

Nevada Hospital Association



Hospital-Based Mass Prophylaxis and Vaccination Strategy

Version 3.2
Replaces SMALLPOX:
An Interim Hospital Plan and Vaccination Strategy

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Table of Contents

Executive Summary	4
Introduction	5
Prophylaxis Strategies	6
Vaccination Strategies	10
Sample Protocol: Pharmacy Procedures	12
Sample Pharmacy Disaster Plan / HICS Checklists	15
Sample Incident Action Plan	18
Use of Emergency Use Authorization (EUA) Medical Products	19

Executive Summary

This booklet has been designed to help hospitals create and manage a mass-prophylaxis and vaccination strategy for their workforce and essential employees. In each of the two categories, vaccination and prophylaxis, the strategies have been divided into an easy to use format that includes: strategy objective, hypothesis of the strategy, method, and conclusions.

A sample pharmacy procedure has been included (page 11) to help hospitals that haven't yet completed that development process. This was included because hospitals that have received hospital preparedness funding for protective stockpiles are required, under the memorandum of agreement that they have signed, to “...*establish standing orders or policy regarding to whom, under what circumstances and how these medications will be distributed*”. This draft policy will help hospitals meet compliance with this requirement.

A pharmacy disaster response plan checklist for the first 12-hour operational period has also been developed and included (page 15). This checklist can be used to help facilitate the development of a specific checklist for your hospital or used as a just-in-time tool if the unthinkable occurs before your hospital has completed an internal checklist/policy development process.

A sample incident management plan has been also been included. This one page summary document will help ensure that all critical information, objectives, safety, and incident command structures are communicated clearly and uniformly to all persons needing the information. The coversheet can be used as a checklist to prompt the Hospital Incident Command System (HICS) planning section during the early stages of any emergency.

Finally, the booklet explains a process called the emergency use authorization (EUA) of medical products that may come into play during any large-scale, federally declared, public health emergency or terrorist attack. This process essentially allows the FDA to modify licensing requirements for medical products as well as the licensing required for the use of certain products. The EUA is a policy, created as part of the BioShield Act of 2004.

Introduction

The Nevada Hospital Association, in coordination with the acute care hospitals within Nevada, developed the *SMALLPOX: An Interim Hospital Plan and Vaccination Strategy* booklet in early 2003. This booklet was created in response to what was considered to be at the time, a high degree of likelihood that Iraq had weapons of mass destruction, and smallpox stores in particular, prior to the United States entering the second Gulf War. This booklet went on to be requested by hospitals from around the nation, and was posted as a resource on several national organizations' websites.

As almost three years have passed; smallpox stores have not been discovered, and smallpox as an illness remains to be experienced. Accordingly, the health care community has asked that the booklet be reconfigured to be less disease specific. Furthermore, they have asked that the booklet encompass the progress made with pharmaceutical stockpiles since January 2003, and include such things as antiviral medications and vaccine strategies for possible flu epidemics.

Based on the request to reduce specificity yet increase the breadth of this manual while simplifying the manner in which the materials are presented, a decision was made to completely redesign the work. In doing this, we have eliminated any reference to the National Smallpox Vaccine Plan (NSVP), and chose to focus on hospital-based strategies and reference plans (including draft documents in cases where the final documents are not yet available) which may affect a hospital's distribution process. The result is a compact, easy to use manual for hospitals, designed to provide preplanning or just-in-time information during any incident when prophylaxis is needed.

Prophylaxis Strategies

Objective: The single objective of a hospital-based prophylaxis strategy is to provide protection to the hospital workers, their family members, and other critical personnel to ensure that hospital operations can continue to be a community resource. Hospital-based prophylaxis strategies should not be confused with community-based mass prophylaxis.

Hypothesis: The hypothesis behind a hospital-based prophylaxis strategy is that employees are more likely to show up for work, even in high risk patient care positions during an epidemic or bioterrorism event, if they believe that they are adequately protected and that they will not bring the disease home to their family.

The hospitals should anticipate the need to provide a minimum 5 day course of treatment to employees to ensure adequate protection until such time as additional medications and supplies can be obtained.

Methods: The Nevada Hospital Association has provided hospitals throughout the state with the ability and funding to establish protective stockpiles of medications. These medications are stored within the hospital's pharmacy and have a dedicated purpose of being available solely for hospital employees and their family members during any large-scale infectious event.

The medications contained within these protective stockpiles include:

Bactrim DS
Doxycycline
Levofloxacin
Amoxicillin

Medications can be substituted with similar medications to facilitate interoperability within the hospital's previously established formularies.

While these stockpiles have a dedicated use, hospitals remain responsible to maintain, store, and manage all pharmaceuticals in a manner consistent with currently accepted and established pharmaceutical handling processes. Additionally, hospitals are required to abide by all local, state, and federal laws regarding the handling, storage, and distribution of pharmaceuticals.

To achieve a timely distribution of these medications hospitals are required to establish standing orders or policy regarding to whom, under what circumstances, and how these medications will be distributed.

Hospitals may rotate protective stockpile medications within their normal pharmaceutical rotations, if allowed by hospital policy, and with the understanding that these medications are being rotated only in an attempt to limit the effects of cache expiration.

Case Study: During the “Anthrax by Mail” scare that occurred in October of 2001 several mass antibiotic distributions took place. During the first several distributions, with lay persons as the patients/exposed population, 10,326 people received antibiotics. The average amount of time per person to screen and provide informed consent was 33 minutes.

When this process needed to be repeated, this time at a hospital for their employees (Oct.28, 2001) the hospital streamlined the distribution process to include only critical tasks such as registration, triage, medical evaluation, dispensing and access to counseling. The throughput time was reduced to an average of 6 ½ minutes for each of the 1,923 hospital employees who received antibiotics.

Lessons Learned:

1. Staff practice and familiarity with the distribution protocol, methods, and processes minimizes the amount of time it takes to begin distribution, once the decision to distribute has been made.
2. Eliminate the natural tendency to provide:
 - a. Informational sessions
 - b. Situational awareness discussions
 - c. Law enforcement activities

These may all be important activities, but they do not need to be co-mingled with the distribution process.
3. Triage should be protocol-based using preprinted forms.
4. Only individuals who don't meet the criteria for medications should be referred for medical evaluation.
5. Allow medications to be dispensed by any provider (nurses, physicians, etc.) and supervised by a pharmacist.
6. Mental health counseling can be provided initially via telephone. During a large-scale incident and/or when hospital Employee Assistance Programs (EAP) become overwhelmed with the volume of employees needing mental health services, the Division of Mental Health and Developmental Services and/or the Southern Nevada Health District will publish a special phone number(s) to access mental health assessment, triage, and referral services in southern Nevada. In northern Nevada, the designated Employee Assistance Coordinator will be asked to contact the Northern Nevada Adult Mental Health Services Administrator, the Northern Regional Disaster Response Coordinator, or their nearest Division of Mental Health and Developmental Services rural clinic.

Conclusions: The best proven strategy for hospital-based prophylaxis is to pre-plan how this will be achieved within your facility and incorporate this function into your regularly scheduled disaster drills or exercises.

- Develop a department specific protocol regarding who, when, and how the protective stockpiles will be called for and assembled.
- Develop a call-out list, similar to the hospital decontamination team call-out list, which identifies who (by both name and position) will assist during any distribution process.
- Develop a preprinted triage protocol/checklist for each of the medications within the stockpile that can be easily duplicated as needed. The triage protocol/checklist should be designed so that it easily identifies if someone has a medical reason or drug interaction reason not to get the prophylaxis. Review checklist with hospital chief of staff and risk management prior to use.
- Develop standing orders with the chief of staff and chief pharmacist regarding what medications will be distributed based on what type of biological agent is suspected.
- Incorporate prophylaxis plan awareness in employee annual PPE training.
- Incorporate mental health follow-up using outside resources, via phone, whenever possible.
- Test, exercise, tailor, and improve your hospital specific plan to meet any of your facility's unique needs and to overcome any anticipated obstacles.

Planning Notes:

When creating or revising a hospital’s internal mass vaccination/prophylaxis policy or procedures, it is important that the process work seamlessly with the plans of the state and local health authorities. This will be of particular importance if the facility is going to rely upon these agencies for logistical support or provisions of supplies and medications.

To facilitate plan integration, several relevant sections of the State’s plan have been referenced below. Hospitals that plan to rely on the Nevada State Health Division for additional personnel and resources should validate the anticipated timeframes and levels of redundancy within this supply-chain model. A formal memorandum of understanding or other individualized document that signifies all relevant parties understand the expectations placed upon them is strongly encouraged to reduce confusion that may occur as a result of the “fog of the moment” during a mass illness.

The Nevada State Health Division (NSHD), states that, “the state will coordinate the provision of additional personnel, resources and facilities that may be needed in a mass illness emergency, and is directly responsible for providing these resources in the 14 rural and frontier counties of Nevada.” (Final Draft 1, Mass Illness Plan 6/05: pg. 20; Chapter 14 Mass Dispensing).

The Nevada State Health Division acknowledges, “*The NSHD, as part of the NSHD Mass Dispensing Plan, will coordinate with the local health authority to ensure services to persons who cannot access designated prophylaxis dispensing sites. These groups may include, but are not limited to: ...patients in hospitals.*”

“*NSHD is responsible for ensuring that vulnerable populations are provided the treatment and care necessary to prevent the spread of disease. These groups are not to be considered “priority” groups; priority and/or high-risk groups will be determined based on the event by the appropriate health authority (i.e., local or state).*”

To access:

Patients in hospitals, the NSHD, in coordination with the local health authority, may:

- 1. Coordinate with hospital administration to determine need for prophylaxis distribution;*
- 2. Deliver medications and vaccinations to hospitals based on need;*
- 3. Ensure hospitals have adequate staff to dispense medications and/or administer vaccinations; and*
- 4. Seek license waivers if necessary.”*

Vaccination Strategies

Very few of the CDC Category A-C biological warfare agents have vaccines available. Smallpox and Anthrax currently have vaccinations; Ebola has a vaccination in development. A vaccine for any form of pandemic flu would be estimated to be developed approximately 6 months following identification of the strain.

Objective: The single objective of a hospital-based prophylaxis strategy is to provide protection to the hospital workers, their family members, and other critical personnel to ensure that hospital operations can continue to be a community resource. Hospital-based vaccination strategies should not be confused with community-based mass vaccination.

Hypothesis: The hypothesis behind a hospital-based vaccination strategy is that employees are more likely to show up for work, even in high risk patient care positions during an epidemic or bioterrorism event, if they believe that they are adequately protected and that they will not bring the disease home to their family.

The hospitals should anticipate that in case(s) of a pandemic or the occurrence of a hostile government or terrorist deliberately releasing a known or fabricated biological weapon into society, that a vaccine will become available at some point during the event. Based on this assumption, hospitals are urged to develop and exercise hospital-based vaccination plans.

As was recognized during the 2003, National Smallpox Vaccination Program, access to adequate quantities of vaccine may be limited due to supply, production capacity or other unforeseen event. Hospitals should develop vaccination plans that allow for a phased approach should these types of circumstances present again.

Methods: Currently, stockpiles of vaccine do not exist within the Nevada health care system. It is anticipated that vaccine would be provided to hospitals during any type of public health emergency on a priority basis. Likewise it is anticipated that a period of days would elapse from the time that a public health crisis begins to emerge, until such time as emergency vaccinations were ordered for health care workers and/or the public.

It is recommended that hospitals incorporate vaccination plans into their prophylaxis strategies. These vaccination plans should be designed to run simultaneously with an active hospital-based prophylaxis program, to help facilitate flu vaccination along with an antiviral prophylaxis campaign, should the need arise.

At a minimum, hospitals should develop a list of positions that would need immediate vaccination during a public health crisis. These positions should include: emergency department personnel, intensive care personnel, and other persons who would provide direct care to patients within isolation, as well as anybody who would be required to perform services within any established containment areas. The list should be designed so that an early intervention team could be established, if very low quantities of vaccine are

received first. A phased in approach adding additional personnel can be created later, when more specifics as to the vaccine and the illness are identified.

Conclusions:

The best proven strategy for hospital-based vaccination is to pre-plan how to achieve the operation within your facility and incorporate this function into one of the regularly scheduled disaster drills or exercises.

- Develop department specific protocol regarding who, when, how and from who the vaccine will be called for and received.
- Develop standing orders with the chief of staff and chief pharmacist regarding how and to whom the vaccine will be administered, based on what type of biological agent is suspected.
- Develop call-out list, similar to the hospital decontamination team call-out list, which identifies who (by both name and position) will assist during any vaccination process.
- Incorporate vaccination plan awareness in employee annual PPE training.
- Incorporate mental health follow-up using outside resources, via phone, whenever possible.
- Test, exercise, tailor and improve your hospital specific plan to meet any of your facility's unique needs and to overcome any anticipated obstacles.

Sample Protocol

HOSPITAL XYZ
Mass Casualty Incident (MCI) Response
Pharmacy Procedures

Effective Date: _____
Supersedes: _____

1. Purpose:

To outline procedures to be followed by hospital pharmacy personnel in the event of a MCI or other public health emergency.

2. Policy:

All pharmacy personnel shall respond per established procedures to all Mass Casualty Incident (MCI) events announced by the PBX operator.

Pharmacy personnel shall be familiar with emergency distribution of protective stockpile, processes as delineated within this policy.

a. Personnel:

Minimum staff dedicated for emergency dispensing of the protective stockpile, in addition to all available routine, on-duty, pharmacy staff includes:

- (1) Pharmacy Supervisor
- (1) Staff Pharmacist
- (2) Pharmacy Technicians

b. Equipment and Supplies:

Equipment and supplies dedicated to the protective stockpile program are located _____. These supplies shall be utilized first, as per standing medical orders.

c. Dosing:

Dosing references for all protective stockpile medications and/or vaccines include: standing orders; CDC recommendations and or health authorities recommendations.

3. Action Plan:

Step Number	Responsible Persons	Action(s) Required
1	All Staff	Upon hearing MCI notification or internal disaster notify PBX operator.
2	PBX	Notify (per notification policy) staff of the MCI and nature of the emergency.
3	Charge Pharmacist	Determine if nature of emergency / MCI warrants emergency distribution of protective pharmaceutical stockpile.
4	Charge Pharmacist	Notify Director of Pharmacy or designee of the need to distribute protective pharmaceutical stockpile. Activate Pharmacy Disaster Plan / Hospital Emergency Incident Command System plan within designated timeframes (attached).
5	Pharmacy Director or Designee	Determine number of staff required to accommodate the disaster and authorize initiation of Pharmacy Disaster Plan Call List. Designate personnel responsible for completing call-in process.
6	Pharmacy Director or Designee	Assume role of Pharmacy Unit Leader and continue implementation of Pharmacy Disaster Plan / Hospital Emergency Incident Command System plan.
7	Pharmacy Supervisor or Purchasing Agent	Assess available inventory of medications appropriate for the MCI / event and; Assess available inventory and estimated number of personnel and what number of days (duration of time) pharmacological chemoprophylaxis can be maintained.
8	Purchasing Agent	Contact supply chain director or equivalent drug wholesaler and other hospitals within the brand/chain to assess availability of additional drug supplies.

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9	All Staff	Dispense medications as instructed by Pharmacy Director and as ordered by the Hospital Incident Commander.
10	Pharmacy Director	Compose after action report at the completion of the distribution operation and submit to Hospital Risk Manager, Emergency Planner, Safety Committee and Incident Commander.

SAMPLE

Pharmacy Disaster Plan / Hospital Emergency Incident Command System Plan
Check List for First 12 Hour Operational Period

Event Hour 00:00 - 01:00

- () **Immediately**, following notification of an MCI/public health emergency, obtain a briefing on the nature of the incident and all available pertinent information.
- () **Decision Point. Is activation of the Protective Stockpile Necessary?**
If, NO: continue to support MCI/HICS structure as necessary.

If YES: Continue the checklist.
- () **Activate** emergency recall list with the goal of calling in minimal number of staff to begin establishing the pharmacy staging area for drug procurement and dispensing activity. Consider calling in more staff if projected number of patients and personnel to be provided prophylaxis dictates.
- () **Inventory** medication and vaccination supplies and drugs on site to appropriately treat patients and provide prophylaxis to personnel associated with the specific incident.
- () **Assign** person to become the single point of contact for the pharmacy department and the hospital logistics officer.
- () **Provide** hospital logistics officer with list of anticipated pharmaceutical needs beyond what you have on-site, for the next 12 hours, based on anticipated patient counts and prophylaxis requirements.
- () **Develop** a one-page, bullet-point pharmacy situation report and provide to hospital incident commander. Repeat every hour for first 12 hours and then every 4 hours thereafter or as requested.

Event Hour 01:00 - 02:00

- () **Determine** number of staff members (persons) who could receive prophylaxis based on available on-hand supplies. Remember to include number of pediatric doses for staff family members.

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- () **Assess** availability of additional medications, vaccines, and/or supplies from supply chain (including: wholesalers, hospitals within brand/ chain or local drug suppliers).
- () **Confirm** order to provide prophylaxis. Confirm: right individuals; right route; right medication; no expired medications; no known allergies to the medications.
- () **Dispense** protective stockpile medications to selected personnel as instructed by Pharmacy Director and ordered by the Hospital Incident Commander.
- () **Communicate** any additional supply, equipment or medication needs to the logistics chief.
- () **Update** one-page, bullet-point pharmacy situation report and provide to hospital incident commander.

Event Hour 02:00 - 04:00

- () **Continue to Dispense** protective stockpile medications to selected personnel as instructed by Pharmacy Director and ordered by the Hospital Incident Commander.
- () **Receive** sit_rep from Hospital Incident Commander.
- () **Consider** calling in more staff if projected number of patients and personnel to be provided prophylaxis dictates.
- () **Re-Inventory** medication and vaccination supplies and drugs on site to appropriately treat patients and provide prophylaxis to personnel associated with the specific incident.
- () **Provide** sit_rep to all pharmacy staff members and solicit action plan suggestions and notification of any identified issues or concerns.

Event Hour 04:00 - 08:00

- () **Develop** position transition plan so that personnel can smoothly transition at the end of their shifts without major disruption to the operation.
- () **Continue to Dispense** protective stockpile medications to selected personnel as instructed by Pharmacy Director and ordered by the Hospital Incident Commander.

- () **Receive** sit_rep from Hospital Incident Commander.
- () **Reassess** pharmacy staffing matrix. If the projected number of patients and personnel to be provided prophylaxis dictates, call in more staff. If the tempo of prophylaxis operation is slowing, release staff as possible.
- () **Re-Inventory** medication and vaccination supplies and drugs on-site to appropriately treat patients and provide prophylaxis to personnel associated with the specific incident.
- () **Provide** sit_rep to all pharmacy staff members and solicit action plan suggestions and notification of any identified issues or concerns.
- () **Evaluate** at what time (specific date and time) the pharmacy will have to cease continued operations based on current tempo of operation, supplies on hand, and pharmacy personnel available.
- () **Estimate** what quantity of each supply, medication and/or vaccine is being used per hour.
- () **Update** one-page, bullet-point pharmacy situation report and provide to hospital incident commander. Include the evaluation results and supply consumption estimates listed above.

Event Hour 08:00 - 12:00

- () **Continue to Dispense** protective stockpile medications to selected personnel as instructed by Pharmacy Director and ordered by the Hospital Incident Commander.
- () **Receive** sit_rep from Hospital Incident Commander.
- () **Reassess** pharmacy staffing matrix. If the projected number of patients and personnel to be provided prophylaxis dictates, call in more staff. If the tempo of prophylaxis operation is slowing, release staff as possible.
- () **Re-Inventory** medication and vaccination supplies and drugs on-site to appropriately treat patients and provide prophylaxis to personnel associated with the specific incident.
- () **Update** one-page, bullet-point pharmacy situation report and provide to hospital incident commander.

**Sample
Mass Prophylaxis/ Vaccination Incident Management Plan**

Hospital XYZ - Incident Action Plan

I. Incident Name: r/o Avian Flu	II. Date: DD/MM/YYYY	III. Incident Commander: Jones, K. RN
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IV. Incident Type: Flu Epidemic - highly contagious. Person-to-person transmission suspected. Case Definition - PENDING	V. Suspected Illness: R/O Avian Flu Symptoms Include: Fever Cough Respiratory Distress / Pneumonias Fatigue / Muscular Pain NV in children <5
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VI. Incident Goals:	What is it that the hospital wants to accomplish?
	1 Prevent transmission within hospital 2 Treat Symptoms 3 Provide Patient Comfort as possible 4 Educate Patient Family Members re: Disease Spread and Protective Measures 5 6

VII. Incident Objectives	How is the hospital going to accomplish it's goals?
	1 All staff members to be fitted with N95 mask 2 Personnel Identified as working in "High Risk" areas: Offer antiviral prophylaxis as vaccine not available 3 Issue "High Risk" personnel PAPR for use during shift 4 Screen all visitors outside of hospital for S&S of flu 5 Isolate infected or suspected patients that require admission using either A.I.I. rooms or cohort on third floor, west wing 6 Teach patient family members how to provide comfort measures safely using universal precautions 7 Update Incident Commander q. 1 hour w/ number of suspected flu admitted patients

Page 1 of x .

Attachments:

HEICS Org. Chart	
Task Assignment Checklist	
Situation Report(s)	
Health and Safety Plan	
Infection Control Plan	
Communications Plan	
Logistics Plan	
Incident Map	
Other	

Page		of		.
Page		of		.
Page		of		.
Page		of		.
Page		of		.
Page		of		.
Page		of		.
Page		of		.

Implementation of Emergency Use Authorization (EUA) Medical Products

If the Secretary of Health and Human Services has declared an emergency using those powers afforded him within the Public Health Service Act or based on the determinations of either the Secretary of Defense and/or Secretary of Homeland Security that a domestic emergency or military emergency exists, or has significant potential to exist, then the Food and Drug Administration (FDA) may issue what is referred to as an Emergency Use Authorization (EUA).

A EUA may authorize the use of specific, unapproved medical products and/or specific, unapproved use of an approved medical product during the period of declared emergency or during heightened risk of attack. For example, one such unapproved use of an approved medical product that is being considered is the use of Amoxicillin as prophylaxis for anthrax. Another example would be the distribution of a prescription drug by non-licensed providers (i.e. paramedics administering vaccines and/or fire fighters distributing oral antibiotics or antiviral medications.)

The test that the FDA will use to determine the risk-reward analysis is simple; does the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product. While EUAs may not be issued until after an emergency has been declared, the FDA is strongly encouraging an entity with a possible candidate product to contact the FDA prior to the determination of any actual or potential emergency, so the evaluation can take place in a slow and deliberate manner vs. evaluation under possible exigent circumstances.

Once a EUA is authorized, health care providers can expect two fact sheets to be produced and made available to them: one fact sheet specific for the health care provider, and one fact sheet designed for the recipient or patient. These fact sheets will provide similar information, although with varying levels of detail. At a minimum, instructions for the use of the product, known major interactions, known efficacy, adverse events, alternative therapies (if any) significant known and potential risks and benefits, consequences of not using the product, new findings, and contact information for questions and or to report previously unknown findings, etc.

Providers are cautioned about making any assumptions of which products may or may not receive a EUA during certain circumstances. Hospital policies should be developed to adapt and accommodate any issued EUA; however, it is important to realize that at this time, liability issues and protection to manufactures, providers, and others has not been addressed regarding these potential authorizations.