow station. *In short, staff reductions at quick stations have the potential to produce large (though potentially short-lived) queues, while staff reductions at slow stations may produce smaller queues of longer duration.*

## E. Additional Factors Affecting the Efficiency Of DVC Operations

Several factors in addition to the design of the DVC floor plan and station placement may also affect the efficiency of DVC operations. These include:

### 1. Accessibility

Families are an important and often overlooked group with unique accessibility issues from the standpoint of DVC design, since they will likely travel as a single large group. Therefore, DVC layouts should be flexibly configured to accommodate both individuals and large family groups as the "patient." Plans that incorporate inaccessible locations or transit routes (e.g., DVCs placed at sites with stairs or other features that restrict movement of people with assistive mobility devices) may require additional personnel to provide assistance to affected individuals.

### 2. Translation services

Lack of adequate translators may seriously impede processing of non-English speaking patients and therefore cause bottlenecks that may slow overall DVC operations. Communities with limited personnel for translation may want to pre-print or pre-record material for specific response scenarios in appropriate languages.

### 3. Dispute resolution

DVC policies regarding triage and dispensing may lead to disagreements between staff and patients. In order to prevent these disagreements from causing bottlenecks at the station where they occur, DVC planners should designate a specific location within the DVC and an operational protocol for mitigating anticipated disputes (e.g., establishing guidelines governing whether a single individual can be given medications for multiple other individuals).

### 4. Geography

Population density and geographic location may influence the development and implementation of prophylaxis plans. For example, finding appropriate locations for DVC operations in rural areas requires consideration of unique transportation, resupply, and communication issues compared to those encountered in urban settings.

***News from the field****: Lessons learned about clinic dynamics at the San Francisco smallpox vaccination clinic exercise, June 17, 2003 (processing approximately 200 people per hour):*

1. *Make a single flow control point* <u>*outside*</u> *the clinic to regulate patient arrivals.*
2. *Patient questions (about symptoms and clinic operations) can bottleneck the greeting station, causing backups out the front door. Refer these to briefings.*
3. *Make sure signage is clear, visible, multilingual, and consistent in message.*
4. *Make sure all clinic staff give consistent directions.*
5. *Long queues can easily co-mingle, causing confusion and "missed" stations.*

Source: http://www.dph.sf.ca.us/Reports/June17Drill/FnlJune17Rpt.pdf

# 5. DVC Calculations: Estimating Clinic and Staff Numbers

The following section presents an overview of one method for calculating the number of DVCs necessary for a mass prophylaxis campaign and the number of staff needed to operate a given DVC. Planners interested in the mathematical details behind this approach and in performing more detailed calculations are referred to the accompanying computer model, the Bioterrorism and Epidemic Outbreak Response Model (BERM) and its technical appendix (which is reproduced as an appendix to this report).

## A. Number of DVCs

Planners can determine how many DVCs they will use for a mass prophylaxis campaign in one of three ways:

1. By determining the **total number of sites available** in their community. This would require fitting all necessary DVC activities into those pre-selected sites. An example of this was the 1995 Minnesota meningococcal meningitis vaccination campaign that took place at a single site with approximately 300 staff.[36]

**Advantage**: Fits the mass prophylaxis plan to existing community structures
**Disadvantage**: May result in mismatch between sites and population/available staff size

2. By determining the **total number of staff needed to operate a clinic** (e.g., deciding that, for security or other reasons, each DVC should have no more than 100 core staff operating at a given time). Dividing the total staff required for a prophylaxis campaign (determined using the BERM model) by the per-DVC staff size gives the number of DVCs that should be established.

**Advantage**: Ease of planning (one size fits all)
**Disadvantage**: Requires estimate of total staff needed for campaign

3. By estimating the **maximum number of patients that could be processed** at a standard DVC (that is, the patient flow rate). These estimates can be derived from a number of sources: nationally publicized exercises (e.g., ranging from roughly 200 patients per hour for a single smallpox vaccination clinic (San Francisco, 2003) to up to 1,200 patients per hour for a single high-flow anthrax antibiotic dispensing clinic (New York City, 2002)); from previous local experience with influenza vaccination and other public health clinics; or from calculations based on the duration of patient briefings at the proposed DVCs, as described below. The number of DVCs needed is then calculated by dividing the community-wide patient flow rate (which is just the number of patients needing prophylaxis or vaccination divided by the number of days or hours allotted for the campaign) by the per-clinic patient flow rate.

**Advantage**: Fits the mass prophylaxis plan to population size and response time
**Disadvantage**: May be difficult to estimate per-DVC patient processing rate

The following scenario illustrates this last method using the length of briefings to determine DVC flow rate, and therefore overall number of DVCs:

1. Calculating per-DVC patient processing rate:

City A has a population of one million residents, all of whom require prophylaxis in 6 days or less using DVCs that have mandatory briefings for all patients. Planners have decided that each DVC in City A will have three briefing areas capable of handling 50 patients apiece and that each briefing (with a question and answer period) will take 20 minutes. Since these briefings are mandatory, they represent the **critical rate-determining step** for patient flow: assuming that there are sufficient patients to fill every briefing, each DVC will have a **maximum** patient flow rate of

3 briefing rooms x
50 patients per briefing x
20min per briefing =a 3 briefings per room per hour

= 450 patients per hour, or 8 patients per minute.

This means that for the proposed DVC to process patients without bottlenecks, it must be designed to handle 8 patients per minute from entry to exit. If not, then either briefings will go unfilled (because patients cannot get to them) or stations downstream from the briefings will be overwhelmed and will back up (when patients emerge from the briefing rooms).

The reader can create a basic spreadsheet model to calculate the maximum patient flow rate for any DVC that has mandatory briefings. This model lets you see the effects of varying the number of briefing rooms, the number of patients per briefing, and the time needed for each briefing.

Using any standard spreadsheet program, create the following fields:

| NAME | FORMULA | EXAMPLE |
|---|---|---|
| **Number of briefing rooms** | =A | e.g., 3 |
| **Number of patients/briefing** | =B | e.g., 50 |
| **Duration of each briefing (minutes)** | =C | e.g., 20 minutes |
| **Maximum patient flow per clinic given these parameters (per minute)** | =(AxB)÷C=D | e.g., 7.5 patients per minute |
| **Maximum patient flow per clinic given these parameters (per hour)** | =(AxBx60)÷C=E | e.g., 450 patients per hour |

For comparison, recent vaccination campaigns against meningococcal meningitis in Alberta, Canada and Minnesota achieved processing times of between 2.7 and 13 patients per minute per DVC.[85, 86]

2. Calculating community-wide flow rate:

Next, the rate of prophylaxis for the entire population must be calculated. For City A, the overall rate of prophylaxis for the entire population is one million divided by the six days available for treatment, or 116 patients per minute. If each DVC can process 8 patients per minute (calculated above), then 14 DVCs are needed to provide prophylaxis to the entire community in the allotted time (assuming 24-hour operation of each DVC). In contrast, if DVC processing is limited to only 2.7 patients per minute (as was seen in the Alberta, Canada meningitis vaccination campaign), then 43 DVCs are needed to carry out community-wide prophylaxis in the specified time frame of six days. To model these calculations, the reader may continue to build the spreadsheet as follows:

| NAME | FORMULA | EXAMPLE |
|---|---|---|
| **Population size** | =F | e.g., 1,000,000 |
| **Number of days for prophylaxis** | =G | e.g., 3 |
| **Community-wide patient flow rate (patients per minute)** | =F÷G÷24÷60=H | e.g., 231 patients per minute |
| **Community-wide patient flow rate (per hour)** | =F÷G÷24=I | e.g., 13,889 patients per hour |
| **Number of clinics required to achieve prophylaxis goal in allotted time** | =H÷D<br>or = I÷E | e.g., 30.8, which rounds up to 31 clinics |

The estimated number of DVCs required to complete a prophylaxis campaign is one of the most critical calculations in all of mass prophylaxis planning. There are considerable logistical differences in setting up, staffing, and running a handful compared to several dozen DVCs. Every local DVC planning team should attempt to determine the number of DVCs required for community-wide prophylaxis under different response scenarios.

## B. Number of Staff

One of the most difficult features of DVC planning is determining how many staff would be needed to work at a given station within a DVC. The accompanying Bioterrorism and Epidemic Outbreak Response Model (BERM) allows calculations of the number of staff needed to carry out a prophylaxis campaign using two different pre-specified DVC designs, one for antibiotic dispensing and another for vaccination.[84] The calculations underlying these estimates are described in detail in the model's Technical Appendix, but deserve comment here as well. The main concept underlying these calculations is the notion that every DVC should be capable of what is called "steady-state operation." This means that every clinic should be capable of operating at full capacity without developing progressively larger bottlenecks, which would show up as queues. In other words, the operational goal of any DVC should be that, at minimum, it does not continuously back up to the point of complete shutdown. A DVC operating at this "steady-state" has achieved a balance between the number of staff, the number of patients, and the time needed for those staff to process those patients such that there is no increase in bottlenecks or queues. While this may never actually occur during real-life operations (due to a variety of factors such as unpredictable surge arrivals, etc.), all DVCs should, at a minimum, be designed to achieve steady-state operation.

Fortunately, it is possible to calculate the number of staff needed to run a system that is operating in a steady-state manner. These calculations can provide planners with two important sets of data: either estimates of the minimum number of staff needed to process patients at a given rate of arrival and for a given processing time, or estimates of the maximum processing time permitted for a given number of staff to process patients at a given rate of arrival. The next section is a summary of the Technical Appendix of the BERM model for readers interested in how these calculations are carried out.

## C. The Bioterrorism and Epidemic Outbreak Response Model (BERM)

The BERM model was created by researchers at Weill Medical College of Cornell University in 2003 under contract to the Department of Health and Human Services, Agency for Healthcare Research and Quality (AHRQ).[84, 87] In contrast to previous spreadsheet models of bioterrorism response that have focused on resources needed for a military medical response, this model is designed for civilian response to bioterrorism and epidemic outbreaks requiring mass prophylaxis.[88] Its goal is to assist public health and emergency management planners to create customized community mass prophylaxis plans using a DVC-based dispensing approach.

Model inputs include community population size, time frame for response, characteristics of DVC operations (e.g., hours of operation, number of shifts, rest-time for workers), rate of patient processing at each DVC (calculated using one of the three methods described above) type of operation (pill dispensing or vaccination), operational setting (e.g., pre-event in which only a small proportion of patients will need medical attention vs. large-scale event in which up to 20% of patients will be symptomatic on arrival to the DVC), and DVC processing speed (baseline, slow, or fast). Depending on the type of operation chosen, the model runs off one of two generic DVC layouts of either an antibiotic dispensing clinic (similar to those set up in Washington, D.C. after the 2001 anthrax attacks) or a vaccination clinic (similar to the CDC smallpox vaccination model, but modified by the Weill/Cornell researchers). These clinic layouts represent a composite of several published plans, including those of the CDC, U.S. Public Health Service, Central Florida Regional Domestic Security Task Force, and the California Emergency Medical Services Authority.[80, 89-91] Each layout defines the number and type of stations where **core staff** are needed. Additionally, users can customize the model by inputting the number and type of **support staff** needed for operation of a single DVC.

Once this information is entered into the model, it calculates what is needed for operating a multi-DVC-based, community-wide mass prophylaxis in the specified time frame. Specifically, it gives estimates of the number of DVCs needed to treat the entire community as well as the number and type of core and support staff at each DVC, for each shift, and for the entire prophylaxis operation. If the model results indicate that more staff are needed than are available in the community, then users can easily re-calculate how long it would take to cover the entire population using the actual number of staff on hand.

The ultimate purpose of the BERM is to allow planners to "think with numbers" as they go about formulating realistic mass antibiotic dispensing and vaccination contingency plans for their target populations. Using a model that provides numerical estimates forces critical examination of assumptions about prophylaxis clinic design and about the availability of human and materiel resources. Estimates derived from this model should be viewed as one type of data among many that may be useful for planning (other data might include previous local experience with immunization campaigns, or results of training exercises for bioterrorism response).

As with any model, the accuracy of the numerical estimates provided by this program depends on the quality of the underlying data on which they are based. For example, the station-specific processing time estimates used in this model have a large impact on outcomes (to demonstrate this, observe the change in overall staffing estimates for a given scenario under slow, baseline, and fast processing times). In order to improve ease-of-use, the model provides these three pre-set choices for processing times and three pre-set choices for disease prevalence (pre-event, small-scale event, or large-scale event). The trade-off here is with "realism" of the outputs, since real-world events rarely conform to such neat categories. However, examining how community-wide prophylaxis plans would need to adapt to these nine (3 x 3) scenarios may go a long way to exposing heretofore unidentified stresses on prophylaxis plans already in place or under development. (Additionally, for those who are interested in finer-grained customization of BERM outputs, the model includes a separate page for altering and customizing every element of these baseline scenarios.)

# Section Three: From Principles to Practice: Examples of Antibiotic Dispensing and Vaccination Clinic Plans

Since the 2001 U.S. anthrax attacks, a number of scientific studies have underscored the importance of rapid mass prophylaxis of civilian populations to prevent casualties in real-life and hypothetical disease outbreak scenarios.[37, 43, 92-94] This Section suggests ways to use some of the design principles introduced in the last Section to develop efficient patient flow plans for mass prophylaxis clinics. Following the BERM model, it includes examples of both antibiotic dispensing clinics (e.g., for prophylaxis against inhalational anthrax) and vaccination clinics (e.g., for pre- or post-event vaccination against smallpox).

## 6. Example of an Antibiotic Dispensing Clinic Plan

### A. Background

Mass antibiotic prophylaxis would be needed for outbreaks of disease due to any of the three bacterial pathogens on the CDC list of "Category A" agents posing the maximum risk to public health and welfare: anthrax, plague, or tularemia.[6] Anthrax, for example, is a spore-forming bacterium that can infect humans via inhalation, direct contact, or ingestion, and is highly lethal if untreated.[17] The 2001 experience with inhalational anthrax suggests that approximately half of those presenting with fulminant inhalational anthrax may die despite advanced medical care. However, there is considerable evidence that use of prophylactic antibiotics may prevent the development of fatal anthrax even in patients who have inhaled an infectious dose of anthrax spores and who have early symptoms of the disease, such as fever, cough, severe headache, nausea, and chest discomfort.[32, 37]

While scientific uncertainty remains about the average duration of the asymptomatic incubation period in patients exposed to anthrax, the 2001 U.S. experience suggests that in a number of cases there was ample time and opportunity for initiation of prophylactic antibiotics after exposure.[1] Over the past five years, the Federal government has overseen the purchase and stockpiling of a number of antibiotics that may be effective in prophylaxis against inhalational anthrax as well as against plague and tularemia. These medications, which are managed and delivered by Strategic National Stockpile (SNS), were used in the Florida, New York/New Jersey, and National Capital Region anthrax response.[40-43, 56, 71]

### B. Design Considerations

An antibiotic dispensing clinic suited to anthrax post-exposure prophylaxis (or pill-based prophylaxis for other biological pathogens) would need to accomplish a limited number of goals, the most important of which is getting the correct antibiotic to the correct patient in the shortest amount of time. Since patient compliance with prescribed medication regimens and side effects from those medications proved to be an unexpectedly important factor in the 2001 U.S. anthrax response, an additional goal would be to provide educational material and the opportunity for patients to ask questions of emergency health care providers.[31-33] To assist in epidemiological investigations, patient follow-up, and resource management for the mass prophylaxis response, a further goal of the clinic design would be to allow for the documentation of patient-related information either through written forms or through question and answer sessions with clinic staff.[40] Clinic planners may want to include a separate area for on-site crisis counseling to help manage individuals who are incapacitated by stress or anxiety.[78] Finally, each clinic should have a designated area for triage and management of acutely ill individuals who require emergency transfer out of the dispensing clinic to a health care facility.

For bacterial agents that pose the risk of patient-to-patient spread (e.g., pneumonic plague), an additional goal would be to separate any symptomatic individuals from the asymptomatic populace as soon as they reach the clinic. In this setting, application of appropriate respiratory precautions (e.g., by giving symptomatic individuals OSHA-rated N-95 masks or the equivalent immediately upon identification) may minimize the risk of intra-clinic spread of disease. While it is always preferable to prevent infection when possible, it should be noted that even if a patient were to become infected with a contagious disease inside the dispensing clinic, the chance of that infection progressing to actual symptomatic illness should be greatly diminished by the use of prophylactic medications.

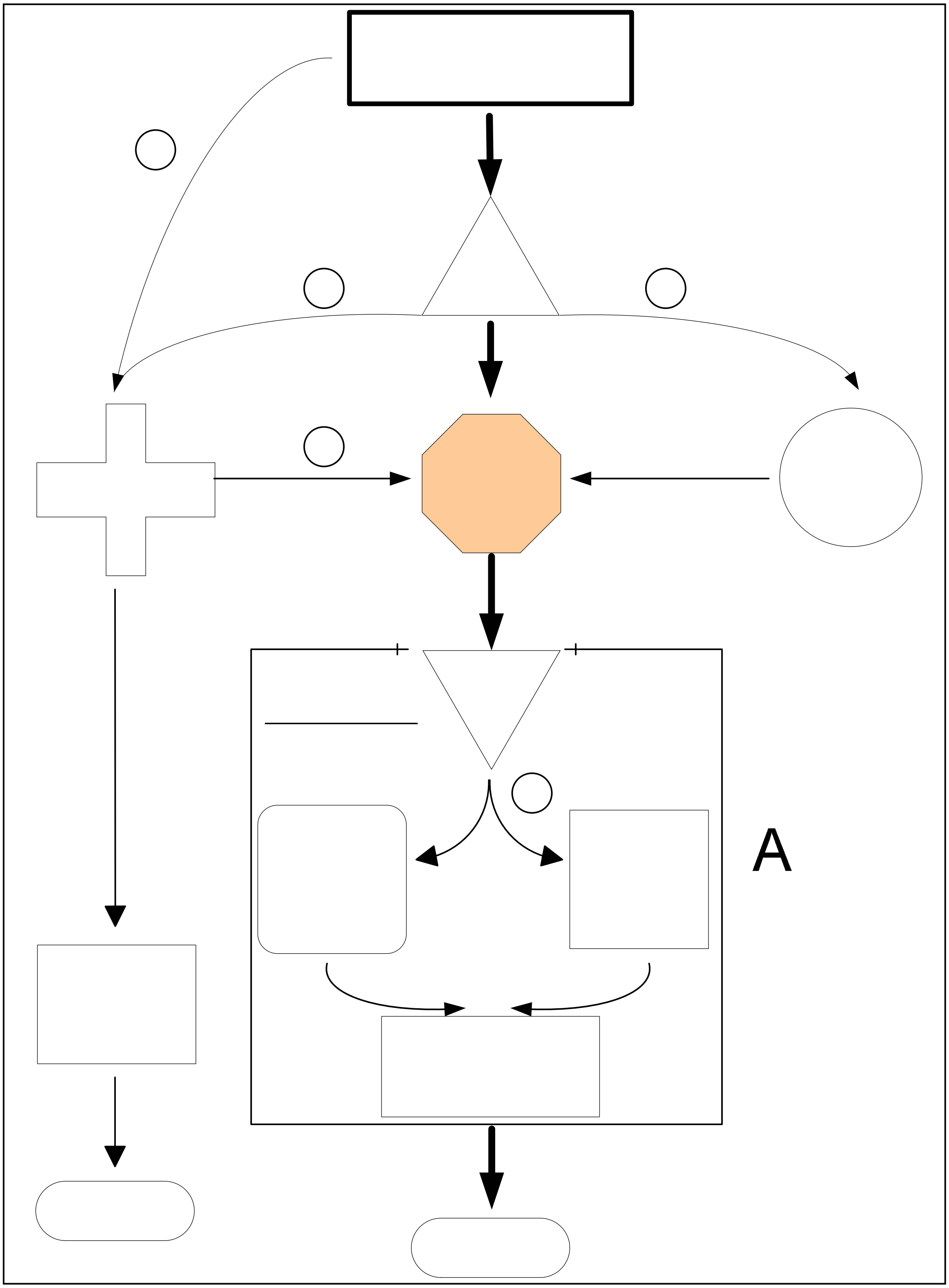
## C. Model Patient Flow Plan

These design considerations led to the antibiotic dispensing clinic flow plan shown below (Figure 3), which was highly influenced by the published reports of Montello and Haffer regarding the design and operation of the dispensing clinics used for the 2001 National Capital Region anthrax response.[56, 71] Patients are greeted immediately inside the clinic by a staff member whose sole purpose is to identify anyone who is acutely ill in order to send them immediately for medical evaluation. In the case of a contagious disease, the staff member would also supply the affected individual with a mask at this time. The remaining patients would be given forms to fill out; it is preferable to give out forms prior to any briefing, since the individuals performing the briefing may want to refer to information or questions on the forms.

The next step is the first triage station. Triage may be accomplished by reading the patient's form (e.g., by visually scanning checkboxes for questions about symptoms) or may be accomplished through a limited series of questions. This general triage step seeks to identify patients who have symptoms that warrant either medical or psychological evaluation and/or management. Patients who screen positive at this stage are sent either to the medical evaluation or to crisis counseling stations. All others proceed to the briefing area, where they may be joined by individuals returning from those two stations (i.e., individuals whose symptoms or concerns were evaluated and addressed by health care professionals and whose condition was deemed stable enough to warrant return to the main clinic).

From the briefing, patients proceed to drug triage, where patients needing special assistance with drug prescribing (e.g., alternative drug regimens, dosage adjustment) are identified and sent to a designated dispensing area where pharmacists or other trained health professionals can tailor the dispensed regimen to a patient's individual medical requirements (e.g., due to other medical conditions or age, height, or weight considerations). All other patients proceed to an "express" dispensing area where no further decisions regarding type or quantity of medication are necessary. Splitting dispensing this way increased efficiency in the 2001 anthrax response.[56, 71] After receiving their antibiotics, patients may deposit their forms and exit.

**Figure 3: Example of an Antibiotic Dispensing Clinic Plan**



# 7. Example of a Vaccination Clinic Plan

## A. Background

Both smallpox and the viral hemorrhagic fever (VHF) viruses are classified by the CDC as "Category A" biological agents posing the maximum risk to public health and welfare.[6] At the time of this writing, a well-tested, highly effective, and widely available vaccine exists only for smallpox, although considerable scientific effort is being devoted to developing countermeasures for VHFs. Smallpox infection carries a 30% mortality rate in unvaccinated individuals; in previously vaccinated individuals who develop the disease (e.g., in whom immunity has waned years after vaccination), the mortality rate drops to 3%.[95, 96] U.S. residents under the age of 30 have virtually no immunity to the disease, and older adults likely have little remaining immunity since immunizations and booster shots for the general public were halted in 1971.[97]

Despite its high mortality and morbidity, smallpox has two features that should give a measure of optimism to public health officials planning a mass vaccination response. First, the virus is not among the most contagious from person to person (compared to measles, for example), requiring exposure to respiratory droplets that usually occurs only among household or health care contacts.[98] Second, successful vaccination within four days of exposure to the virus can halt infection.[99] Over the past three years the federal government has overseen the purchase and testing of large quantities of smallpox vaccine, so that, as of this writing, there is sufficient vaccine to inoculate every U.S. resident.[100] The challenge for public health planners is to devise feasible strategies to accomplish that task in a reasonable time frame.

## B. Design Considerations

A smallpox mass vaccination campaign most likely would be carried out at designated smallpox clinics. Any smallpox clinic design must accommodate two unique features of smallpox vaccination. First, vaccination involves creating a localized infection with a live virus (vaccinia, or cowpox) so special instructions must be given for post-inoculation wound care to prevent inadvertent spread of the virus in the recipient (e.g., auto-inoculation of the eye) or in others.[101] Second, since the Food and Drug Administration (FDA) has only approved DryVax® for general public use, all recipients of other vaccines must give witnessed informed consent under an Investigational New Drug (IND) protocol prior to the inoculation.[102] Additional design considerations include:

- **Pre- and post-event dual-use capability.** Clinic plans should address the needs of campaigns that occur in the absence of any known smallpox outbreak ("pre-event") or in the setting of a known or suspected release of the virus ("post-event").

- **Clinic contact precautions.** Plans should address the need for rapid presumptive identification and respiratory isolation of suspected cases or contacts in a post-event setting.

- **Crisis Counseling.** Plans should be able to accommodate mental health crisis counseling stations in both pre- and post-event scenarios.

- **Testing.** Plans may need to accommodate stations for pregnancy testing and/or rapid HIV testing or stations at which information for off-site testing may be provided. Although there are no absolute contraindications to vaccination for a suspected case or contact in a post-event scenario, individuals may still decline the vaccine based on personal evaluation of risks and benefits. These individuals may then be recommended for isolation, as noted below.

- **Isolation considerations.** Plans need to address isolation counseling in a post-event setting for those suspected cases or contacts who decline vaccination. This station would be linked to transport to designated isolation facilities.

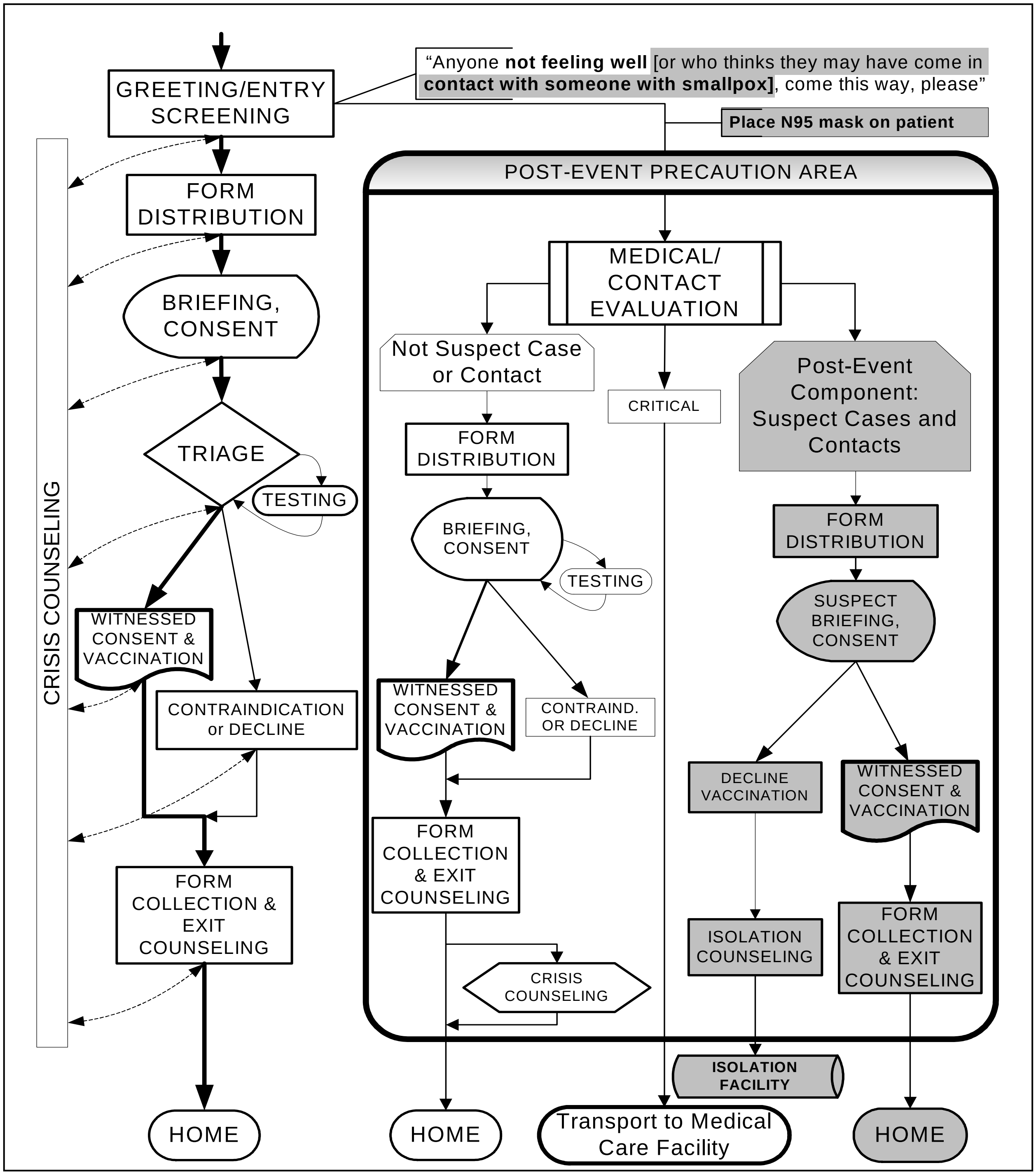
## C. Model Patient Flow Plan

These design considerations led researchers at the Department of Public Health at Weill Medical College of Cornell University to develop the sample smallpox clinic patient flow plan shown below (Figure 4). Stations, spoken text, and annotations in grey (located on the right in the diagram) would be used in a post-event scenario only. All other stations would be used in both pre- and post-event settings.

The general clinic layout exemplifies the notion of "express lines" described in the previous section, in that the clinic divides into uncomplicated (left-hand side) versus complex (right-hand side) service lines. In the post-event (grey) version of the clinic, anyone thought to be a potential case or contact would be immediately separated from the general flow of patients for physically separate processing in a designated "Post-Event Precaution Area."

The following sub-sections describe in detail how this model clinic would function in both pre- and post-event settings.

**Figure 4: Example of a Vaccination Clinic Plan**



### 1. Pre-Event Patient Flow

In a pre-event mass vaccination campaign, only the stations in the left-hand and center portion of this flow diagram would be used (i.e., only the un-shaded portions). All persons entering the vaccination center would be met by a greeter/screener and asked if they felt acutely ill (any positive response in this pre-event setting would indicate a non-smallpox intercurrent illness like acute asthma, myocardial infarction, acute panic, etc.). These symptomatic patients would be taken immediately to the medical evaluation area where health care professionals could assess the severity of symptoms and the likelihood of a serious underlying medical condition requiring further medical care.

No uniform respiratory precautions would be needed for these symptomatic patients in a pre-event scenario. Acutely ill patients may be transported to a medical care facility, while those with a negative medical evaluation could either be sent back through the standard processing line or be sent to a duplicate set of stations with smaller staff in a separate area for those symptomatic patients. Although duplication of stations in a pre-event setting may appear redundant, keeping these ill patients out of the general flow of asymptomatic individuals may result in greater overall efficiency of the DVC operation (i.e., avoiding bottlenecks due to increased triage and management processing times for ill individuals).

Next, all potential vaccinees would be given forms and the means to fill them out (i.e., a writing instrument and either a clipboard or a tabletop on which to write). These individuals then would be directed to briefing areas where either videotaped or live briefings would take place with the opportunity for questions. Patients may be stationary (i.e., seated) for these briefings or may have the opportunity to view them while moving in line. After the briefing, persons with no self-identified contraindications to vaccination would be given the opportunity to sign the witnessed informed consent declarations for receipt of the vaccine.

Individuals would then exit the briefing area to the triage area, where persons with no contraindications would have their written information verified by staff and those with potential contraindications further questioned. From the triage station, rapid testing for pregnancy and/or HIV may be offered to those interested or those uncertain about their status. In this pre-event setting, some people may be denied vaccination due to contraindications or may decline vaccination due to personal weighing of its risk/benefit ratio. Others will proceed to vaccination stations where those who have not yet signed their consent form may do so and have it witnessed.

Prior to exiting the vaccination center, individuals would proceed to the form collection and exit counseling station where DVC staff could reiterate key points of vaccination site care and would check completeness of forms for data entry. At any point in proceeding from entry to exit, patients would have the opportunity to go to the mental health/crisis counseling station located on-site. Those persons who opt for counseling may re-enter the vaccination patient flow where they left.

## 2. Post-Event Patient Flow

In a post-event setting, all symptomatic individuals and those who may have come in contact with a smallpox case would be physically separated from the main patient flow at the earliest possible station. On the accompanying patient flow diagram, the grey-shaded comments and stations would be used during post-event operation. The most important difference is that these new stations will be physically distinct from the main (non-case, non-contact) patient flow. The purpose of separating the processing areas of these non-case, non-contact patients from presumed cases and contacts is to minimize the potential exposure of healthy vaccine recipients to individuals with possible smallpox exposure or infection.

As in pre-event clinic operation, entry screeners would ask all individuals walking through the door whether they feel ill. In the post-event setting, these screeners would also ask whether individuals have been exposed to someone who has smallpox. Anyone feeling ill or reporting direct contact with a smallpox patient would be sent to the Post-Event Precaution Area and would be instructed to put on an N95 ventilator (mask) to reduce the possibility of droplet transmission of the smallpox virus (an N95 ventilator provides 95% filter efficiency of particles with a diameter of less than 0.03 micrometers and where oil particles are not present).[98] These individuals would then undergo screening at the medical evaluation station, where detailed questioning about symptoms and exposures and, if needed, an abbreviated physical examination could be performed. As shown in the diagram, these patients would be classified into one of four categories:

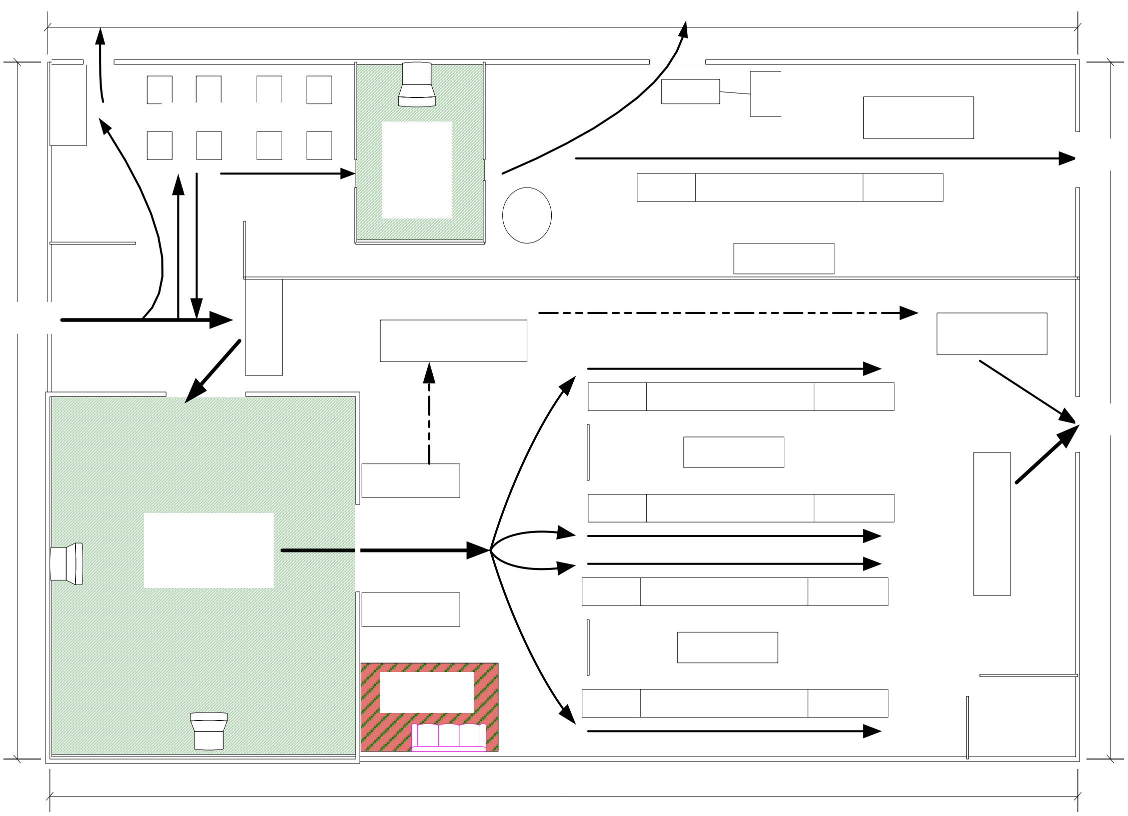
- An acute non-smallpox illness such as myocardial infarction that would require immediate transport to a health care facility (labeled "CRITICAL" in the diagram)
- A subacute illness that is not suggestive of smallpox and does not require immediate transport to a health care facility, or no significant illness
- An illness syndrome that is suggestive of smallpox (e.g., fever and/or severe backache and/or rash)
- A likely exposure to a case of smallpox but no evidence of symptomatic disease

Once sent to the presumed contact area, individuals in all four categories remain wearing a mask as they undergo briefing, vaccination, exit counseling, and/or transportation. This will minimize droplet transmission from truly infectious individuals (through containment under the mask) to uninfected individuals with either suspected or documented contact (whose masks will prevent inhalation of possibly infectious droplets). Upon exit from the clinic, only those individuals with suspected smallpox or contact would be encouraged to maintain use of the mask until they reach a treatment or domiciliary facility as recommended by CDC.[102] These facilities may range from designated health care centers to the individual's home. Since there are no absolute contraindications to vaccination for presumed cases or contacts in a post-event setting, predetermined protocols will be required to manage individuals in these categories who decline vaccination. Since under evolving federal and state protocols these unvaccinated patients may be required to undergo isolation for a specified period of time, the clinic design includes a station for counseling and administrative processing of these individuals.

## D. Sample Floor Plan

Figure 5 shows how the aforementioned model smallpox clinic could fit into the area of a typical high school basketball court (84ft. x 50ft.), a possible site for DVC activities in the event of a large-scale prophylaxis campaign. Note that the presumed contact area, including a separate smaller briefing station, is physically distinct from the non-contact areas. This floor plan shows only one large briefing area in the non-contact area located on the court, although more could be set up in adjacent rooms. Vaccine preparation, data entry, and clinic supplies also may require use of adjoining rooms or staging areas.

**Figure 5: Sample Smallpox Vaccination Center Floor Plan**



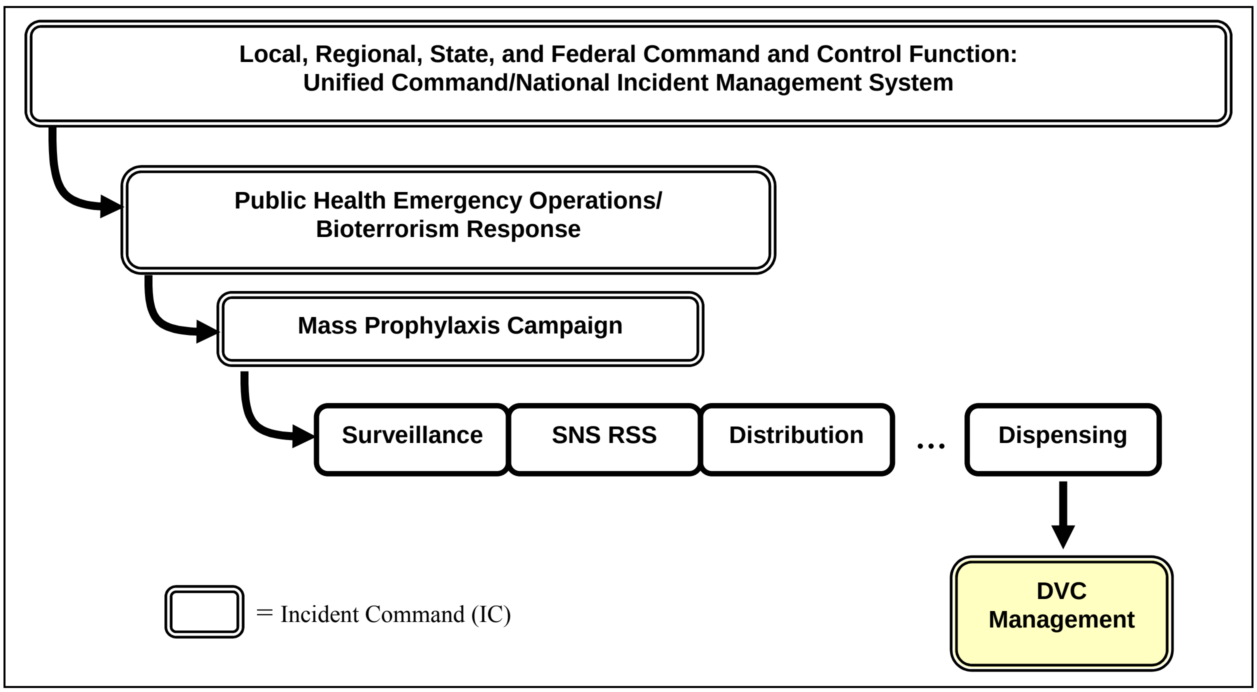
# Section Four: Clinic Management/Command Structure

## 8. Overview of Mass Prophylaxis Command Structure

Incident management systems enable emergency responders to manage the coordinated response to mass casualty incidents and other emergency scenarios.[74] A bioterrorism event or infectious disease outbreak may be a large-scale event (e.g., similar in size and scope to an earthquake or flood) requiring the activation of a community all-hazard response plan. However, the response to a large-scale bioterrorism event poses special challenges in that it may require use of local, state, and federal medical stockpiles; coordination of multiple state and federal agencies with non-overlapping fields of expertise (e.g., law enforcement and public health); and outreach to a large proportion (if not all) of the community for prophylaxis and treatment. As such, bioterrorism and epidemic outbreak response epitomizes the type of complex multi-jurisdictional operation for which the recently published National Incident Management System (NIMS) has been designed.[74] The local implementation of a NIMS-based Command and Control function, described here, would need to integrate with regional, state, and federal response plans.

Mass prophylaxis involves a number of multiply–coordinated activities (e.g., the Receipt, Store and Stage (RSS) centers for Strategic National Stockpile supplies, where federal assets are transferred to state control), but dispensing operations using DVCs pose perhaps the greatest logistical challenge. As noted in Section One, DVC operations are the critical point of contact between public health /emergency preparedness activities and the wider public. The complexity and importance of DVC operations necessitate that DVCs have a clearly defined command structure that integrates seamlessly into the broader mass prophylaxis campaign command structure which, in turn, integrates into the existing local, regional, or state emergency management system. This nested command structure is illustrated in Figure 6:

**Figure 6: DVC Command Integration**



# 9. DVC Command Structure

The National Incident Management System exemplifies a national movement toward developing an all-hazards approach to natural disasters and terrorist events at the local level using the principals of incident command (IC).[76] IC should also serve as the framework for management of each DVC, because it provides a standardized structure that can be easily integrated into larger campaign and all-hazards plans. Furthermore, the inherent flexibility of IC allows for easy expansion or contraction over time as the mass prophylaxis response demands.

Conceptually, the command system should be utilized in the planning, mobilization, operation, and demobilization of each DVC. As demanded by the characteristics of the response (e.g., population density), multiple DVCs can be organized in an expanded IC structure, easily integrated into the mass prophylaxis campaign management system and a community's Emergency Operations Plan (EOP), and ultimately placed under a multi-agency and multi-jurisdictional Unified Command (UC). Figure 6 has shown the relation of the DVC IC structure to other mass prophylaxis elements and the overall UC system. Figure 7 details the internal command structure of a sample DVC. The various components, explained in detail below, may be added or removed as required by the complexity and size of the DVC.

## A. Core Functions

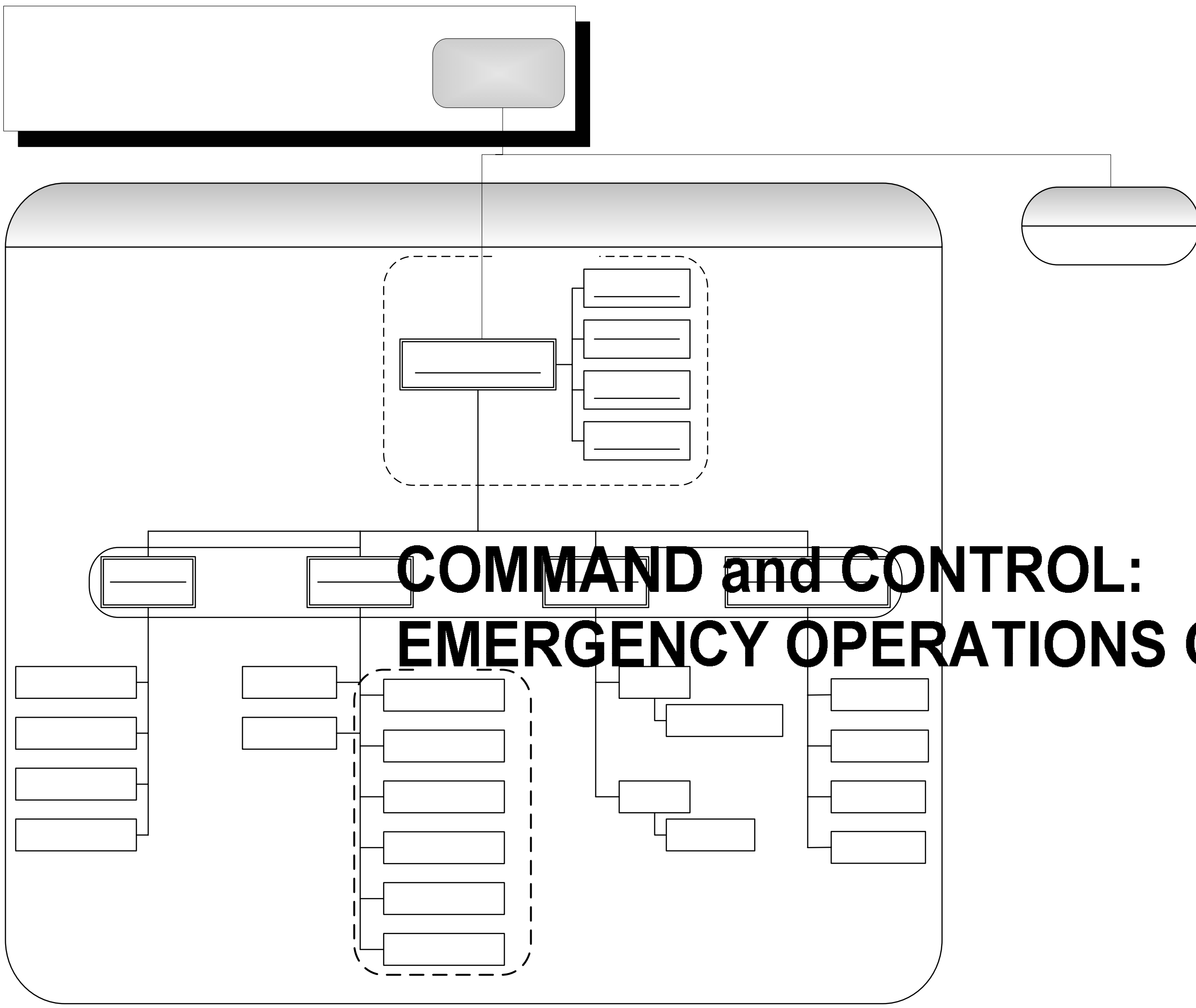
### 1. Staff Positions

The Incident Command System (ICS) serves as the framework for all of the managerial support staff positions in the DVC. Standardized titles should be used whenever possible to minimize misunderstandings in terminology among different responding agencies. The core managerial units and staff are as follows:

#### *a. DVC Command and Control*

The DVC Command and Control unit of the ICS functions as the highest direct managerial unit of all individual DVC procedures. Decisions regarding DVC procedures and control of information flow, both intra- and inter-DVC, are centralized in the DVC Command and Control unit. The DVC Command and Control unit is located in the DVC Incident Command Post (DVC ICP), which should be contained within the DVC yet free from direct patient traffic to ensure easy and immediate accessibility to various ICS managers. The DVC Command and Control unit comprises a single Site Commander (DVC SC) and a DVC Command Staff. In campaigns requiring more than one DVC, each DVC SC will report to a single Dispensing Operations Commander (DOC) who, in addition to overseeing all of the DVCs, will serve as the liaison to the community's Emergency Operations Center (EOC), the "nerve center" of the larger central Command and Control function.

**Figure 7: Model DVC Command Structure**




1) *DVC Site Commander (SC) and Dispensing Operations Commander (DOC)*
   The SC is responsible for overall management of DVC operations and for the formation of the DVC Site Action Plan (SAP—see A.2, below) with collaboration from the Planning and Operations Sections (see A.1.b.1 and A.1.b.2, below). Optimally, the SC will be a public health or emergency management official. The SC has executive responsibility for directing all aspects of deployment, operation, and maintenance of the DVC.

   Campaigns using multiple DVCs will require an SC for each DVC, who will report to a single DOC located within the community's Emergency Operations Center (EOC). This DOC should be a senior public health official who can coordinate the operating activities of all DVCs in the campaign. The DOC is responsible as well for communication between the EOC and the DVCs to ensure that DVC management and operations integrate into the mass prophylaxis campaign system and the larger central Command and Control function.

2) *DVC Command Staff*:

a) The DVC Public Information Officer (PIO) serves as the local liaison between the EOC Joint Information Center (JIC) and the local community. The PIO, under directives from the SC, DOC, and ultimately the EOC, coordinates the release of information to the general public prior to the initiation of the mass prophylaxis program (e.g., DVC location; description of process), the release of updated directives as necessary, and progress reports. While each community's central Command and Control function will have its own senior information officers, the presence of DVC-level PIOs (if permitted by staffing constraints) may help foster a community-DVC link that ensures that the public receives accurate, focused, and timely information to support operational goals such as efficient patient flow.

b) The DVC Liaison Officer serves as the DVC contact point for all involved responding agencies, including police, public health, emergency management, hospital, Federal, and other activated DVCs. The Liaison Office coordinates information and directives with representatives from all participating agencies to ensure focused and cooperative action.

c) The DVC Medical Director and Chiefs of the Operations and Logistics sections (see b.2 and b.3, below), assists the SC and DOC in determining the timing of restocking of supplies from the distribution center. Additionally, the DVC Medical Director coordinates use of clinical protocols (e.g., written decision trees) to guide triage, prophylaxis, and treatment of patients. Finally, the Medical Director serves as quality control manager regarding all clinical activities in the DVC.

d) The DVC Safety Officer is responsible for security at the DVC and directs activity of the security staff inside the DVC. In addition, this officer manages the health and safety of all DVC staff and ensures that operating conditions meet all Federal, state, and county health and safety regulations.

### *b. DVC General Staff*

The DVC General Staff is the organizational level comprising the major functional sections of the DVC and includes the following:

1) *DVC Planning Section*

The DVC Planning Section collects, evaluates, and disseminates real-time information regarding DVC operations. The Planning Section also monitors and reports resource use and allocation and prepares Situation Reports (SitReps) to be incorporated in the development of the next SAP (see 2, below).

2) *DVC Operations Section*
   The Operations Section directs and coordinates DVC operational activities and ensures proper implementation of the SAP. Section subgroups under DVC Operations may include a Medical Section (covering triage and medical evaluation), a Pharmacy Section (covering dispensing of prophylactic medicines and vaccines and treatment regimens used for seriously ill patients), a Mental Health Section, and a Transportation Section, as well as the DVC Security Unit.

3) *DVC Logistics Section*
   The Logistics Section responds to information generated from the Planning Section and coordinates the provision of required services and materials. Additionally, the Logistics Section will directly support the needs of the DVC staff (e.g., food, medical treatment).

4) *DVC Finance/Administration Section*
   The Finance/Administration Section is responsible for DVC costs and financial considerations. The Finance/Administration Section records staffing hours, procurement costs, and unused and returnable SNS inventories. Furthermore, the Finance/Administration Section monitors the patient flow entering and exiting the DVC, including the collection of patient information/forms upon DVC exit. Finally, the DVC Finance/Administration Section may oversee the Translators Unit that will vary in size as determined by the needs of the community.

**2. Development of the DVC Site Action Plan (SAP)**

The DVC Site Action Plan (SAP) serves as a detailed operational guide to the deployment and operation of individual DVCs and should be an extension of the larger campaign goals of the Incident Action Plan (IAP) established by the campaign's central Command and Control function. The DVC SAP should address the following:

- Policies, priorities, and objectives determined by the DVC Command and Control, integrated into the larger Unified Command function,

- Organizational plans to meet these objectives developed by the DVC Planning and Operations Units

- Support and service plans to accomplish the organizational plans developed by the DVC Logistics Unit (with input from the Security Officer).

- Financial and resource considerations compiled by the Financial/Administration Unit.

The DVC SAP should explicitly state the prophylaxis goals of the operational period (e.g., number of patients to prophylax over the next 24 hours) and detail all tactical actions (e.g., staffing levels at individual stations) and supporting information. This SAP should be updated prior to the initiation of the next operational period and reflect the developments of previous periods. It is important to note that SAP must be developed uniquely by each DVC to meet its specific needs as time unfolds; however, it should integrate into the larger campaign IAP (developed in the EOC of the community's central Command and Control function) and thus should be in accordance with the larger campaign goals.

**3. Job Action Sheets and Protocols**

Each staffing position in the ICS should have a prioritized Job Action Sheet describing in detail the roles and responsibilities associated with that particular position. Job Action Sheets serve to standardize position duties and allow staff to move easily from one position to another as the response dictates. Clinical protocols are required to guide several of the core DVC functions (including triage, medical evaluation, and drug triage and dispensing). These protocols, which must be developed prior to any implementation of the DVC plan, are incorporated into Job Action Sheets as a prioritized item number (e.g., Item #2: triage arriving patients according Triage Protocol sheet). Optimally, each DVC will have an identical structure and thus Job Action sheets should be uniformly developed by the DOC under the direction of the community's EOC. However, due to such factors as size limitations or unique target population characteristics, a particular DVC may require a unique staffing structure and thus specialized Job Action Sheets.

## B. Additional Functions

The ICS provides managerial structure for additional functions including staff room and board, receipt, storage, and staging of resources, and intra-DVC transportation for both staff and patients. Additionally, the modular flexibility (i.e., functional units) of the ICS allows incorporation of volunteer staff. For example, the DVC Reception/Greeting Unit can contain a Volunteer Team to handle appropriate duties. The DVC SAP should provide detailed procedures for utilizing volunteers in DVC operations.

## C. Flexibility And Redundancy

The ICS provides a time- and experience-tested management structure that has been adopted by many state and local emergency response agencies. ICS combines clear delineation of roles and reporting channels with flexibility and adaptability to local requirements and resources. A mass prophylaxis program framed in the ICS structure can rapidly respond to changes in local DVC goals, resources, and personnel.

The size and scope of a mass prophylaxis campaign requires coordinated collaboration among different agencies that previously may not have undertaken joint large-scale community operations (e.g., public health and law enforcement, U.S. Postal Service and emergency management) and may have very different jurisdictional levels (e.g., county versus Federal). The ICS structure (and related Incident Management System (IMS)) allows for efficient interagency collaboration and communication. The ICS operates with "unity of command," whereby information flows from each organizational member to only one designated manager, creating an internal quality control system.

ICS also allows for the coordination of multiple DVCs with clear lines of communication. Each DVC has a single individual responsible for a defined functional area that is consistent across all DVCs. A mass prophylaxis program utilizing multiple DVCs linked to an overall Command and Control function framed in ICS permits the efficient gathering of community-wide data and the shifting of staff and resources between DVCs (e.g., from a demobilizing DVC to those DVCs receiving an accelerating patient flow rate).

In order to maintain appropriate staffing levels in a crisis situation, emergency management planning often calls for “3-deep” staffing whereby every position has two back-up personnel. However, given the potential size of staff required for a mass prophylaxis campaign, this ratio may be infeasible. An alternative would be to ensure each staff member’s familiarity with the roles and responsibilities of two additional and related positions, creating in effect a reverse one to three ratio. For example, a medical evaluator could familiarize herself with the triage and pharmacy protocols in case there was need for additional staff at these positions. A protocol-driven ICS structure allows for easy review of different staff duties. Additionally, an ICS structure creates an inherent layer of redundancy, as managers are familiar with the operational protocols guiding the members of the group.

The chief drawback of ICS is the need to adopt a new technical vocabulary and response structure for those unfamiliar with its roles and concepts. Consequently, time for education and training in ICS should be factored into DVC plans. This up-front training time may require significant buy-in in terms of staff time and resources from all of the agencies involved in planning for mass prophylaxis campaigns. However, simple Job Action Sheets, a clear, uniform command structure, and defined protocols allow for rapid training that, when necessary, can be done during the activation and/or escalation of a response.

## D. Command And Control Integration

Operation of a DVC during an actual bioterrorism event would be a complex endeavor requiring dynamic management to ensure efficient operation and success of the overall prophylaxis campaign. Depending on the magnitude of the terrorist event, the size and location of the affected community, and the existing emergency response infrastructure, the Command and Control function may be too far removed from actual dispensing activities to effectively manage the minute-by-minute operational requirements of a functioning DVC. Employing a DVC-specific modified ICS structure as described in this section should improve the effectiveness of DVC operations and contribute to the success of the overall prophylaxis campaign *provided that* this DVC ICS functions as an extension of the community’s central Command and Control function.

# References


1. Jernigan J, Stephens D, Ashford D, et al. Bioterrorism-related inhalational anthrax: the first 10 cases reported in the United States. *Emerg Infect Dis.* 2001 Nov-Dec;7(6):933-44.

2. WHO. Situation Updates - Severe Acute Respiratory Syndrome (SARS). Available at: http://www.who.int/csr/sarsarchive/en/. Accessed March 31, 2003.

3. Webby RJ, Webster RG. Are we ready for pandemic influenza? *Science.* Nov 28 2003;302(5650):1519-1522.

4. *A Governor's Guide to Emergency Management: Volume 2 - Homeland Security*. Washington, D.C.: National Governor's Association; 2002.

5. *Receiving, Distributing, and Dispensing the National Pharmaceutical Stockpile: A Guide for Planners. Version 9.* Atlanta, GA: Centers for Disease Control and Prevention (CDC); April 2002.

6. Darling RG, Catlett CL, Huebner KD, Jarrett DG. Threats in bioterrorism. I: CDC category A agents. *Emerg Med Clin North Am.* 2002;20(2):273-309.

7. Meyer DV, Smith LE, Ahlquist A, Bray DA, Miller JM. Laboratory Response Network - Web-based Help Desk, Proficiency Testing, and Reporting. *Proc AMIA Symp.* 2003:933.

8. Mothershead JL, Tonat K, Koenig KL. Bioterrorism preparedness. III: State and federal programs and response. *Emerg Med Clin North Am.* May 2002;20(2):477-500.

9. O'Toole T, Inglesby TV. Epidemic response scenario: decision making in a time of plague. *Public Health Rep.* 2001;116(Suppl 2):92-103.

10. Perkins BA, Popovic T, Yeskey K. Public health in the time of bioterrorism. *Emerg Infect Dis.* Oct 2002;8(10):1015-1018.

11. Morse A. Bioterrorism preparedness for local health departments. *J Community Health Nurs.* Winter 2002;19(4):203-211.

12. Yetman RJ, Parks D, Taft E. Management of patients exposed to biologic weapons. *J Pediatr Health Care.* 2002;16(5):256-261.

13. Godley J. Bioterror emergency readiness: a local responsibility. *Manag Care.* Nov 2003;12(11 Suppl):13-15.

14. Thomson D. Mass immunization in the control of infectious disease. *British Medical Journal.* 1966;5511:427-433.

15. WHO. *Public Health Response to Biological and Chemical Weapons.* Geneva: World Health Organization, 2001.

16. Syndromic surveillance for bioterrorism following the attacks on the World Trade Center--New York City, 2001. *MMWR Morb Mortal Wkly Rep.* 2002;51 Spec No:13-15.

17. Buehler JW, Berkelman RL, Hartley DM, Peters CJ. Syndromic surveillance and bioterrorism-related epidemics. *Emerg Infect Dis.* Oct 2003;9(10):1197-1204.

18. Irvin CB, Nouhan PP, Rice K. Syndromic analysis of computerized emergency department patients' chief complaints: an opportunity for bioterrorism and influenza surveillance. *Ann Emerg Med.* Apr 2003;41(4):447-452.

19. Mostashari F, Fine A, Das D, Adams J, Layton M. Use of ambulance dispatch data as an early warning system for communitywide influenzalike illness, New York City. *J Urban Health.* Jun 2003;80(2 Suppl 1):i43-49.

20. Bravata DM, Owens DK, Buckeridge DL, et al. *Bioterrorism Preparedness and Response: Use of Information Technologies and Decision Support Systems*: AHRQ Publication No. 02-E028. Rockville, MD: Agency for Healthcare Research and Quality.; June 2002.

21. Danzig R. *Catastrophic bioterrrorism: what is to be done?* Washington, DC: Center for Technology and National Security Policy, National Defense University; August, 2003 2003.

22. Sox G, Maxymiv K. *Exercising the Strategic National Stockpile: Lessons Learned and Tools for Application.* Washington, DC: Association of State and Territorial Health Officials (ASTHO); 2004.

23. Bentley JD. Hospital preparedness for bioterrorism. *Public Health Rep.* 2001;116(Suppl 2):36-39.

24. Wetter DC, Daniell WE, Treser CD. Hospital preparedness for victims of chemical or biological terrorism. *Am J Public Health.* 2001;91(5):710-716.

25. Henning KJ, Brennan PJ, Hoegg C, O'Rourke E, Dyer BD, Grace TL. Health system preparedness for bioterrorism: bringing the tabletop to the hospital. *Infect Control Hosp Epidemiol.* Feb 2004;25(2):146-155.

26. Taylor CW. Surge capacity: preparing your healthcare system. *Emerg Med Serv.* Aug 2003;32(8):91-92.

27. Shapiro DS. Surge capacity for response to bioterrorism in hospital clinical microbiology laboratories. *J Clin Microbiol.* Dec 2003;41(12):5372-5376.

28. Hupert N, Mushlin AI, Callahan MA. Modeling the public health response to bioterrorism: using discrete event simulation to design antibiotic distribution centers. *Med Decis Making.* Sep-Oct 2002;22(5 Suppl):S17-25.

29. Hupert N, Bearman GM, Mushlin AI, Callahan MA. Accuracy of screening for inhalational anthrax after a bioterrorist attack. *Ann Intern Med.* Sep 2 2003;139(5 Pt 1):337-345.

30. Follow-up of deaths among U.S. Postal Service workers potentially exposed to Bacillus anthracis--District of Columbia, 2001-2002. *MMWR Morb Mortal Wkly Rep.* Oct 3 2003;52(39):937-938.

31. Navas E. Problems associated with potential massive use of antimicrobial agents as prophylaxis or therapy of a bioterrorist attack. *Clin Microbiol Infect.* Aug 2002;8(8):534-539.

32. Shepard CW, Soriano-Gabarro M, Zell ER, et al. Antimicrobial postexposure prophylaxis for anthrax: adverse events and adherence. *Emerg Infect Dis.* Oct 2002;8(10):1124-1132.

33. Tierney BC, Martin SW, Franzke LH, et al. Serious adverse events among participants in the Centers for Disease Control and Prevention's Anthrax Vaccine and Antimicrobial Availability Program for persons at risk for bioterrorism-related inhalational anthrax. *Clin Infect Dis.* Oct 1 2003;37(7):905-911.

34. Inglesby TV, O'Toole T, Henderson DA. Preventing the use of biological weapons: improving response should prevention fail. *Clin Infect Dis.* 2000;30(6):926-929.

35. Barbera JA, Macintyre AG. The reality of the modern bioterrorism response. *Lancet.* 2002;360(Suppl):s33-34.

36. Franz DR, Zajtchuk R. Biological terrorism: understanding the threat, preparation, and medical response. *Disease-A-Month.* 2002;48(8):493-564.

37. Bell DM, Kozarsky PE, Stephens DS. Clinical issues in the prophylaxis, diagnosis, and treatment of anthrax. *Emerg Infect Dis.* 2002;8(2):222-225.

38. Layton M. Bioterrorism preparedness checklist - local public health agency perspective. Paper presented at: WHO Meeting on Informal Discussions on Strengthening National Preparedness and Response to Biological Weapons, Rome 2002. URL: http://www.who.int/emc/pdfs/WHOmeetingMarciLayton1.pdf. Accessed April 2, 2004

39. Binder P, Attre O, Boutin JP, et al. Medical management of biological warfare and bioterrorism: place of the immunoprevention and the immunotherapy. *Comp Immunol Microbiol Infect Dis.* Oct 2003;26(5-6):401-421.

40. Blank S, Moskin LC, Zucker JR. An ounce of prevention is a ton of work: mass antibiotic prophylaxis for anthrax, New York City, 2001. *Emerg Infect Dis.* Jun 2003;9(6):615-622.

41. Esbitt D. The Strategic National Stockpile: roles and responsibilities of health care professionals for receiving the stockpile assets. *Disaster Manag Response.* Jul-Sep 2003;1(3):68-70.

42. Martin G. Anthrax: lessons learned from the U.S. Capitol experience. *Mil Med.* Sep 2003;168(9 Suppl):9-14.

43. Partridge R, Alexander J, Lawrence T, Suner S. Medical counterbioterrorism: the response to provide anthrax prophylaxis to New York City US Postal Service employees. *Ann Emerg Med.* Apr 2003;41(4):441-446.

44. Inglesby TV, Grossman R, O'Toole T. A plague on your city: observations from TOPOFF. *Clin Infect Dis.* 2001;32(3):436-445.

45. U.S. Postal Service may deliver medicine in the event of a catastrophic incident. *U.S. Postal Service* [February 18 2004 Press Release]. Available at: http://www.usps.com/communications/news/press/2004/pr04_015.pdf. Accessed April 2, 2004.

46. Butler JC, Cohen ML, Friedman CR, Scripp RM, Watz CG. Collaboration between public health and law enforcement: new paradigms and partnerships for bioterrorism planning and response. *Emerg Infect Dis.* 2002;8(10):1152-1156.

47. Reich DS. Modernizing local responses to public health emergencies: bioterrorism, epidemics, and the model state emergency health powers act. *J Contemp Health Law Policy.* Spring 2003;19(2):379-414.

48. GAO. *Public Health Response to Anthrax Incidents of 2001.* Washington, DC: United States General Accounting Office; October 2003. GAO-04-152.

49. GAO. *Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities for Bioterrorism Response.* Washington, DC: United States General Accounting Office; August, 2003. GAO-03-924.

50. Flowers LK, Mothershead JL, Blackwell TH. Bioterrorism preparedness. II: The community and emergency medical services systems. *Emerg Med Clin North Am.* 2002;20(2):457-476.

51. Knouss RF. National disaster medical system. *Public Health Rep.* 2001;116(Suppl 2):49-52.

52. Landesman LY. *Public health management of disasters: a practice guide.* Washington, D.C.: American Public Health Association; 2001.

53. Blendon RJ, DesRoches CM, Benson JM, Herrmann MJ, Taylor-Clark K, Weldon KJ. The public and the smallpox threat. *N Engl J Med.* 2003;348(5):426-432.

54. Greenberg MI, Jurgens SM, Gracely EJ. Emergency department preparedness for the evaluation and treatment of victims of biological or chemical terrorist attack. *J Emerg Med.* 2002;22(3):273-278.

55. Schultz CH, Mothershead JL, Field M. Bioterrorism preparedness. I: The emergency department and hospital. *Emerg Med Clin North Am.* May 2002;20(2):437-455.

56. Montello MJ, Ostroff C, Frank EC, Haffer AS, Rogers JR. 2001 anthrax crisis in Washington, D.C.: pharmacists' role in screening patients and selecting prophylaxis. *Am J Health Syst Pharm.* 2002;59(12):1193-1199.

57. Malecki J, Brumback CL. Need for physicians trained in preventive medicine and public health: implications for a bioterrorism response. *J Public Health Manag Pract.* Mar-Apr 2003;9(2):89-90.

58. Rippen HE, Gursky E, Stoto MA. Importance of bioterrorism preparedness for family physicians. *Am Fam Physician.* May 1 2003;67(9):1877-1878.

59. Bartlett JG. Mobilizing professional communities. *Public Health Rep.* 2001;116(Suppl 2):40-44.

60. Barbera J, Macintyre A, Gostin L, et al. Large-scale quarantine following biological terrorism in the United States: scientific examination, logistic and legal limits, and possible consequences. *JAMA.* 2001;286(21):2711-2717.

61. Glass TA. Understanding public response to disasters. *Public Health Rep.* 2001;116(Suppl 2):69-73.

62. Bloem K. Treating the sick: capacity of the US Health Care System to respond to an epidemic. *Public Health Rep.* 2001;116(Suppl 2):34-35.

63. Greenberg MI, Hendrickson RG. Report of the CIMERC/Drexel University Emergency Department Terrorism Preparedness Consensus Panel. *Acad Emerg Med.* Jul 2003;10(7):783-788.

64. Laughrun GM. Preparing your hospital to respond to a terrorist attack. *Am J Health Syst Pharm.* 2002;59(14):1329-1330.

65. Pollard WE. Public perceptions of information sources concerning bioterrorism before and after anthrax attacks: an analysis of national survey data. *J Health Commun.* 2003;8 Suppl 1:93-103; discussion 148-151.

66. Kuhr S, Hauer JM. Intergovernmental preparedness and response to potential catastrophic biological terrorism. *J Public Health Manag Pract.* 2000;6(4):50-56.

67. Bioterrorism: coordination and preparedness - Heinrich, J. *Subcommittee on Government Efficiency, Financial Management, and Intergovernmental Relations. Committee on Government Reform*. Washington, D.C.: United States General Accounting Office; 2001.

68. Stephenson J. Monkeypox outbreak a reminder of emerging infections vulnerabilities. *JAMA.* Jul 2 2003;290(1):23-24.

69. Terriff CM, Tee AM. Citywide pharmaceutical preparation for bioterrorism. *Am J Health Syst Pharm.* Feb 1 2001;58(3):233-237.

70. Auf der Heide E. *Disaster Response: Principles of Preparation and Coordination*. St. Louis: Mosby; 1989. Chapter 8, Triage.

71. Haffer AS, Rogers JR, Montello MJ, Frank EC, Ostroff C. 2001 anthrax crisis in Washington, D.C.: clinic for persons exposed to contaminated mail. *Am J Health Syst Pharm.* 2002;59(12):1189-1192.

72. Benedek DM, Holloway HC, Becker SM. Emergency mental health management in bioterrorism events. *Emerg Med Clin North Am.* May 2002;20(2):393-407.

73. Stein BD, Tanielian TL, Vaiana ME, Rhodes HJ, Burnam MA. The role of schools in meeting community needs during bioterrorism. *Biosecur Bioterror.* 2003;1(4):273-281.

74. Ridge T. *National Incident Management System.* Washington, DC: Department of Homeland Security; March 2004.

75. Koplan J. CDC's strategic plan for bioterrorism preparedness and response. *Public Health Reports.* 2001;116(Suppl 2):9-16.

76. Auf der Heide E. *Disaster Response: Principles of Preparation and Coordination*. St. Louis: Mosby; 1989. Chapter 9, The Incident Command System (ICS).

77. Brown BS, Prior SD. Public health and public trust: the defining dyad for the 21st century. *Int J Emerg Ment Health.* Fall 2002;4(4):239-244.

78. Hall MJ, Norwood AE, Ursano RJ, Fullerton CS. The psychological impacts of bioterrorism. *Biosecur Bioterror.* 2003;1(2):139-144.

79. Vanderford ML. Communication lessons learned in the Emergency Operations Center during CDC's anthrax response: a commentary. *J Health Commun.* 2003;8 Suppl 1:11-12.

80. State of California Mass Prophylaxis Guide. *Emergency Medical Services Authority of California*. Available at: http://www.emsa.cahwnet.gov/dms2/draft_mass_prophy_final.pdf. Accessed April 2, 2004.

81. Simple triage and rapid treatment. *CERT-Los Angeles*. Available at: http://www.cert-la.com/triage/start.htm. Accessed 09/09/02, 2002.

82. Suspected exposure to bioterrorism agent emergency department triage guidelines. *Stanford University Medical Center Bioterrorism and Emergency Preparedness Task Force* [web-page]. 12/08/01. Available at: http://www.stanfordhospital.com/pdf/bioterrorism/EDTriageGuideline.pdf. Accessed November 15, 2002.

83. Holloway HC, Norwood AE, Fullerton CS, Engel CC, Jr., Ursano RJ. The threat of biological weapons. Prophylaxis and mitigation of psychological and social consequences. *JAMA.* 1997;278(5):425-427.

84. Hupert N, Cuomo J. Bioterrorism and Epidemic Outbreak Response Model (BERM). *Agency for Healthcare Research and Quality (AHRQ)*. Available at: http://www.ahrq.gov/research/biomodel.htm. Accessed April 2, 2004.

85. Capital Health. *Mass immunization campaigns: A "how to" guide based on experience during the February 2000 Capital Health meningococcal immunization campaign*. Alberta, Canada; 2000.

86. Osterholm MT. How to vaccinate 30,000 people in three days: realities of outbreak management. *Public Health Rep.* 2001;116(Suppl 2):74-78.

87. New model developed for outbreak readiness. *Healthcare Benchmarks Qual Improv.* Sep 2003;10(9):101-102.

88. Giovachino M, Carey N. Modeling the consequences of bioterrorism response. *Mil Med.* 2001;166(11):925-930.

89. *Emergency Management and Public Health: How Are Emergencies Handled in the Commonwealth of Massachusetts?*: Massachusetts Department of Health; 2001.

90. *California Hospital Bioterrorism Response Planning Guide*. Sacramento, California: Department of Health Services and Emergency Medical Services Authority of California; 2002.

91. *Guidelines for the development of local action plan for use of the following assets: state pharmaceutical*

*stockpiles (SPS) and National Pharmaceutical Stockpile (NPS).* Florida: Florida Department of Health, Office of Emergency Management; 2002.

92. Kaplan EH, Craft DL, Wein LM. Emergency response to a smallpox attack: the case for mass vaccination. *Proceedings of the National Academy of Sciences of the United States of America.* 2002;99(16):10935-10940.

93. Halloran ME, Longini IM Jr., Nizam A, Yang Y. Containing bioterrorist smallpox. *Science.* 2002;298(5597):1428-1432.

94. Bozzette SA, Boer R, Bhatnagar V, et al. A model for a smallpox-vaccination policy. *N Engl J Med.* Jan 30 2003;348(5):416-425.

95. Henderson DA, Inglesby TV, Bartlett JG, et al. Smallpox as a biological weapon: medical and public health management. *JAMA.*1999;281(22):2127-2137.

96. Breman JG, Henderson DA. Diagnosis and management of smallpox. *N Engl J Med.* 2002;346(17):1300-1308.

97. Lane JM, Goldstein J. Evaluation of 21st-century risks of smallpox vaccination and policy options. *Ann Intern Med.* Mar 18 2003;138(6):488-493.

98. Mack T. A different view of smallpox and vaccination. *N Engl J Med.* 2003;348(5):460-463.

99. Breman JG, Arita I, Fenner F. Preventing the return of smallpox. *N Engl J Med.* 2003;348(5):463-466.

100. Fauci AS. Smallpox vaccination policy--the need for dialogue. *N Engl J Med.* 2002;346(17):1319-1320.

101. Lane JM. Smallpox and smallpox vaccination. *N Engl J Med.* 2002;347(9):691; author reply 691-692.

102. Smallpox Response Plan and Guidelines (Version 3.0). Centers for Disease Control and Prevention. Exp. Date 06/2003. Available at: http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp. Accessed February 21, 2003.

# Glossary

**Bioterrorism:** The intentional release of disease-causing bacteria, viruses, toxins, and/or spores on civilian populations in order to induce fear and panic by causing illness and/or death.

**Biowarfare:** The use of disease-causing bacteria, viruses, toxins, and/or spores upon military personnel to achieve strategic objectives during warfare.

**Category A Biological Agents/Diseases:** Biological agents classified as high-risk by the Centers for Disease Control and Prevention (CDC) because of their relative ease in dissemination and transmission, their high infectivity and virulence, impact on public order, and requirement of unique and extraordinary public health preparedness and response.[6] These agents are: anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers.

**Dispensing:** The process of providing medical prophylaxis to targeted populations in the community. The third step in the drug delivery chain from stockpile to distribution to dispensing.

**Dispensing/Vaccination Center (DVC):** A single location where antibiotic or vaccine dispensing activities occur. Also know as a Point of Dispensing, or POD.

**Distribution:** The process of delivering bulk medical materials (e.g. SNS supplies) from stockpile and staging areas to the dispensing centers. Second step in drug delivery chain from stockpile to distribution to dispensing.

**Incident Command System:** An organizational structure for emergency response based on clear and consistent definitions of roles, responsibilities, and reporting channels of all participating personnel.

**Logistics:** Refers to resource procurement and management to achieve objective goals; the section of ICS responsible for providing facilities, services, and materials for the incident (not personnel).

**Mass Prophylaxis:** The process by which an entire community is to receive prophylactic drugs/vaccines over a defined period of time in response to possible exposure to a biological agent.

**National Pharmaceutical Stockpile (NPS):** See Strategic National Stockpile (SNS)

**Strategic National Stockpile (SNS):** The Federal cache of pharmaceuticals, vaccines, medical supplies, equipment, and other items to augment local supplies of critical medical care targeted to high-priority diseases and conditions (based on the CDC Category A agents). Also refers to the program and support staff managing and operating this cache. Formerly known as the National Pharmaceutical Stockpile (NPS).

**Operations:** Refers to implementation of planned processes using resources provided by Logistics; the section of ICS responsible for all tactical processes at the incident.

**Protocol:** A detailed script, decision tree, or patient flow diagram intended to guide decisions and action at specific DVC stations (e.g., triage).

**Push Package:** The unit cache of medical supplies created by the SNS that will be shipped to an incident within 12 hours of Federal authorization.

**Surveillance:** The process of monitoring community-wide illness syndromes or disease occurrence to detect a possible bioterrorist attack or natural outbreaks of unusual diseases.

**Triage:** The systematic and protocol-driven evaluation of patient-based information to determine type of treatment or assistance needed. DVC triage may direct patients to further medical evaluation, mental health evaluation, pharmacist-assisted drug dispensing, or none of the above.

**Vendor Managed Inventory (VMI):** Large caches of specific pharmaceutical agents stored by manufacturers under preexisting contractual arrangement with CDC SNS and available for mass shipment to affected areas as needed for continuing prophylaxis and response activities after use of one or more Push Packages.

## Acronyms:

**DOC** = Dispensing Operations Commander
**DVC IO** = Dispensing/Vaccination Center Information Officer
**DVC SC** = Dispensing/Vaccination Center Site Commander
**DVC** = Dispensing/Vaccination Center (also known as POD)
**EOC** = Emergency Operations Center
**HAN** = Health Alert Network
**IAP** = Incident Action Plan
**IC** = Incident Commander of campaign
**ICS** = Incident Command System
**IMS** = Incident Management System
**JAS** = Job Action Sheet(s)
**SAP** = Site Action Plan for DVC
**SitRep** = Situation Reports
**SNS** = Strategic National Stockpile and Strategic National Stockpile Program (formerly NPS)

# Appendixes

# Appendix A. Advisory Board

| | |
|---|---|
| Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services….. | Sally Phillips, R.N., Ph.D. |
| Arnold and Marie Schwartz College of Pharmacy Long Island University…………………………….. | Robert V. DiGregorio, Pharm.D. |
| Centers for Disease Control and Prevention……………… | Richard Nolan<br>David Adcock<br>Joe Henderson |
| National Association of County and City Health Officials………………………………. | Zarnaaz Rauf, M.P.H.<br>Larry Raine, Dr.P.H. |
| New York City Department of Health and Mental Hygiene………………………………… | Susan Blank, M.D., M.P.H.<br>Isaac Weisfuse, M.D., M.P.H. |
| New York City Office of Emergency Management……….. | Samuel Benson, AEMT-P<br>Edward Gabriel, AEMT-P, M.P.A. |
| Office of the Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services………………….……………….. | CDR Matthew Tarosky, Pharm.D. |
| Orange County FL Health Services Division, Office of Disaster and Emergency Services……............ | David L. Freeman, REMT-P |

# Appendix B. Thematic Bibliography

## I. DVC Examples and Draft Plans


1. Haffer AS, Rogers JR, Montello MJ, Frank EC, Ostroff C. 2001 anthrax crisis in Washington D.C.: clinic for persons exposed to contaminated mail. *Am J Health-Syst Pharm.* 2002;59:1189-1192.

2. Montello MJ, Ostroff C, Frank EC, Haffer AS, Rogers JR. 2001 anthrax crisis in Washington, D.C.: pharmacists' role in screening patients and selecting prophylaxis. *Am J Health-Syst Pharm.* 2002;59:1189-1192.

3. "Three-day bioterrorism drill begins in an Oklahoma town." Associated Press. *The New York Times*. 2002; April 13:A11.

4. "Official react to bioterrorism drill." Brown, JL. *The Washington Post*. 2002; April 12. URL: http://www.washingtonpost.com/wp-dyn/articles/A36763-2002Apr12.html. Accessed 9/10/02.

5. Inglesby TV. Observations from the Top Off exercise. *Public Health Reports*. 2001 Supplement 2;116:64-75.

6. Osterholm MT. How to vaccinate 30,000 people in three days: realities of outbreak management. *Public Health Reports*. 2001 Supplement 2;116:74-78.

7. "Guidelines for the development of a local action plan for use of the following assets: state pharmaceutical stockpile (SPS) and Strategic National Stockpile(SNS)." Florida Department of Health, Office of Emergency Operations. April 2002.

8. "National pharmaceutical stockpile: guidelines for counties." Central Florida Regional Domestic Security Task Force. Draft Version 3. August 16, 2002.

9. *State of California Mass Prophylaxis Planning Guide*. Emergency Medical Services Authority of California. 2003. Available at: http://www.emsa.cahwnet.gov/dms2/draft_mass_prophy_final.pdf. Accessed April 2, 2004

10. Smallpox Response Plan and Guidelines (Version 3.0). Centers for Disease Control and Prevention. Web Site: http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp. Accessed on February 21, 2003.

## II. Web-Based Resources

11. "Anthrax clinical pathways for clinics (updated 01/09/02)." SUMC Bioterrorism and Emergency Preparedness Task Force, Stanford University Medical Center. URL: http://www.stanfordhospital.com/pdf/bioterrorism/anthraxclinicalpathwaysclinics.pdf. Accessed 9/10/02.

12. "Suspected exposure to bioterrorism agent emergency department triage guidelines (updated 12/08/01)." SUMC Bioterrorism and Emergency Preparedness Task Force, Stanford University Medical Center. URL: http://www.stanfordhospital.com/pdf/bioterrorism/EDTriageGuideline.pdf Accessed 9/10/02.

13. "Bioterrorism preparedness checklist – local public health agency perspective." Layton, M. Informal Discussions on Strengthening National Preparedness and Response to Biological Weapons; World Health Organization. March 6-8,2002. URL: http://www.who.int/emc/pdfs/Marcy%20Layton.pdf. Accessed 9/10/02.

## III. National Association of County and City Health Officials (NACCHO)

14. "Infrastructure, organizational, policy, and resource implications for implementing CDC guidelines for managing and using a deployed national pharmaceutical stockpile." NACCHO planning document 8/02

15. "Prototype position description for the top manager for coordination and support of a statewide SNS preparedness program." NACCHO planning document 8/02.

16. Clearinghouse records of city, county, and state emergency preparedness plans. NACCHO. URL: http://bt.naccho.org/print.asp. Accessed 9/10/02.

## IV. Public Health Disaster Management

17. Landesman LY. *Public health management of disasters: a practice guide*. Washington, D.C.: American Public Health Association; 2001

18. Auf der Heide, Erik. *Disaster Response: Principles of Preparation and Coordination.* Center for Excellence in Disaster Management & Humanitarian Assistance: Honolulu, 2001. Chapter 8: Triage. URL: http://216.202.128.19/dr/DisasterResponse.nsf/section/08?opendocument. Accessed 9/10/02

19. "CERT-Los Angeles: simple triage and rapid treatment." URL: http://www.cert-la.com/triage/start.htm. Accessed 9/10/02

20. "Health disaster management: guidelines for evaluation and research in the Utstein style: executive summary." Task Force on Quality Control of Disaster Management. URL: http://pdm.medicine.wise.edu/executiv2.htm Accessed 9/10/02.

21. Hamburg MA. Challenges confronting public health agencies. *Public Health Reports*. 2001 Supplement 2;116:59-63.

22. Glass TA. Understanding public response to disasters. *Public Health Reports*. 2001 Supplement 2;116:69-73.

23. O'Toole T, Inglesby TV. Epidemic response scenario: decision making in a time of plague. *Public Health Reports*. 2001 Supplement 2;116:92-103.

24. O'Toole, T. The problem of biological weapons: next steps for the nation. *Public Health Reports*. 2001 Supplement 2;116:108-111.

25. Fee E, Brown TM. Preemptive biopreparedness: can we learn anything from history? *American J of Pub Health*. 2001 May; 91(5):721-726.

26. Rubin J. Institutional networks: regional response to disasters. *Public Health Reports*. 2001 Supplement 2;116:45-48.

27. Kuhr S, Hauer JM. Intergovernmental preparedness and response to potential catastrophic biological terrorism. *J of Pub Health Management and Practice.* 2000 July;64(4):50-56.

28. Bartlett JG. Mobilizing professional communities. *Public Health Reports*. 2001 Supplement 2;116:40-44.

29. The Treatment of Mass Civilian Casualities in a National Emergency. McCarroll JR, Skudder PA, Eds. *Medical Education for National Defense*, Washington, D.C. 1967.

30. *Summary Report on National Emergency Medical Care*. The American Medical Association, Chicago, IL. 1959.

31. *Community Outreach – Mass Prophylaxis*: *A Mass Casualty Care Strategy for Biological Terrorism Incidents.* US Army Soldier and Biological Chemical Command, Homeland Defense Office, Department of Defense; June 1, 2002.

32. Inglesby TV. Preparedness for terrorist attack. Federal Document Clearing House Congressional Testimony. Capitol Hill Hearing Testimony. Senate Governmental Affairs. April 18, 2002 Thursday.

33. Ridge T. *National Incident Management System.* Washington, DC: Department of Homeland Security; March 2004.

## V. Hospital Preparedness and Capacity


34. Bentley JD. Hospital preparedness for bioterrorism. *Public Health Reports*. 2001 Supplement 2;116:36-39.

35. Bloem K. Treating the sick: capacity of the US health care system to respond to an epidemic. *Public Health Reports*. 2001 Supplement 2;116:34-35.

36. Wetter DC, Daniell WE, Treser CD. Hospital preparedness for victims of chemical or biological terrorism. *American J of Pub Health*. 2001 May; 91(5):710-716.

37. Giovachino M, Carey N. Modeling the consequences of bioterrorism response. *Mil Med*. 2001;166(11):925-930.

38. Johnson LA. Hospitals, state health system readying staff, equipment for terrorism. Associated Press. BC Cycle; June 6, 2002.

39. *17 Critical Benchmarks for Bioterrorism Preparedness Planning*. FDCH Federal Department and Agency Documents. Regulatory Intelligence Data. Department of Health and Human Services. June 6, 2002.

40. *California Hospital Bioterrorism Response Planning Guide*. California Department of Health Services and Emergency Medical Services Authority of California. June, 2002. URL: http://www.emsa.cahwnet.gov/dms2/ca_hosp_guide.pdf. Accessed 9/10/02


## VI. Federal Response


41. "Technical assistance for anthrax response," Interim-Final Draft for Review June 2002. National Response Team. 2002, August 2.

42. Kennedy EM. National leadership in confronting bioterrorism: 2. *Public Health Reports*. 2001 Supplement 2;116:116-118.

43. Knouss RF. National disaster medical system. *Public Health Reports*. 2001 Supplement 2;116:49-52.


## VII. Agency for Healthcare Research and Quality (AHRQ) and Centers for Disease Control and Prevention (CDC)


44. Bravata D, McDonald K, Owens D, et al. Bioterrorism Preparedness and Response: Use of Information Technologies and Decision Support Systems (Evidence Report/Technology Assessment No. 59 (Prepared by University of California San Francisco-Stanford Evidence-based Practice Center under Contract No. 290-97-0013).

AHRQ Publication No. 02-E028. Rockville, MD: Agency for Healthcare Research and Quality. June 2002.

45. "Biological and chemical terrorism: strategic plan for preparedness and response." Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Recommendations and Reports*. 2000, April 21; 49(RR-4):1-14.

46. "Prevention and control of influenza: recommendations of the advisory committee on immunization practices." Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report*. 2002, April 12;51(RR-3):1-31.

47. "Update: investigation of bioterrorism-related anthrax and interim guidelines for exposure management and antimicrobial therapy, October 2001." Centers for Disease Control and Preparedness. *Morbidity and Mortality Weekly Report*. 2001 October 26; 50(42):909-919.

48. Phillips S, Burstin H, Dillard CD, Clancy CM. AHRQ's bioterrorism research portfolio: real linkages in real time. *Health Serv Res.* Feb 2004;39(1):xi-xv.

## VIII. World Health Organization Guidelines

49. "Public health response to biological and chemical weapons." *WHO Guidelines*. World Health Organization; November 2001.

## IX. National Pharmaceutical Guidelines

50. *Receiving, Distributing, and Dispensing the National Pharmaceutical Stockpile: A Guide for Planners. Version 9 – Draft.* Centers for Disease Control and Prevention; April 2002.

## X. Smallpox

51. Smallpox Response Plan and Guidelines (Version 3.0). Centers for Disease Control and Prevention. Web Site: http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp. Accessed on February 21, 2003.

52. Henderson DA, Inglesby TV, Bartlett JG, Ascher MS, Eitzen E, Jahrling PB, et al. Smallpox as a biological weapon: medical and public health management. Working Group on Civilian Biodefense. JAMA 1999;281(22):2127-37.

53. Mack T. A different view of smallpox and vaccination. N Engl J Med 2003;348(5):460-3.

54. Fauci AS. Smallpox vaccination policy--the need for dialogue. N Engl J Med 2002;346(17):1319-20.

55. Breman JG, Henderson DA. Diagnosis and management of smallpox. N Engl J Med 2002;346(17):1300-8.

56. Kaplan EH, Craft DL, Wein LM. Emergency response to a smallpox attack: the case for mass vaccination. Proc Nat Acad Sci United States of America. 2002;99(16):10935-40.

57. Halloran ME, Longini IM, Jr., Nizam A, Yang Y. Containing bioterrorist smallpox. Science 2002;298(5597):1428-32.

58. Bozzette SA, Boer R, Bhatnagar V, Brower JL, Keeler EB, Morton SC, et al. A model for a smallpox-vaccination policy. N Engl J Med 2003;348(5):416-25

## XI. Psychological Effects of (Bio-)Terrorism and Management

59. Galea S, Ahern J, Resnick H, et al. Psychological sequelae of the September 11 terrorist attacks in New York City. *N Eng J Med*. 2002;346(13):982-7.

60. Hoge CW, Pavlin JA. To the editor: psychological sequelae of September 11. *N Eng J Med*. 2002;347(6):443-444.

61. Yehuda R. Post-traumatic stress disorder. *N Eng J Med*. 2002;346(2):108-130.

62. Holloway HC, Norwood AE, Fullerton CS, Engel CC, Ursano RJ. The threat of biological weapons: prophylaxis and mitigation of psychological and social consequences. *JAMA* 1997;278(5):425-427.

63. Glass TA, Schoch-Spana M. Bioterrorism and the people: how to vaccinate against panic. *Clin Infect Dis*. 2002 Jan 15;34(2):217-223.

# Appendix C. Technical Appendix: Modeling DVC Operations

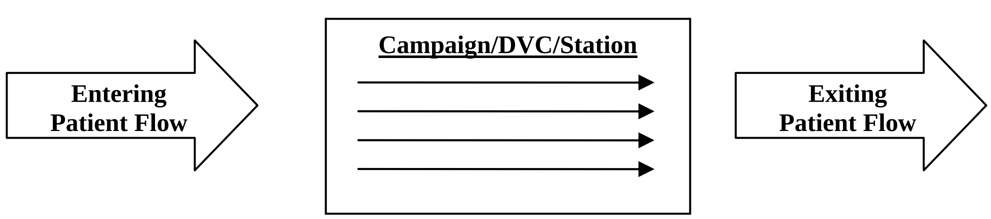
**Note:** In the following discussion, the term “DVC patient flow rate” refers to the planning concept of an average rate of patient processing over the duration of the mass prophylaxis response, not as an actual measure of the unpredictable rate at which patients may show up at DVCs in the aftermath of a bioterrorist attack. The equations and spreadsheet models presented here use this average patient flow rate for two reasons. First, there is no good data to guide prediction of patient surge arrivals at DVCs, so any model that tried to estimate surge arrivals would be inherently prone to error. Second, it is likely that, with appropriate use of law enforcement and public information campaigns, planners could maintain constant patient flow rates at their DVCs by controlling entry.

The goal of mass prophylaxis planning is to ensure that dispensing of necessary antibiotics, vaccines, or other medical supplies to target populations occurs within a designated time frame. In certain cases, the time frame for response will be fixed (e.g., in a widespread smallpox attack wherein vaccination of all potential contacts should take place within 4 days of exposure). However, most other factors in the response scenario will either be variable (e.g., population affected) or under planners’ control (e.g., number of DVC sites, number of staff, and station process times).

## A. Modeling Approach

The spreadsheet programs included with this Planning Guide allow planners to model DVC activities based on two assumptions. First, all actions in the DVC are considered *deterministic,* rather than stochastic, processes. While this eliminates naturalistic variability from elements like patient interarrival time and station processing times, it greatly enhances the simplicity and understandability of model estimates. Second, these spreadsheet programs give results for DVCs at what is called “steady-state operation.” The definition of steady-state in this setting is that queues occurring at any station in any given DVC in the system do not experience a net increase in length over the course of the prophylaxis campaign. Another way of saying this is that the rate of arrivals equals the rate of departures from the DVC as a whole and from every station in the DVC, as shown in the figure:

**AVERAGE ENTERING (PT/MIN) = AVERAGE EXITING (PT/MIN)**



The first step in modeling DVC activities is to determine this average patient flow.

### 1. Determining Campaign, DVC, and Station Flow

Under the deterministic steady-state assumption, individuals arrive at each DVC station at a constant rate throughout operation of the prophylaxis campaign. The flow at these stations can be calculated from features of the campaign as a whole (i.e., overall processing rate across a community), the number of DVCs, and the DVC patient flow plan. For ease in calculations and to avoid errors, these flows should all be in the same unit of time (e.g., per minute).

#### *a. Average Campaign Flow*

Average campaign flow represents the total number of individuals processed per unit of time across the entire affected community. It is a function of the total population in the target community (e.g., town population) and the length of the prophylaxis campaign. Algebraically,

i) $R_{Campaign} = Pop \div T$

Where: $R_{Campaign}$ = Average campaign flow (or rate)
Pop = Total size of population (or number of patients)
T = Length of Time for campaign

This calculation will give a campaign flow rate of patients per unit time of campaign. T can be days, hours, or minutes. To set T at minutes, first determine how many hours per day the campaign will be operating (e.g., the DVCs will be open 24 hours per day). The equation for T in terms of minutes becomes:

ii) $T = D \times H \times M$

Where: D = Length of campaign in days
H = Hours of operation per day
M = Minutes of operation per hour

Combining i) and ii) gives a calculation of campaign flow in terms of Patients per Minute, as follows:

iii) $R_{Campaign} = Pop \div (D \times H \times M)$

For example, a campaign targeting 10,000 people over 5 days, operating at 8 hours per day will have an average flow of $10{,}000 \div (5 \times 8 \times 60) = 4.17$ pts/min.

Assuming $R_{Campaign}$ is fixed and constant, it becomes the variable to which all staffing calculations ultimately become tethered. Consequently, changes in either staff per DVC, number of DVCs, or station process times, for example, will necessarily cause changes in each other such that the campaign flow remains constant.

***b. Average DVC Flow***

The average DVC flow (denoted as $R_{DVC}$) is a measure of the total patients per unit of time each DVC in a campaign can process. Three methods of determining the average DVC flow include a) User-defined; b) Briefing-defined; c) DVC number-defined.

*1) User-defined DVC Flow*

The average number of patients per unit of time processed can be based on past experiences or live exercises (denoted as $R_{DVC-UD}$). However, as explained in more detail below in Section 3: Staffing Calculations, the number of staff per station and per DVC is directly proportional to this flow. Consequently, a higher flow (i.e., larger number of patients processed per unit time) demands a larger number of working staff. Spatial constraints (i.e., number of staff a given DVC can accommodate) may not allow for this number and thus the DVC flow may need to be decreased.

*2) Briefing-defined*

On-site briefings to ensure patient education and consent may be required by Federal, state, or local regulations (e.g., as currently required for all Investigational New Drug (IND) protocols). Because of both their duration (i.e., briefings likely will have the longest process time of all DVC stations) and their scope (i.e., all patients will have to be briefed), briefings will determine the patient flow for each DVC. Regardless of their placement within a DVC flow plan, the briefing will impact other stations both upstream and downstream. Upstream stations should be capable of achieving the briefing flow in order to fill the briefing space to capacity (and thus prevent wasted space and materials). At the same time, upstream stations should not operate faster than the briefing flow as this will produce queues of increasing length outside of the briefing area. Downstream stations should also be capable of achieving the briefing flow to prevent queues of increasing length.

Consequently, planners creating DVCs with on-site briefings should determine their DVC flow by equating it to the briefing flow (denoted as $R_{DVC-BD}$). The briefing flow is a function of two characteristics: the number of patients simultaneously briefed (the product of number of briefing rooms and room capacity) and the length of the briefing. Algebraically,

$$\text{iv) } R_{DVC} = R_{DVC-BD} = (N_{Rooms} \times N_{Patients\ per\ room}) \div T_{Briefing}$$

Where: $N_{Rooms}$ = Number of briefing rooms

$N_{Patients\ per\ room}$ = Capacity of each room

$T_{Briefing}$ = Length of each briefing (in minutes for $R_{DVC-BD}$ to be equal to patients per minute)

*3) DVC Number-defined DVC Flow*

In certain cases, planners may decide on a maximum number of DVCs in their campaign prior to calculating patient flow. The average DVC flow can be calculated as follows:

$$\text{v)}\ R_{DVC} = R_{DVC\text{-}ND} = R_{Campaign} \div N_{DVC}$$

Where: $R_{DVC\text{-}ND}$ = Average DVC patient flow using the number-defined method

$N_{DVC}$ = Maximum number of DVCs within the campaign.

Combining equation iii) with v) will allow calculation of DVC flow in patients per minute as follows:

$$\text{vi)}\ R_{DVC} = R_{DVC\text{-}ND} = Pop \div (D \times H \times M \times N_{DVC})$$

***c. Average Station-Specific Flow***

The station-specific flow is a function of 2 variables: the average DVC flow and the proportion of that flow that arrives at the station of interest. This proportion is determined by features of DVC patient flow plan. The DVC flow plan determines the paths that patients may travel. The proportion of patients who take a given path is determined by calculating the percentage taking that path at each branch point along the way (percentages which must be assigned by planners). These station-specific probabilities are then multiplied by the overall patient flow for the DVC ($R_{DVC}$) as calculated above. Algebraically, for any station *i*, within a DVC pathway containing a total of I sequentially numbered stations, the corresponding station-specific flow ($R_{Si}$) can be calculated as follows:

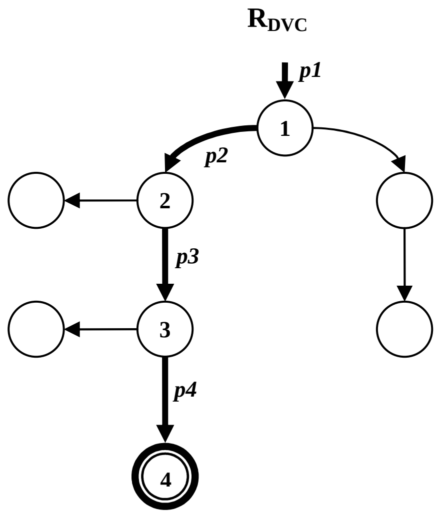
$$\text{vii)}\ R_{Si} = R_{DVC} \times \prod_{i=1}^{I} (P_i)$$

Where: $i$ = Sequential number of station located within flow path of DVC

I = Total number of stations within flow path containing this station

$P_i$ = Proportion of patients entering into station $i$

The following example demonstrates this method. This diagram represents a simple DVC layout. Circles represent individual stations within the DVC and the station of interest is highlighted.




To calculate the station-specific average flow of Station 4, first identify the pathway a patient would follow from entrance into the DVC to reach the station (represented by the thick lines) and multiply the corresponding estimated probabilities. Finally, multiply this result by the average DVC flow. By example:

Assume: $R_{DVC}$ = 10 pts/min

$p1 = 1.0$
$p2 = .80$
$p3 = .8$
$p4 = .5$

User-defined values

Then: $R_{S4} = (p4 \times p3 \times p2 \times p1) \times R_{DVC}$ or
$= (.5 \times .8 \times .8 \times 1.0) \times 10$ pts/min
$= 3.2$ pts/min

Certain stations may have multiple pathways of entrance. In such case, the product of the chain of probabilities of each associated pathway should be added and this total then multiplied by $R_{DVC}$.

## 2. Determining the Number of DVCs

The total number of DVCs must be sufficient to process the total population within the given time frame or the campaign will not be a success. Consequently, the most direct method of calculating the total number of DVCs is to divide the average campaign flow by the average DVC flow, as follows:

viii) $N_{DVC} = R_{CAMPAIGN} \div R_{DVC}$

The total number of DVCs within a campaign is inversely proportional to the average flow of each DVC. Decreasing the average DVC flow will increase the number of necessary DVCs. Decreasing the number of DVCs (e.g., because of resource limitations) will increase the necessary average DVC flow to process a population within the given time frame of the campaign. Fixing the number of DVCs or the DVC flow rate (e.g., by mandating that all DVCs must operate at 100 patients per minute) will force a change in the overall campaign flow and therefore in the overall time needed to complete the prophylaxis campaign.

## 3. Staffing Calculations

The number of staff required for a prophylaxis campaign can be calculated for each station within a DVC, for the DVC as a whole, and for the campaign in total. The number of staff is a function of patient flow, average process time, and the ratio of staff to patient. Under the deterministic representation of a steady-state (where queues, if existent, are constant in length), staff can be calculated using the following general formula:

ix) $S = R \times T \times I$

Where: S = Staff
R = Entering patient flow
T = Process time
I = Ratio of staff to patients

Calculating staff then becomes a matter of plugging in the appropriate R as explained in Section 1, ensuring the unit of time measure for T and R are consistent, and determining the ratio of staff to patients for the activity.

### *a. Station-specific staffing*

Two factors determine the optimal number of staff at a DVC station: patient flow (the average number of patients arriving at a station per unit time) and the station-specific processing time (the time needed to process the average patient at that station). When a DVC is running at steady-state operation, staff activities and patient arrivals are balanced so that no *new* bottlenecks or queues form. (Note: a system that is functioning at steady-state can have queues, but they do not get any longer during the steady-state operation.) A simple formula shows how these two factors determine the optimal number of staff for each station under steady-state operation:

x) $S_{Station} = R_{Station} \times T_{Station} \times I_{Station}$

Where $S_{Station}$ = Staff at station
$R_{Station}$ = Patient flow arriving at station (patients per minute)
$T_{Station}$ = Processing time for station
$I_{Station}$ = Staff-to-Patient ratio at station (e.g., I=1 if one staff member is required for the entire duration of processing of each patient)

***b. Total DVC staffing***

The total number of staff needed to run a DVC is the sum of the number of staff needed at each station:

xi) $S_{DVC} = \sum S_{Station.}$

## B. Definitions of DVC Efficiency

Two measures reflect the efficiency of DVC design: bottlenecks and staff utilization. If more patients arrive than can be processed by DVC staff, a bottleneck will occur at one or more of the stations inside the DVC. A bottleneck at a single station can decrease efficiency of the entire DVC by reducing processing rates at other stations in one of two ways: long lines at one station may interfere with operations at other stations (e.g., by blocking access), and staff may be shifted to the affected station, thereby compromising efficiency of other areas. To solve bottlenecks, DVC managers may need to increase the total number of DVC staff or decrease processing times (e.g., by shortening forms or protocols).

If the DVC plan overestimates either the need for staff at a given station or the need for entire DVCs to achieve community-wide prophylaxis, waste in the form of staff underutilization or excess "down-time" will occur. As noted, in a large-scale mass prophylaxis operation staff will be one of the resources in shortest supply. In that case, inefficient use of staff at one station or DVC can be expected to decrease the efficiency of some other aspect of the prophylaxis campaign. In plain language, if staff at a DVC or station find themselves idle during a large-scale event, the DVC plan that assigned them to that station needs reevaluation.