



NAVAL POSTGRADUATE SCHOOL

MONTEREY, CALIFORNIA

THESIS

**HOSPITAL BASED FIRST RESPONDER MASS
PROPHYLAXIS PLAN**

by

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March 2005

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HOSPITAL-BASED FIRST RESPONDER MASS PROPHYLAXIS PLAN

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ABSTRACT

As the United States improves its collective awareness and emergency preparedness in the face of increased terrorist activity, more efforts are being made to create and enhance community readiness for catastrophic events. There have been substantial efforts to improve the nation's bioterrorism preparedness. Better planning, equipment, training, surveillance, and pharmaceutical caches have elevated the nation's readiness for biological attacks. In order to effectively meet the challenges created by a bioterrorism attack, its first lines of defense, the first responders, must be rapidly prophylaxed to allow the continuance of their mission.

Many states and localities have tackled the gigantic undertaking of mass prophylaxis plans to provide chemoprophylaxis to civilians should the need arise. Many cities have developed and tested their plans to provide general public mass prophylaxis. It is assumed, or briefly mentioned, that the mass prophylaxis of first responders will occur, but few plans have been developed. The primary objective of this research is to develop, test, and make recommendations for a straightforward, adaptable mass prophylaxis plan to meet the prophylactic requirements of local first responders in the event of a biological attack.

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I. INTRODUCTION

In the United States citizens rely heavily on first responders to meet their needs in the face of an emergency. Fire, law enforcement, ambulance transport, and hospital personnel, are all part of the emergency response system that they depend on in the face of a crisis. Much planning has gone into meeting the public's needs during a bioterrorism attack, but little has been done to ensure that first responders will be adequately prophylaxed.

Personal protective equipment such as masks, gloves, purified air systems and detection instrumentation is increasing along with education and training for first responders, but chemoprophylaxis needs to be satisfactorily addressed. This has not been an intentional omission; much has been achieved considering budget, time, and personnel limitations. The availability of necessary antibiotics and immunizations for a bioterrorism attack has increased exponentially over the last ten years. The Strategic National Stockpile (SNS), Metropolitan Medical Response System (MMRS) and local stockpiles and caches have greatly improved access for chemoprophylaxis. It is a plan to deliver, educate, and administer the required chemoprophylaxis specifically to first responders that is missing. The definition of first responder for the scope of this thesis includes fire, law enforcement, emergency medical services, and hospital providers.

A. PURPOSE

The goal of terrorists is to disrupt the democratic society; therefore, failure to provide timely prophylaxis to first responders in a bioterrorism attack will magnify the chaos sure to ensue. Most bioterrorism planning assumes that first responders will be prophylaxed at the point they are included in response planning. The greatest inclusion is a brief reference to the need for rapid first responder's prophylaxis without a means to achieve the protection.

The public depends on a ready first responder work force in the face of a bioterrorism event. But without plans for mass prophylaxis, timely dispensing of first responder chemoprophylaxis is doubtful. Developing a hospital-based first responder mass-prophylaxis plan will provide more coordinated prophylaxis distribution to first

responders and may decrease disease incidence, severity, and mortality, and allow first responders to be available for their designated roles in a bioterrorism event.

Providing protection to the community's guardians allows first responders to proceed with their duties in detection, mitigation, preparedness, and response to daily and catastrophic events. The purpose of this thesis is to develop and test a mass prophylaxis plan that addresses the needs of local first responders in the event of a biological terrorist attack. It must be a model consistent with current hospital emergency incident command plans that can be used as a template by other hospitals, or as an annex to communitywide planning, to provide protection for their first responders.

Much time and effort has gone into large-scale mass prophylaxis plans to create scenarios that address the needs of the public in the face of a bioterrorism release. Reference on perceived need, timing, and type of chemoprophylaxis has abounded from trusted and reliable sources including The Center for Disease Control and Prevention (CDC), World Health Organization (WHO), and many leading healthcare researchers in the county. (MMWR Recommendations and Reports. April 4, 2003). Software programs, such as Maxi-Vac, assist with determination of staffing needs in a general public mass prophylaxis clinic. (Smallpox Vaccination Clinic Guide. Annex 3-7. 2002). This CDC example model states that it "assumes that clinics can be operating at near full efficiency to meet vaccination goals once the decision to offer voluntary vaccination is made." Many reviewed plans work on the assumption that these staff members, often first responders, will have been previously prophylaxed.

Mixing first responders into a mass prophylaxis arena delays their availability in a potentially critical need period. In "Vaccination Ventures" (Pine, 2003) under the challenges section it was hypothesized that vaccination staff would be arriving with the masses to be vaccinated first. These staff members would be meeting the same problems as the public with congestion, parking, communication, and potential exposure from contaminated population.

Location can be integral to plan effectiveness. The CDC Strategic National Stockpile Guide states that an increased number of smaller dispensing sites could reduce congestion and safety concerns (SNS Guide). The State of California Mass Prophylaxis Planning Guide (Sacramento, 2003) recommends the use of Fast Track Clinics within the site to accommodate medical personnel, public health, and first responders, which would

help segregate them from the public, but provides no further direction and relies on this same workforce to provide the medication.

There can be major differences in planning and practice. Experience-based protocols can provide lessons learned for mass prophylaxis planning. New York City anthrax mass antibiotic prophylaxis, (Blank, 2003), and Shiprock, New Mexico community responses to epidemics, such as meningitis, measles, hanta-virus, and plague, (Houk, 2003), provide experiential lessons that can be applied to future planning.

Having a hospital-based decentralized chemoprophylaxis site for a federally declared bioterrorism event geared to first responders will increase manageability by simplifying logistics. Traffic, patient flow, site familiarity, communication, and non-SNS dependent stockpiles can all contribute to more rapid dispensing and personnel turnaround.

B. THESIS ARGUMENTS

This thesis argues the need for a separate first responder mass prophylaxis site and plan from the generalized public mass prophylaxis site and plan that addresses the first responder's specific needs and rapid prophylaxis. The provision of rapid protection allows their availability to meet the community's medical and safety needs. Placing first responders into public mass prophylaxis sites forces them to face the logistical chaos associated with any large-scale event. The author also explores the state and regulatory requirements associated with medication and vaccine dispensing to ensure compliance with large-scale mass prophylaxis clinic venues.

Developing a first responder plan separate from general public mass prophylaxis plans places additional requirements on emergency planners, but this thesis proposes that the advantages to separating first responders from a venue designed for thousands, hundreds of thousands, or millions of recipients, far outweigh the additional effort.

The broader purpose of this thesis is to develop a first responder mass prophylaxis plan that not only will provide protection against a host of pathogen threats to Orange County, California, but also will be adaptable to communities across the United States.

Chapter II examines requirements for first responder mass prophylaxis, including state and federal regulatory requirements. Chapter III outlines a first responder mass

prophylaxis plan including dispensing stations, associated documentation, traffic-flow patterns and aftercare. Chapter IV reviews implementation of the plan in a first responder mass prophylaxis exercise and includes debriefings, hot washes, evaluations and recommended changes to the plan. Chapter V presents a summary, conclusions, and suggested areas for further research.

II. REQUIREMENTS FOR FIRST RESPONDER MASS PROPHYLAXIS

Terrorists have used biological attacks throughout history to achieve varying objectives. With the eradication of smallpox and the advent of antibiotics and vaccines, biological assaults had been long thought of as an outdated and minor threat. The 2001 anthrax attacks opened the public's eyes to the very real threat bioterrorism presents in the modern world. Authorities now agree that a single case of smallpox would be a worldwide emergency. (www.cdc.gov)

Defining plan requirements assists in meeting mass prophylaxis objectives. Developing a plan consistent with the incident command system mandated by Joint Commission and Hospital Accreditation (JCAHO) for hospitals and utilized by fire and law enforcement agencies is imperative to provide protection to first responders in the event of a biological release. The following are the necessary planning factors that will increase the effectiveness of first responder protection:

- The plan needs to be flexible enough for use with various agents
- The plan needs to be able to be adapted to fit with existing emergency preparedness plans
- The plan needs to provide for rapid implementation in the event of a bioterrorism attack
- The plan needs to take hospital budget limitations for plan development and trials into account
- The plan must use reliable sources as its basis
- The plan must comply with state and federal requirements

A. PLAN FLEXIBILITY

Flexible emergency planning has evolved from individual scenario planning to an all-hazards approach. So, too, must bioterrorism planning. The more scenarios the plan addresses, the higher its value. Community planners must develop a basic template that can be adjusted to the requirements of each threat or combination of threats.

The Hospital Emergency Incident Command System (HEICS) provides guidance for flexible application as it is designed for the wide range of man-made, naturally

occurring, and terrorist planned situations. Developing a flexible plan eliminated the need for dozens of variations to a common problem, building on commonalities of the situations instead of their unique features (www.ems.gov).

To meet most needs of chemoprophylaxis the plan must address both vaccines for viral pathogens and antibiotics for bacterial weapons of mass destruction. Examples include vaccinia vaccine for smallpox and oral ciprofloxacin for anthrax.

B. PLAN ADAPTABILITY

As with plan flexibility, having a plan that is adaptable, that can be used by an entire community, and is replicatable in other communities, increases its usefulness. Simplicity and clarity of objectives and functions that meet first responder, agency, and regulatory requirements allows more hospitals to adopt the plan, improving interoperability with varying agencies and facilities

C. RAPID IMPLEMENTATION

Bioterrorism events require a rapid community response. Failure to act quickly can translate into more disease spread, and higher mortality and morbidity to first responders. Although pathogen dissemination can be problematic, modern transportation, air travel, mass transit, and grand scale venues that contain large populations utilizing common heating/ventilation/air conditioning (HVAC) systems all can facilitate transmission of deadly pathogens. At-risk populations able to mingle with fellow citizens, such as immune suppressed individuals on chemotherapy, HIV/AIDS, and transplant recipients are particularly vulnerable to most pathogens.

Bioengineering allows production of large volumes, or highly virulent strains of common microbes such as haemophilus influenza (H-flu) or botulism, increasing the likelihood of successful bioterrorist attack. All of these factors increase the need for a rapid response. The at-risk population, including the immunosuppressed and the extremes of age, has a higher rate of contact with first responders and is historically more vulnerable to any organism, often becoming the first victims in an attack. Therefore, rapid first responder prophylaxis not only protects first responders but may decrease pathogen transmission to the at-risk population.

D. BUDGET LIMITATIONS

Strategic planning and budgeting are unfortunately left out of most emergency preparedness planning sessions. Instead, time is often spent responding to crisis situations, putting off plans that may help avoid, or at least mitigate, these calamitous events. The largest and most costly threat in lack of first responder mass prophylaxis strategic planning is not providing the protection to our first responders. Leaving them vulnerable to the attack pathogen results in either their unavailability to complete the community mission as first responders, or work unprotected, risking disease contraction and possibly assisting the terrorists in spreading the disease to an even higher at-risk population.

Even with the substantial Homeland Security funding, budgets are stretched to the limits in most healthcare settings. Adding the strain of the new responsibility of providing chemoprophylaxis to first responders must be judiciously planned to provide the maximum amount of coverage using the least amount of money. In the event of an actual pathogen release, funding from Homeland Security, the Federal Emergency Management Agency (FEMA), federal, state, and local agencies, including the American Red Cross, will help defray the cost of providing first responder prophylaxis. What has greater budgetary implications are the often unfunded development and testing of prophylaxis plans.

Creating a strategic plan demonstrates how focused planning decreases or eliminates many of the encountered problems with mass prophylaxis. Focused planning allows better strategies that limit bioterrorism threat potential and may even discourage well-organized terrorists from using biological agents due to the United States' lessened bioterrorism vulnerability. Prudent planning and using current business models, the analysis will help identify problem areas where further efforts may turn the weaknesses into strengths resulting in a more protected and prepared locality.

E. RELIABILITY

Disease information and treatment recommendations in the event of a bioterrorism attack are distributed to all first responders regardless of acceptance or refusal of vaccine/medication. Information should be written and verbal and based on

reliable sources, trusted by both the medical and general public such as the Centers for Disease Control and Prevention. Trusted sources increase the merit of the message and individual acceptance.

Easily understood references in a stressful time period of a bioterrorism attack improves the probability of first responders making a well-informed decision. Understanding of disease physiology and transmission improves the probability of compliance with treatment regimens and aids in limiting disease spread. Educational materials should be coordinated for all agencies to avoid mixed or conflicting messages. (Rothstein, 2003).

F. STATE AND FEDERAL REQUIREMENTS

Depending on the extent of the bioterrorism attack, state and federal requirements may be waived for a first responder mass prophylaxis clinic. The rationale behind most requirements is to protect the citizens of this country and when possible, plans should address and meet state and federal these requirements.

1. Board of Pharmacy Regulations

The 2004 Lawbook for Pharmacy states in Section number 4062 that:

...Notwithstanding Section 4059 or any other provisions of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4046 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

To conform to Board of Pharmacy regulations, it is necessary to develop a mechanism for the collection of biographical information that captures:

- a. Medical history
 - i. Past medical history
 - ii. Current medications
 - iii. Allergies
- b. First responder consultation with appropriate personnel
- c. Type medication/immunization dispensed
- d. Written aftercare for continued monitoring and complete course of therapy for oral chemoprophylaxis or wound care and local reaction for vaccinations
- e. First responder consent

2. Ryan White Act

The Ryan White Act was enacted by Congress in 1990 to ensure proper notification of emergency response employees (Fire fighters, paramedics, and emergency medical technicians) of exposure and proper reporting guidelines to infectious diseases. The Act included the existence of a designated official or officer of all emergency response employees in the state. These designated officials or officers are key in continuing care in a first responder mass prophylaxis scenario allowing for secure and confidential communication of therapeutic regimens in the event of a bioterrorism release.

Subtitle B: Emergency Response Employees - Requires the public health officer of each State to designate one official or officer of each employer of emergency response employees in the State to receive notification and make requests.

Authorizes the Secretary to commence a civil suit to obtain temporary or permanent injunctive relief for any violation of these provisions. (Ryan White Comprehensive AIDS Resources Emergency Act of 1990, United States Congress.)

3. Health Insurance Portability and Accountability Act

State and local regulations require the documentation of personal and medical history before dispensing medications. Regulations may be waived in a calamitous event, but should be planned for to address smaller scope incidents and provide the highest level of first responder personal information protection. The United States Congress, under

the Health Insurance Portability and Accountability Act, regulates first responder personal information.

The Health Insurance Portability and Accountability Act of 1996 required the Department of Health and Human Services (DHHS) to establish national standards for electronic health care transactions, addressing the security and privacy of health data. (<http://www.cms.hhs.gov/hipaa>).

In addition, Section 1177 of the Health Information Portability Act (HIPAA) - Wrongful disclosure of individually identifiable health information - lists offenses and penalties for misuse of health information.

SEC. 1177. (a) OFFENSE.--A person who knowingly and in violation of this part--"(1) uses or causes to be used a unique health identifier;"(2) obtains individually identifiable health information relating to an individual; or"(3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b).

(b) PENALTIES.--A person described in subsection (a) shall--"(1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;"(2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both. (Health Information Public Law 104-191 United States Congressional Record, August 21, 1996.)

Anytime personal information is documented into medical records, especially medical records that will be transported through different agencies, proper handling must be used. Developing a plan that is HIPAA compliant will help avoid costly penalties and protect first responder information.

III. DEVELOPING A FIRST RESPONDER MASS PROPHYLAXIS PLAN

Once first responder mass prophylaxis requirements are determined, a plan, including policies and procedures, must be developed. The purpose of the plan is to serve as a guideline for the community and provide direction and coordination in providing mass prophylaxis to first responders and their immediate families. The plan should address the requirements listed in Chapter Two, remain flexible to varying causative pathogens and their associated therapeutic recommendations, and adaptable to multiple healthcare institutions.

Current mass prophylaxis plans focus on community preparedness for the general public. These plans use SNS, MMRS caches, Chempacks, and other state and local pharmaceutical reserves. As additional planning has evolved over the past year, more references are being made to the need for first responder mass prophylaxis needs, but at best, the community plans include special lines or fast tracks away from the general public to accommodate first responders at the mass prophylaxis clinic sites.

It is this author's recommendation that separate, decentralized first responder mass prophylaxis sites are imperative to providing timely protection to our first responders, decreasing the out-of-service interval required to dispense the prophylaxis, while improving the first responder's ability to carry out their community mission.

A. DISPENSING PROCEDURE AND PROCESS FLOW

1. First Responder Mass Prophylaxis Policy

The policy for the hospital-based first responder mass prophylaxis plan was to offer first responders screening for chemoprophylaxis in a county, state, or federally recognized bioterrorism attack. Hospitals would utilize medical screening, aftercare, and pharmaceutical agents recommended by the county Emergency Medical Services Agency, State Emergency Medical Services, or the Center for Disease Control and Prevention

(CDC) guidelines. Hospital, EMS, MMRS, or SNS caches could be used individually, or collectively to fulfill initial first responder chemoprophylaxis requirements. (See Attachment 1)

2. Initiation of the Plan

The decision to initiate a first responder mass prophylaxis plan is a serious one. Multiple levels of consideration need to be addressed. Besides logistical and financial challenges, routine prophylaxis can cause side effects, including anaphylaxis, destruction of naturally occurring flora, drug resistance, and even death. Consideration will only be made after a local, state, or federal declaration of prophylaxis recommendation.

The decision to initiate this first responder mass prophylaxis plan lays with the hospital Chief Executive Officer or administrator on call. A smallpox release would require little debate to initiate vaccination procedures for first responders, but a limited anthrax release would require more discussion as to the efficacy of widespread, long-term chemoprophylaxis with doubtful exposure. Therefore, the plan recommends the decision to activate be made in conjunction with recommendations from the Chief Medical Officer, Infection Control Program Director, Pharmacy Director, and the Employee Health representative. (See Figure 2)

3. Communication

Open lines of communication are crucial to the plan's success. Initial procedures include the immediate notification of crucial personnel. See Figure 1 for a description of who is included and how their communication is organized. Multiple redundant communication modes are available.

NOTIFICATION AND ACTIVATION OF FIRST RESPONDER MASS PROPHYLAXIS CLINIC

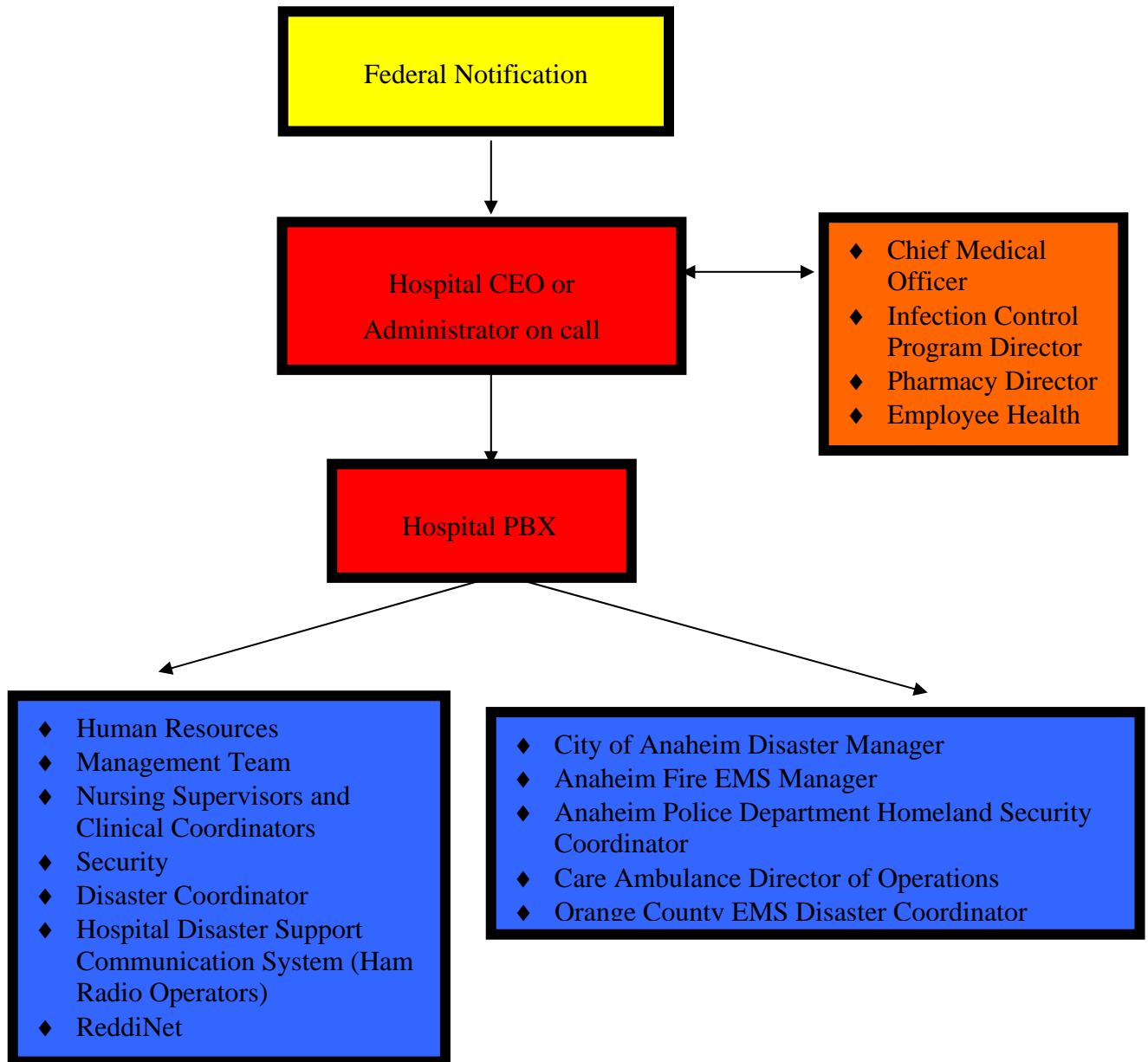


Figure 1. Notification and Activation of First Responder Mass Prophylaxis Clinic

4. Documentation

Forms were developed to record information based on local, state, and federal documentation requirements. A log was generated at the clinic registration area that listed first responder/immediate family member name, arrival time, and host agency. In addition, each person received a First Responder Health Screening Form. (See Attachment 2)

The First Responder Health Screening Form was used to document biographical information:

- Time in
- Patient Name
- File number
- Social Security Number and/or Badge Number
- Home or Work Address
- Employer Name
- Work Phone
- Contact Phone
- Age
- Date of Birth
- Weight
- Gender

Medical information:

- Allergies
- Current Medications
- Medical Conditions
- Pregnancy/Breast Feeding/Birth Control

Consent is an essential section of the First Responder Health Screening Form. A first responder is not required to take recommended prophylaxis. Vaccinations and medication regimes are not without side effects and remain a personal choice for each recipient. A dated, witnessed signature signifying informed consent of the first responder is completed before the vaccination or medication will be dispensed.

Documentation on the First Responder Health Screening Form includes a first responder/immediate family member signature acknowledging receipt of the medication/vaccination, associated counseling, and aftercare instructions. The final two signatures are for the consulting professional and mass prophylaxis staff ensuring First Responder Health Screening Form completion.

5. Dispensing and Consultation

To dispense medications the pharmacy must commence the dual operations mode plan. Pharmacy personnel are tasked with transporting packaged chemoprophylaxis medications/vaccinations to the Dispensing and Consultation Station and staffing the assigned area. The Board of Pharmacy requires extensive dispensing information and consultation documented on the First Responder Health Screening Form. Information includes name, prescription received (either for vaccination or medication), medical provider notes and signature, drug name, quantity, strength and dosage form, manufacturer, lot number, and expiration.

6. First Responder Aftercare

Once the first responder receives the medication/vaccination, nursing staff reviews the form for completeness and accuracy, answer questions, and offer follow-up with own provider agency, Public Health Department, or employee health. Questions beyond their scope of practice are referred back to the Physician Screening Station.

B. LOGISTICS

1. Clinic Staff

Physicians, nurses, and pharmacy staff are usually associated with mass prophylaxis clinics but it takes a wide variety of personnel to run a successful clinic. Chaos and panic are to be expected during a bioterrorism event. Offering expeditious prophylaxis not yet available to the general public will increase the need for secrecy and site security. Site security personnel will be responsible for securing access to the mass prophylaxis area, posting signage and barriers to limit access to the mass prophylaxis clinic. Signage should be designed that directs targeted population without notifying the general public of the clinic purpose.

In addition to security personnel, environmental services will provide tables and chairs for the Sign-in Area, Health Screening Station, Physician Screening Station, Dispensing and Consultation Station and the Final Instructions and Check-Out Station.

Registration personnel are responsible to staff the Sign-in Area, and greet and log-in first responders/immediate family members with their name, arrival time, and host agency. The generated log will be given to the Infection Control Nurse for information dissemination to designated officers at each agency. Registration staff will distribute a numbered file with CDC information sheets of the specific pathogen/disease, and the First Responder Health Screening Form to each first responder or immediate family member to assist with personal privacy and help coordinate information.

Physicians will staff the Physician Screening Station. They are responsible to review the completed First Responder Health Screening Form and screen for contraindications, assist with informed consent, and distribute prescriptions in the form of pre-printed prescription labels to qualifying first responders/immediate family members. In addition, physician staff will direct those receiving prescriptions to the Dispensing and Consultation Station. Clinic staff will direct participants who do not meet criteria, or those who do not wish chemoprophylaxis, to the Questions and Follow-up Station. (See Figure 1)

The pharmacy will commence dual operations mode, transporting packaged chemoprophylaxis medications/vaccines to the Dispensing and Consultation Station. They will staff this station, providing the medication/vaccine and consultation as needed.

Nursing personnel staffs the Question and Follow-up Station, reviewing the First Responder Health Screening Form for completeness and accuracy. Nursing will answer questions and ensure follow-up with own provider agency, personal physician, Public Health Department, or employee health. For additional questions they will refer the participants back to the Physician Screening Station.

At the clinic conclusion, Infection Control personnel will use the registration log to contact appropriate designated officers at first responder agencies with a list of personnel attending the Mass Prophylaxis Clinic, complying with all state and federal guidelines for handling personal medical information.

PRE-PRINTED MEDICATION LABELS

Medication: CIPROFLOXACIN
Strength: 500 mg tablets Number four
Manufacturer: Bayer
Lot Number: 1234
Expiration: 5/2005
(Simulated Rx and medication for Exercise)

Medication: LEVOFLOXACIN
Strength: 500MG Number: two
Manufacturer: Tavanic
Lot Number: 1234
Expiration: 5/2005
(Simulated Rx and medication for Exercise)

Medication: DOXYCYCLINE
Strength: 500MG Number: four
Manufacturer: Pacific
Lot Number: 1234
Expiration: 5/2005
(Simulated Rx and medication for Exercise)

Figure 2. Preprinted Medication Labels

2. Location

Much discussion has ensued on location of mass prophylaxis clinics. There is no argument that large-scale public mass prophylaxis clinics should be located far away from hospitals. In any disaster scenario, hospitals are viewed as safe havens and can be easily overwhelmed with the convergence of multitudes of affected and merely worried masses. Often referred to as the “worried well,” this large group of people can exhaust critical resources by clogging healthcare systems unnecessarily.

Adding additional patients in the form of first responders and their immediate families needing mass prophylaxis can compound the chaos. Arguments for a non-hospital based first responder mass prophylaxis clinic site are valid. Unfortunately, finding a site and, more importantly, available staffing, is difficult. The purpose of designing a separate first responder mass prophylaxis clinic is to provide rapid protection to first responders so that they can continue with their mission of serving the public. The logistics of creating an off-site clinic location are more challenging and time consuming than a hospital-based clinic, delaying required protection.

Staffing an off-site location is even more problematic in the midst of a disaster. Having a hospital-based plan allows access to the different departments needed to staff the clinic. Available staff and resources, including necessary pharmaceuticals, decreases the time needed to implement the plan. The availability decreases the time to prophylaxis, and reduces the chance of disease contraction, morbidity and mortality from the causative agent.

A compromise was reached in this mass prophylaxis plan by holding the first responder mass prophylaxis clinic in the medical office building adjacent to the hospital. The chosen site allowed access to needed personnel while distancing the activity from the emergency department and main hospital.

3. Traffic-flow

Regulated traffic-flow through the mass prophylaxis clinic can help improve efficiency, avoid security lapses, and provide for privacy when needed. Separate entrances and exits help decrease congestion. Potential traffic-flow patterns should be first developed on paper and then tested for efficiency in exercises to identify potential problems and solutions for better throughput. (See Figure 3)

C. REFERENCE

Historically, fear and chaos are hallmark in any disaster scenario, especially one that includes bioterrorism agents. It is important that the recommendations for the protection of first responders come from widely accepted and respected sources. The

more accepted the authority used to base recommendations and therapeutic modalities upon; the more authorities will be able to mitigate widespread fear.

This First Responder Mass Prophylaxis Plan relies upon generally accepted governmental experts, including the Centers for Disease Control and Prevention for disease information and recommendations for prophylaxis. In addition, follow-up information is based upon standardized discharge programs used in daily patient care such as MicroMedix software programs.

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MASS PROPHYLAXIS CLINIC FLOW MODEL

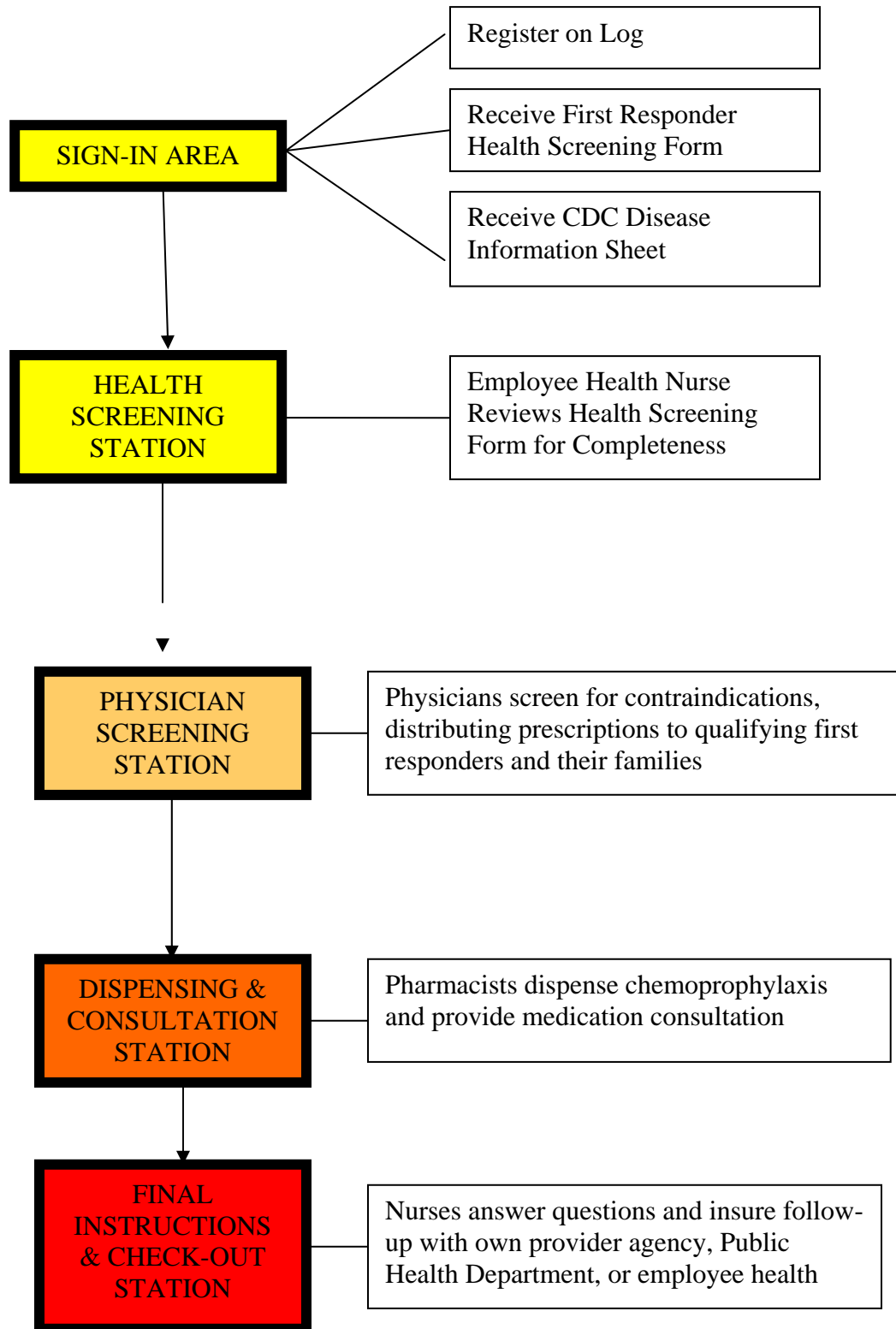


Figure 3. Mass Prophylaxis Clinic Flow Model

The following policy developed for this thesis for Anaheim Memorial Medical Center represents Attachment A

REFERENCE
NUMBER:
FILE NAME: First Responder Mass
Prophylaxis Plan
SUPERSEDES:
ORIGINATED: 04/21/04
REVIEWED: 10/21/04
PAGE: 1 OF 3
APPROVAL:

Richard Whitney Date

Mary Massey Date

**POLICIES/PROCEDURES
ANAHEIM MEMORIAL MEDICAL CENTER
EMERGENCY PREPAREDNESS MANUAL**

**SUBJECT: Mass Prophylaxis of First Responders
in a Bioterrorism Event**

PURPOSE:

To provide guidelines for safe and effective mass prophylaxis of first responders in a bioterrorism event.

DEFINITIONS:

- A. First responder is defined as on-duty fire, law enforcement, emergency medical services, Hospital Disaster Support Communication System volunteers, hospital personnel and their immediate families.

POLICY:

First responders will be offered screening for chemoprophylaxis in a county, state, or federally recognized bioterrorism attack, utilizing medical screening, aftercare, and pharmaceutical agents as directed by Orange County Emergency Medical Services, State of California Emergency Medical Services (EMS), or Center for Disease Control and Prevention (CDC) guidelines. Hospital, EMS, Metropolitan Medical Response System (MMRS), or Strategic National Stockpile (SNS) caches may be used individually, or collectively to fulfill initial first responder chemoprophylaxis requirements.

PROCEDURE:

A. Notification and Activation

1. Initiation of first responder mass prophylaxis will be at the direction of the hospital Chief Executive Officer (CEO) or administrator on call. The decision may be made in conjunction with recommendations from:
 - a) Chief Medical Officer
 - c) Infection Control Program Director
 - d) Pharmacy Director
 - e) Employee Health

B. First Responder Mass Prophylaxis Distribution Duties

1. PBX will notify of First Responder Mass Prophylaxis Clinic:
 - a) AMMC Human Resources
 - b) AMMC Management Team
 - c) AMMC Nursing Supervisors and Clinical Coordinators: Pagers 46352 and 46359
 - d) AMMC Security extension: Extension 5150
 - e) AMMC Disaster Coordinator: Pager 46396 and 44052
 - f) Hospital Disaster Support Communication System (Ham Radio Operator) through call-up system
 - g) ReddiNet

Additional Contact Numbers if needed are:

City of Anaheim Disaster Manager: (714) 765-xxxx [May also be contacted through MetroNet Dispatch (714) 765-xxxx]

Anaheim Fire Department EMS Manager: (714) 765-xxxx [May also be contacted through MetroNet Dispatch (714) 765-xxxx]

Anaheim Police Department Homeland Security Coordinator: (714) 765-xxxx [May also be contacted at (714) 765-xxxx or (714) 765-xxxx]

Care Ambulance Director of Operations: (714) 828-xxxx

Orange County Emergency Medical Services Disaster Coordinator: (714) 834-xxxx. [May be contacted at (714) 834-xxxx.]

2. Security:
 - a) Secure access to the mass prophylaxis area at the basement of the Medical Office Building stairwell entrance
 - b) Post signage/barriers limiting access to the mass prophylaxis area
 - c) Direct parking

3. Environmental Services:
 - a) Provide table and chair set-up for:
 - a. **Sign-in area**
 - b. **Health Screening Station**
 - c. **Physician Screening Station**
 - d. **Dispensing and Consultation Station**
 - e. **Final Instructions and Check-out Station**

4. Registration:
 - a) Staff **Sign-in area**
 - b) Greet and log in first responders with name, time and host agency
 - c) Distribute **CDC information sheet** and **First Responder Health Screening Form** to each first responder or immediate family member
 - d) Direct to **Health Screening Station**

5. Pharmacy:
 - a) Commence dual operations mode plan in the Emergency Department Conference Room.

- b) Transport packaged chemoprophylaxis medications/vaccinations to the **Dispensing and Consultation Station**
 - c) Provide personnel for **Dispensing and Consultation Station** in classroom C/D
6. Physician:
- a) Staff **Physician Screening Station**
 - b) Review completed **First Responder Health Screening Form**
 - c) Screen for contraindications, distributing prescriptions to qualifying first responders
 - d) Direct first responders receiving prescriptions to the **Dispensing and Consultation Station**. Direct those not meeting criteria, or those who do not wish chemoprophylaxis to the **Questions and Follow-up Station**.
7. Nursing:
- a) Staff **Question and Follow-up Station**
 - b) Review first responder **Mass Prophylaxis Health Screening Form** for completeness and accuracy
 - c) Answer questions and insure follow-up with own provider agency, Public Health Department, or employee health. For additional questions refer back to **Physician Screening Station**.
8. Department Directors and Managers:
- a) Department directors and managers will be responsible to notify on-duty personnel of availability of chemoprophylaxis screening during a bioterrorism attack and relieve staff in small groups to proceed to the mass prophylaxis area.
9. Infection Control:
- a) Contact appropriate designated officer personnel at first responder agencies with
list of first responders attending Mass Prophylaxis Screening.
- Contact personnel includes:
 AMMC/MHS: Occupational Health ext. 5285
 Anaheim Fire Department: EMS Manager: (714) 765-xxxx [May also be contacted through MetroNet Dispatch (714) 765-xxxx]
 Anaheim Police Department Homeland Security Coordinator: (714) 765-xxxx [May also be contacted at (714) 765-xxxx or (714) 765-xxxx]
 Care Ambulance Nurse Manager: (714) 828-xxxx
 Orange County Fire Department: EMS Coordinator at 714-573-xxxx
 Fullerton Fire Department: EMS Coordinator pager (714) 806-xxxx

AUTHORITY:

1. State of California Mass Prophylaxis Planning Guide, June 2003.
2. Center for Disease Control and Prevention Bioterrorism Readiness Plan: A Template for Healthcare Facilities. Available at www.bt.cdc.gov
3. California Hospital Bioterrorism Response Planning Guide. California Department of Health Services. Revised May, 2004.

(Attachment 1)

FIRST RESPONDER HEALTH SCREENING FORM

Section 1: (To be completed by first responder) Time in: _____

Patient Name: _____ File Number: _____

Social Security Number and/or Badge Number: _____

Address: Home or Work (circle) _____

Employer Name: _____

Work phone: _____ Contact phone: _____

Age: _____ Date of Birth: _____ Weight: _____ (lbs) Gender M/F
cell or home
mm/dd/yy

Do you have any allergies? Yes No If yes, list: _____

Do you take any medications, including over the counter medications? If yes, list: _____

Have you ever had any of the following medical conditions?

Asthma/Emphysema/COPD	Yes	No	Diabetes	Yes	No
Stomach Problems	Yes	No	Cancer	Yes	No
Hepatitis/Liver Disease	Yes	No	Stroke	Yes	No
Spleen Removal	Yes	No	Seizures	Yes	No
Organ Transplant	Yes	No	HIV/AIDS	Yes	No
Anemia/Sickle Cell Disease	Yes	No	Heart Disease	Yes	No
Other Problems	_____				

Females only: Date of last menstrual period: _____ Are you pregnant: Yes No
mm/dd/yy

Are you breastfeeding: Yes No Do you use birth control? Hormonal/barrier/other

Section 2: HEALTH SCREENING STATION. Informed Consent (To be completed by first responder)

“_____” (I) am seeking medication and or vaccination in accordance with current guidelines from the Centers for Disease Control and Prevention (CDC) and the Orange County Emergency Medical Services Agency. I have received and read the information sheets about the disease, medication, and/or vaccination. I do / do not (circle once) consent to the treatment prescribed.

Signature (self or guardian) date Witness (Printed name/signature)

IV. IMPLEMENTING AND EVALUATING A FIRST RESPONDER MASS PROPHYLAXIS PLAN

Developing a plan is an important part to providing prophylaxis to first responders in the event of a bioterrorist attack, but the plan must be tested to identify areas of improvement, logistical problems, traffic flow impediments, and best practices. To test this thesis a full-scale, multi-agency exercise was designed and implemented.

A. EXERCISE PARTICIPANTS

Anaheim Fire Department
Anaheim General Hospital
Anaheim Memorial Medical Center
Brea Fire Department
Care Ambulance
Fullerton Fire Department
Hospital Disaster Support Communications System
Los Alamitos Medical Center
Orange County Emergency Medical Services
Orange County Fire Authority
Orange County Sheriff's Department Terrorism Early Warning Group
Placentia Linda Hospital
Saint Jude Medical Center
Western Medical Center Anaheim
West Anaheim Medical Center

B. OBJECTIVES OF THE EXERCISE

The objectives of the exercise were chosen to validate the ability to provide rapid mass prophylaxis to first responders using the guidelines described in the First Responder Mass Prophylaxis Policy and Procedure:

- Determine effectiveness of hospital-based clinic location for meeting logistical requirements

- Analyze traffic flow pattern and identify bottlenecks
- Measure first responder throughput times
- Examine efficacy of position assignments, identifying redundant positions or additional assignments that may be needed
- Determine effectiveness of signage clarity for clinic identification, location, traffic flow, station location, and exit
- Trial paperwork capability in fulfilling regulatory requirements
- Identify problematic areas of the First Responder Health Screening Form for clinic staff and first responder use
- Determine effectiveness of communication within the hospital organization and throughout the varying first responder agencies to notify availability, location, and time for prophylaxis clinic
- Test chosen antibiotics for hospital cache against actual first responder health profiles
- Determine effectiveness of plan adaptability for use with pathogens requiring oral chemoprophylaxis and vaccines
- Assess plan flexibility on a diverse group of hospitals
- Test reference materials; information fact sheets, and standardized aftercare instructions
- Determine effectiveness of counseling for first responders refusing prophylaxis

C. EXERCISE COMPONENTS

1. Clinic Locations

a. Objectives

- Determine effectiveness of hospital-based clinic location for meeting logistical requirements
- Assess plan flexibility for a diverse group of hospitals

Location of the clinic site is critical to returning first responders back into service, minimizing out-of-service time and increasing comfort level during a terrorist attack when first responder demands are high.

Seven Paramedic Receiving Center Hospitals within the Blue/Green Disaster Net of Orange County, California were used as test mass prophylaxis clinic sites to dispense medications or vaccines to first responders. The hospitals ranged from small

community hospitals to mid-sized and larger facilities. Both non-profit and for-profit hospitals participated in the exercise. (Figure 4. www.orangecounty.net)



Figure 4. Orange County Map.

First responder knowledge of hospital locations increased comfort level and facilitated maneuvering the site. Experienced with each location's parking for routine delivery of patient care, and education and training, many responded with positive comments on ease of clinic access. There were no comments on inability to locate clinic or access parking. Additionally, the largest group to be prophylaxed was hospital personnel. Unlike other first responders, most hospital personnel are unable to leave the campus to receive prophylaxis without abandoning patients. Locating the clinic adjacent to the facility allowed more hospital workers to participate by minimizing out-of-service time and negating additional parking needs.

The plan demonstrated flexibility as individual hospitals exercised various scenarios, from anthrax and pneumonic plague requiring oral chemoprophylaxis, to viral smallpox requiring vaccinia vaccinations. The First Responder Policy and Procedure provided a structure that flexed to accommodate each scenario.

b. Recommendations

The artificialities of a full-scale exercise allowed for the large number of first responders to be prophylaxed but did not exhibit the volume of “worried well” expected in a bioterrorism attack. Therefore, while locating the clinic adjacent to the hospital worked extremely well for the exercise, it would take an actual event to determine if the additional demands of the clinic would overwhelm the facility. In spite of the lack of “worried well” to test the location, this author recommends utilizing a hospital-based clinic for the identified advantages.

Blue/Green Net participants discussed developing plans to delineate each threatened pathogen, but this exercise demonstrated that one plan capable of flexing to meet the needs of multiple scenarios was not only feasible, but practical, in the mass prophylaxis setting.

2. Communication

a. Objective

To determine the effectiveness of communication within the hospital organization and throughout the varying first responder agencies to notify clinic availability, location, and time

To communicate on the day of the exercise, faxes were sent to stations stating that a drill was to take place at the listed hospitals between the hours of 0900 a.m. and 1200 p.m. on May 24, 2004 testing the ability to provide mass prophylaxis to first responders. No additional incentives were provided. Both clinic staff and first responders receiving prophylaxis were on-duty first responders to allow testing of the system without additional staffing.

Due to the limited available clinic staff and first responders, the number of participants could only be estimated. Sufficient number of volunteers were needed to test the system, but could not be guaranteed until the event was tallied. Several other jurisdictional general public mass prophylaxis exercises recycled victims through their

clinics to ensure adequate test volume. Local Orange County EMS officials identified the problem encountered with recycling victims through mapped patterns. The first time volunteers were directed through a general public mass prophylaxis clinic a time standard was set. As the set of volunteers recycled through, the clinic times were shortened as they became familiar with procedures, decreasing throughput times. Therefore, the number of victims cycled through this first responder mass prophylaxis clinic was limited to the number available. No personnel would be recycled through a second time.

Communication utilizing faxes and land-line phone to individual stations resulted in over one-thousand first responders volunteering to participate in the exercise. Recognizing the important role of communication in any disaster scenario, redundant communication methods were used as back up. Methods included:

- ReddiNet: ReddiNet (Rapid Emergency Digital Data Information Network) is the 900MHz secure microwave radio system that forms a major component in Orange County's emergency management communications system. Located in all Paramedic Receiving Center Hospitals in the county, ReddiNet's real time data can include hospital diversion, public health alerts, and law enforcement updates, providing an excellent forum for first responder mass prophylaxis clinic information.
- 800 MHz Radio: The 800MHz radios are the non-secure, digital countywide coordinated communication system linking fire agencies, ambulance providers, hospitals and OCEMS.
- Ham Radio: Hospital Disaster Support Communications System (HDSCS) is a specialty section of the Amateur Radio Emergency Service that handles non-secure overflow or back-up communications to Orange County medical facilities via ham radio. Ham radio operators participated at each of the hospitals in exercise. (Figure 5)



Figure 5. Ham Radio operators

- Cellular and Landline Telephones, Pagers: Telephones and pagers are available with confidential telephone lists distributed to appropriate personnel.

b. Recommendation

Utilizing commonly used and redundant modes increases the probability of effective communication in a disaster. The more interoperable the communication mode with provider agencies, the easier its use. Law enforcement would benefit from joining the ReddiNet Group but were able to communicate with the other methods.

3. Pharmaceuticals

a. Objectives

- Determine effectiveness of p15n adaptability for use in pathogens requiring oral chemoprophylaxis and vaccines
- Test chosen antibiotics for hospital cache against actual first responder health profiles
- Determine effectiveness of counseling for first responders refusing prophylaxis

Pharmaceuticals for the clinic were simulated with unit dose bags of candy. Labeling was per State Board of Pharmacy requirements with the disclaimer that the candy was a simulation for an exercise. (See Figure 1)

Physicians received first responders with forms providing medical history and a signed decision/release form stating whether they were accepting or declining the prophylaxis. The physician discussed treatment options and provided a preprinted

prescription chosen from the preprinted medication labels or write-in space for additional antibiotic choices. The pre-printed medication labels saved significant time and helped ensure regulatory compliance by providing most of the necessary documentation while including prompts for the remaining data.

Although not all diseases will be covered with the limited antibiotic and vaccine caches, the first responder mass prophylaxis plan proved adaptable to a host of pathogens including anthrax, pneumonic plague, and smallpox. Each hospital had several instances of volunteers choosing not to accept the offered prophylaxis. The refusals required additional first responder counseling and discussion of options. Some of the discussion included allergies, fear of side effects, pregnancy and lactation. One participating hospital included an infectious disease specialist at the Physician Screening Station in anticipation of difficult decisions with prophylaxis. The specialist helped avoid bottlenecks by redirecting problematic cases away from the main distribution line.

b. Recommendations

- Retain the chosen medications and the adaptable policy.
- Continue to use pre-printed medication labels.

The infectious disease specialist at the Physician Screening Station assisted throughput time by directing first responders with complicated medical histories or increased need away from the fast moving clinic line. The added physician is needed for only a few cases, but provided more time to identify those specific needs and treatment options.

4. Information

a. Objectives

Trial reference materials including information fact sheets, and standardized aftercare instructions

The exercise utilized CDC fact sheets for disease pathogen and Micromedix aftercare for medication use and counseling. Past discussion has included storing copies of several potential biological weapons fact sheets and the coordinated medication directions. However, with lessons learned in the 2001 Anthrax Attack it became apparent how quickly information changed and stored data became obsolete.

CDC fact sheets were downloaded from websites and Micromedix software programs on the day of the exercise and copied off for distribution. Education levels varied from housekeepers to department directors, physicians, and battalion chiefs. The distributed information appeared to be well-understood by the participants. Although a portion of the clinic staff, including physicians, were bilingual, forms were printed in English and limited translation was available at the clinic site. The need for additional translation services was identified.

b. Recommendations

Provide additional bilingual clinic staff and forms in languages expected for area. (Multilingual Micromedix and CDC fact sheets are available on-line.)

5. Traffic Flow

a. Objectives

- Analyze traffic flow pattern and identify bottlenecks
- Measure first responder throughput times
- Determine effectiveness of signage clarity for clinic identification, location, traffic flow, station location, and exit

Traffic flow was diagramed using a direct flow pattern for entrance through individual stations and out a separate exit. Signage directed personnel to a First Responder Clinic. Mass prophylaxis was not listed in the verbiage to allow identification of the location without stating the purpose to the general public.

In addition to signage, directions for clinic flow were included on the First Responder Health Screening Form providing routing from Registration through Question and Answer Station. (See Figure 3)

Identification of clinic bottlenecks was accomplished through direct observation. Discussion included adding time markers for each station, but with budget and staffing constraints, hand-written time notations were used only at entry and exit portals.

Throughput time averages were obtained for each hospital. Total averages for the seven participating hospitals were 13.7 minutes. Throughput times compare favorably with other mass prophylaxis clinics. The numbers are outstanding when it is

recognized that the time measurement includes all waiting time. Many mass prophylaxis clinics begin time flow studies after participants have waited in extensive lines, often greater than an hour. This exercise measured the time from the time of arrival through exit. This exercise also included extensive information on the disease and recommended prophylaxis (medication or vaccination) with opportunity for discussion and follow-up with health care experts.

b. Recommendations

- Utilize similar time measurements in future exercise, beginning time flow study at time of arrival.
- Continue to include disease and prophylaxis information in clinic design.

6. Clinic Staff

a. Objectives

Examine efficacy of position assignments, identifying redundant positions or additional assignments that may be needed

Personnel are assigned in a disaster under the Hospital Emergency Incident Command System (HEICS). Staffing for the clinic followed position guidelines as outlined in the First Responder Mass Prophylaxis Policy and Procedure. Additional staff at each station would decrease throughput time but also increase exercise cost. (Figure 6)



Figure 6. First Responder Mass Prophylaxis Clinic

b. Recommendations

Future exercises or actual pathogen release could utilize the HEICS Labor Pool to provide additional staff to positions as the need is identified through direct observation. Rotating staff throughout participating hospitals could assist relieving staff of their patient duties to allow rapid clinic access.

7. Forms

a. Objectives

- Trial paperwork capability in fulfilling regulatory requirements
- Identify problematic areas of the First Responder Health Screening Form for clinic staff and first responder use

Paperwork included a registration form listing first responder name, agency, and arrival time. The most crucial form was the First Responder Health Screening Form. This form not only documented important health information, but also provided direction for both clinic staff and first responders.

Comments from participants and clinic staff were complimentary of the form and its ease of use. Completing the form was the most labor-intensive part of the clinic. Having the form in alternate languages would have relieved interpreters and decreased throughput time.

b. Recommendations

Fax, e-mail and hand delivered distribution of the First Responder Health Screening Form to first responder locations such as police and fire departments and substations, hospital nursing and non-clinical units, and ambulance provider stations will allow access to the form prior to arriving at the screening and dispensing sites of the clinic, helping decrease throughput times for each first responder.

Bilingual forms and information fact sheets would decrease translation use and facilitate participant process understanding.

V. CONCLUSIONS AND RECOMMENDATION

A. SUMMARY

Mass prophylaxis is a costly venture that includes regulatory, personal privacy considerations, and a strict adherence to medical guidelines, but the result of not providing protection is even more expensive. Epidemics and pandemics carry a horrendous cost in personnel, equipment and supplies, area economics, lost workdays, and potentially loss of life.

The exercise proved the First Responder Mass Prophylaxis Plan to be effective in providing rapid protection to first responders. Over one-thousand first responders completed biographical and medical history information, met with physicians for medical screening and prophylaxis, received consultation from pharmacists, and finally aftercare instructions for continued prophylaxis from their own agencies

B. REVIEW OF RESEARCH QUESTIONS AND CONCLUSIONS

In examining the First Responder Mass Prophylaxis Plan the objective is to provide an adequate level of protection in the event of a bioterrorism attack so that first responders are able to fulfill their daily duties. The scope of the plan not only includes all first responders, law enforcement, fire, ambulance providers, and hospital personnel, but also their immediate family members living in the same household. Since the first responders, their immediate families, and the first responder provider agency employers are viewed as customers of the jurisdictional plan, prophylaxis plans should address the group's specific needs during development and implementation phases.

Many factors make the First Responder Mass Prophylaxis Plan a success. The first factor is location. Community plans call for a centralized location to supply mass prophylaxis to hundred of thousands, to millions of people. The logistics of such a large undertaking are enormous. Parking, crowd control, line management, unfamiliarity with pathogens and treatment regimes, multicultural and language needs, and high-risk populations, will require much longer intervals and decrease clinic throughput numbers.

Decentralized first responder mass prophylaxis clinics at local hospitals decreased the total number to be prophylaxed at each site, located the screening and dispensing area at the work site for a large percentage of the first responders, and positioned it within the

work area for the remainder. This decentralization resulted in the avoidance of out of service time and the increase of first responder availability to the community. Hospital locations also presented the first responders a familiar location with familiar staff in a very stressful time.

Developing a first responder mass prophylaxis plan that includes family members also increases the chance for success as provisions of protection for first responder immediate family hinges on personnel showing up to work. Less absenteeism by first responders during critical periods helps provide coverage to more citizens of the community and a more protected first responder work force.

Using established hospital sites increased trust and decreased fear. Locating the clinic at the hospital could stress an already impacted healthcare system, but would provide the most rapid means to provide protection to first responders.

The largest and most costly threat in lack of first responder mass prophylaxis planning is not providing the protection to first responders. Leaving them vulnerable to the attack pathogen results either in their unavailability to complete the community mission as first responders or in their having to work unprotected, risking disease contraction and possibly assisting the terrorists in spreading the disease to an even higher at-risk population.

C. SUGGESTED AREAS FOR FURTHER RESEARCH

This thesis proposed a plan to provide prophylaxis to first responders in the event of a bioterrorism attack. Implementation of the plan to over 1,000 first responders in a multi-jurisdictional exercise provided valuable insight into the feasibility of a rapid, hospital-based mass prophylaxis clinic and allowed identification of several areas of improvement. Further testing of the plan needs to be done to exercise inclusion of first responder's immediate family members and transportation of SNS and MMRS caches to distribution sites.

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