The National Pharmaceutical Stockpile Program: an overview and perspective for the Pacific Islands

Abstract: The National Pharmaceutical Stockpile (NSP) program was created as a national resource and is an essential response component of the Centers for Disease Control and Prevention's (CDC's) larger Bioterrorism Preparedness and Response Initiative. The role of the NPS program is to maintain a national repository of life-saving pharmaceuticals and medical supplies that can be delivered to communities in the event of a biological or chemical terrorist attack or an event involving mass casualties. The NPS is to be a re-supply and backup mechanism to state and local emergency response. Before a decision is made to deploy NPS assets, CDC will collaborate with local, state, and federal officials to determine the nature and extent of the event. Once the federal decision to deploy NPS assets is made, CDC's NPS program will arrange for delivery of assets to reach the affected area within 12 hours.

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Introduction

The U.S. Department of Health and Human Services (DHHS) tasked the Centers for Disease Control and Prevention (CDC) with the creation and maintenance of a National Pharmaceutical Stockpile (NPS) in 1999 at the request of the U.S. Congress. The role of the NPS program is to maintain a national repository of life-saving pharmaceuticals and medical materiel that can be delivered to the site or sites of a terrorist attack involving a chemical or biological agent, or to the site of a mass casualty event, in order to reduce morbidity and mortality in civilian populations. It is anticipated that responding to such events would require large quantities of pharmaceuticals and other medical supplies. These resource needs could easily overwhelm the capacity to respond of most local and state health care systems. The NPS was created as a national resource and is an essential response component of CDC's larger Bioterrorism Preparedness and Response Initiative. The CDC relied on the DHHS 1999 operating plan for the anti-bioterrorism initiative as part of the foundation for planning the NPS program.[1]

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The NPS program works with many partnerships at the federal, state, and local levels as well as within the private sector. Federal partners include the Department of Veterans' Affairs National Acquisition Center, which shares responsibility for all contracts and procurements. The NPS program also works in conjunction with the Department of Defense to coordinate the similar missions of programs that stockpile medications and supplies for protection of military personnel (DOD) and of civilians (NPS). The Office of Emergency Preparedness, another organization within the scope of the DHHS, is a federal partner which has a similar emergency response mission to protect civilians by providing medical care and services in the event of a terrorist attack or other emergency.[2] The NPS program also partners with the Food and Drug Administration, another DHHS agency, to ensure that all regulations regarding Investigational New Drug protocols are followed.

At the state and local level, the CDC's NPS program works in conjunction with health departments and emergency management agencies to ensure that states and city personnel understand the NPS program and are ready to receive and dispense the NPS materials if they are ever delivered to their area.

The NPS also partners with the private sector. NPS program assets are stored at private vendor locations as well as at privately owned warehouses; in secure undisclosed locations around the country. Additionally, private sector partners are responsible for the ground or air transport of NPS program assets.

Whereas the primary mission of the NPS program is to provide the medical supplies and pharmaceuticals needed to respond to a terrorist event, the program has also undertaken a number of initiatives in training and educa-

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Table 1. Category A agents and their associated diseases

Category A Agent	Disease
Bacillus anthracis	Anthrax
Yersinia pestis	Plague
Variola major	Smallpox
Clostridium botulinum	Botulism Toxin
Francisella tularensis	Tularemia
Filoviruses and arenaviruses	Viral hemorrhagic fevers

tion to help states and cities with their plans to receive the stockpile. These include a guidance document for planning, patient information sheets and medication labels in 48 different languages, a planning tool base on Microsoft Word® that can be used to create a basic plan, provision of funding through grants for plan development, a computerized LISTSERV® for easy sharing of ideas and questions over the internet, a training video, and various briefings, conferences, and exercises.

Structure and contents

The NPS inventory structure has three parts: the 12-hour Push Package, Vendor Managed Inventory (VMI) and vaccines. The 12-hour Push Packages contain approximately 95 line items and can reach any affected destination within the United States or its territories within 12 hours of the federal decision to deploy the assets. This type of response is generally used when there is not yet specific identification of the threat. The premise behind using a 12-hour Push Package to respond to a nonspecific threat is that it contains a variety of medications and medical supplies that would be useful for any number of different events.

A 12-hour Push Package can be moved via ground or air, and occupies over 100 specialized cargo containers. It requires 5000 square feet of ground space for proper staging. VMI is inventory that is maintained at various vendor locations across the United States. VMI is usually used to "tailor" a response involving a specific threat agent, and can be shipped out either after a 12-hour Push Package or as an initial response from the NPS program when the threat agent has been identified. It may also be used instead of a 12-hour Push Package for a small scale event that does not warrant the movement of an entire 12-hour Push Package.

The formulary of the NPS program was based on a series of meetings with subject matter experts in chemical and biological terrorism, with additional input from various law enforcement and intelligence agencies. Currently, the formulary focuses on drugs to treat diseases caused by CDC Category A threat agents (Table 1).[2] The formulary is subject to periodic review and can change at any time as a result of new threat information. The formulary contains antimicrobial drugs for Category A biological threat agents appropriate for providing treatment of symptomatic patients and prophylaxis of asymptomatic exposed patients. The antimicrobial agents are supplied in both intravenous and oral formulations. Pediatric patients can be accommodated with chewable tablets and oral suspensions or syrups contained in the NPS. Alternatively, certain antibiotic tablets may be converted into oral suspension by a process known as pharmaceutical compounding. NPS can furnish recipes in the event that this method must be used to provide additional medications in the suspension form. Related medical supplies such as intravenous (IV) fluids, IV fluid administration sets, catheters and syringes are also included as part of the NPS.

In addition to drugs for treatment and prophylaxis for biological agents, the NPS formulary also contains antidotes and medical supplies to address exposure to a chemical agent, such as from nerve gas or organophosphates. NPS also contains airway management supplies such as endotracheal tubes, laryngoscopes, suction devices, oxygen masks, nasogastric tubes, and ventilators. Bandages and dressings that can be used for burns or trauma are also included in the formulary. The goal of the NPS program is to be able to provide therapeutic treatment or post-exposure prophylaxis treatment for 12 million people against anthrax. In addition, NPS contains supplies for more than 34,000 casualties from a nerve agent release.

While the 12-hour Push Package does not contain vaccines, antivirals, or antitoxins, the NPS program can access these products through VMI and pre-established purchasing mechanisms. These products would be shipped only in the event of a disaster requiring the use of vaccines, antivirals, or antitoxins which are currently in limited supply. Products in VMI would be available to the continental US within 24-48 hours.

The NPS program takes a rigorous approach to quality assurance ensure that its assets are secure and in-date (fresh). Facilities must meet the appropriate environmental requirements for pharmaceutical storage such as temperature and humidity control, or protection from

light, where indicated. To guarantee that these standards are met, NPS staff visits each storage location quarterly. A unique rotation-in-place concept is applied at each storage location: the vendor or warehouse partner pulls inventory out of NPS stock when it is within 6 months to 1 year prior of expiration and replaces it with newer stock with a more distant expiration date. The removed stock is then placed back into manufacture's main inventory for resale. The vendors will not resell products with less than 6 months left before date of expiration. Certain products may be candidates for inclusion in the U.S. Food and Drug Administration's shelf-life extension program. This program is utilized by government entities such as the various branches of the armed forces to prevent wastage of pharmaceutical products that maintain their potency and integrity after their original expiration date. Pharmaceuticals that are about to expire are rigorously tested for stability, potency, and integrity using a battery of tests similar to those used when the drug was undergoing initial study prior to marketing. If the drug maintains its potency and meets other requirements during testing, it is assigned a new expiration date that allows for its continued use. Drugs that meet shelf-life extension standards are then re-tested on an annual basis until they fail testing.

Requesting assets from the National Pharmaceutical Stockpile

The NPS is not a first response tool. It was designed to augment and re-supply state and local public health, health care, and emergency medical services, and related programs. The federal decision to deploy the NPS assets will be made following a collaborative effort among local, state, and federal officials to determine the nature and extent of the event. State officials may request NPS assets directly from the CDC or through request for assistance through the Federal Response Plan.

Several local resource factors are considerations for deploying the NPS. These include the following: number of current and projected victims, presence of an identifiable coordinated NPS section to the local or state terrorism response plan, healthcare capacity at the time of the event including ventilator needs, local or state resources such as pharmacies, and whether or not preparation has been made for receiving, distributing, and dispensing the NPS materiel.

Once the request for deployment has been received, the Director of CDC, will consult with officials in the Department of Health and Human Services, Federal Bureau of Investigation, Federal Emergency Management Agency, National Security Agency, other federal partners and local and state officials to evaluate the threat and the local/state ability to respond to the event. If the local/state supplies will not be sufficient, the Director of CDC can order the NPS to deploy.

Planning to receive the NPS assets

Once the decision to deploy the NPS assets has been made, CDC has committed to having the 12-hour Push Package delivered anywhere in the United States and its territories within 12 hours. Local and state officials will need to be ready to receive, distribute, and dispense the NPS assets when it arrives. In April 2002, the NPS program released a guidance document, *Receiving, Distributing, and Dispensing the National Pharmaceutical Stockpile: A Guide for Planners, Version 9.* Emergency or disaster planners may request a copy of the planning guidance by emailing the NPS at NPS_PPT@cdc.gov.

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The following is a brief summary of key points in preparing for the arrival of the NPS assets. Local and state planners are encouraged to develop an operations management team. Members of the team should ideally have backgrounds in general medical materiel management, contracting and purchasing, communications, and security. The operations management team should be responsible for coordinating with agencies that provide security and communications to facilitate movement of NPS assets. The operations team would also coordinate among individuals assigned to the receipt, storage, and stage (RSS) team and inventory control teams.

Individuals will also need to be assigned to the RSS team. The effectiveness of this team will significantly impact how quickly the assets are received by the public for both prophylaxis and treatment. The RSS team will physically unload, store and distribute assets to dispensing sites or treatment centers, and ensures it the proper handling and transfer of controlled substances (narcotics). The RSS team must carefully plan inbound transportation of NPS assets into their community. For instance, the use of military air bases is often *not* the most efficient means to rapidly and safely unload NPS assets. Military bases often have security restrictions that may delay arrival and distribution of NPS assets and may not have the specialized off-loading equipment needed to off-load the aircrafts. Airports should be able to handle wide-bodied commercial cargo jets in special circumstances, NPS can also deliver in multiple smaller aircrafts such as 737s. The use of smaller aircraft would ideally be planned in advance. Airports should have personnel that are specially trained to handle the off-loading of cargo jets. Considerations for

storage facilities should include availability of multiple sites, proximity to dispensing or treatment centers, and access to a variety of modes of transportation such as trucks, railway, helicopters or boats. The storage facilities should also have sufficient space to collect material (approximately 12,000 square feet), conduct inventory control, maintain temperature control (58°F-86°F), and provide sufficient emergency electrical power to maintain 8 self-contained portable refrigeration units that each require 35 watts of electrical power.

The inventory control team manages the NPS inventory. In preparation for receiving NPS material, the inventory control team should have a system for tracking NPS material and equipment and the locations to which material was transferred, a method for apportioning NPS material, a method for tracking stock balances, and a method for recovering unused NPS materials and assets such as cargo containers and ventilators after an event. The cargo containers were specially designed for use by the NPS and remain the property of the NPS after deployment.

Technical Advisory Response Unit (TARU)

The NPS program will send a group of technical advisors that will accompany the 12-hour Push Package to provide 24-hour technical assistance on the ground. The TARU members consist of expert personnel from the NPS program including pharmacists, public health advisors, logisticians, and emergency response specialists. The TARU most often consists of six to eight members and usually arrives in advance of the 12-hour Push Package.

The primary mission of the TARU is to facilitate and execute the "hand off" of assets to the designated representative. The TARU members provide overall management and coordination of NPS resources in the field. The TARU team will work closely with state and local officials to ensure that the NPS resources meet the objectives established by the officials requesting support. The TARU will be able to provide technical assistance with breaking down the 12-hour Push Package for further distribution to dispensing areas. The TARU receives scientific, communication, and logistical support from NPS communications center located at the CDC in Atlanta, Georgia.

NPS program response to September 11, 2001 and anthrax attacks

The NPS program responded to the terrorist destruction of the twin towers of the World Trade Center in New York on September 11, 2001. On that day, the federal decision to deploy NPS assets was made at approximately 1515 hours and within 3 hours, the NPS program's TARU was on site in New York City. One of the NPS program's 12-hour Push Packages was deployed by ground and reached the New York City vicinity within 7 hours. Requested supplies and materials from VMI were deployed by air and by ground and arrived within 12 hours. The NPS program was also able to procure additional items not found on the formulary, such as N-95 air filtration masks, through established purchasing mechanisms with the Department of Veterans Affairs National Acquisition Center.

The NPS program also responded to the anthrax attacks that occurred along the east coast of the United States in October 2001. The first deployment of assets was released to Florida on October 7, 2001 from VMI, and arrived within 8 hours. Over the following 6 week period, more than 143 deployments were made to transport antimicrobials, response teams, supplies, and laboratory specimens. The NPS program response involved nine states and Washington, DC. All NPS program asset deliveries were drawn from VMI and did not require the deployment of a 12-hour Push Package. VMI assets were utilized because the specific threat agent was known. More than 3.75 million tablets of antimicrobial agents were supplied for post-exposure prophylaxis of affected postal workers and employees of contaminated buildings. The NPS program TARU advisors were deployed to six states to provide assistance.

NPS program's response in the Pacific Islands

In the event of a major natural disaster involving the Pacific Islands, assistance and aid would most likely come from multiple government and non-government agencies. Non-government agencies that could respond with assistance include among others the Red Cross and World Health Organization. Additional sources of aid may be offered or sought from countries such as Japan, Australia, New Zealand, and the United States.

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The following Pacific Islands are within the scope of the NPS responsibilities: American Samoa, Commonwealth Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau. Although the Pacific Islands may be involved in a biological or chemical agent event, it is much more likely that a mass casualty situation would be the result of a natural disaster. It is important to emphasize that the mission of the NPS program is geared to respond to a mass casualty situation as the result of a biological or chemical agent or mass

Table 2. Pacific Island population data

Country	Estimated mid year population 2000	Land area km²	Population density People/km²
Guam	148,200	541	274
Federated States of Micronesia	118,100	701	168
Northern Mariana Islands	76,700	471	163
America Samoa	64,100	200	321
Marshall Islands	51,800	181	286
Republic of Palau	19,100	488	39

'Demographic Population Programme, Secretariat of the Pacific Community, BD D5, 98848 Noumea Cedex, New-Caldonia, www.spc.org.nc/demog/pop

trauma event. The driving force behind the NPS formulary is directed at responding to threats from biological or chemical agents, or radiological release. Although supplies and materials within the formulary may also be used in response to a major natural or technological disaster, the NPS formulary was not specifically designed to respond to such events. The medical formulary and supplies are heavily weighted in antimicrobials and associated supplies. As a result, the use of NPS program assets in a natural disaster will need to be reviewed carefully to determine whether the formulary and supplies meet the needs of the community.

To be able to respond within a 12 hours to the US territories such as those in the Pacific Islands, a 12-hour Push Package has been placed within the state of Hawaii. This Push Package will enable for the NPS program to respond quickly to Pacific Islands, and in certain instances, the west coast of the continental United States.

Disaster response in the Pacific Islands may pose some unique challenges. These challenges include but are not limited to, wide geographical distribution of the population, limited communication capabilities, and limited baseline medical resources. In some areas, populations may be scattered throughout multiple outer islands. In many instances, these outer islands are isolated in terms of access by air or water and communication. Recent surveys for disaster preparedness conducted by CDC for the Pacific Emergency Health Initiative indicate that medical resources for daily medical care are in some instances very limited and would be rapidly be depleted in a multi-casualty event. Furthermore, re-supply of medical resources under normal circumstances can take days to weeks.[4]

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In many instances, the standard 12-hour Push Package would be too large a response based on population size for certain nations within the Pacific Islands. (See Table 2) As a result, the NPS program has been working with various government organizations to develop a smaller and more usable version of the 12-hour Push Package. Although smaller in size, this Push Package would contain all the components of a standard Push Package. It will also have other characteristics of a standard Push Package including rapid air deployability, ground capability, and cold chain management for vaccines and temperature controlled items. This scaled-down version of a standard Push Package would be located west of Hawaii and would allow for response to those specific islands listed in Table 2 within 12 hours. VMI assets would be available to those islands within 36-48 hours from approved deployment.

There are several logistical considerations and challenges to moving NPS assets into the Pacific region. Airport runways may be too short to accommodate large wide-body aircraft. Navigation or electronic landing systems that allow aircraft to land in zero-visibility weather may not be available at all airports. The NPS program recognized in planning for a response to the Pacific Islands that smaller airstrips would often be utilized. The smaller Push Package tailored to the Pacific Islands was specifically designed to fit on one small-body aircraft such as a 727 or smaller. These types of aircraft are able to land on the smaller airport runways this specially tailored Push Package could also be moved by ship no smaller than a 60ft cargo carrying vessel. The smaller Push Package would not require off-loading equipment such as a "K-Loader" which may be very limited in this region. Ideal storage facilities to receive, store, and

distribute the NPS assets may be limited and may not allow for redundancy of facilities. Transportation issues to consider include the use of pickup trucks or larger vehicles when available to move assets. Use of alternative modes of transportation (such as boats or helicopters) should be anticipated since some communities are served by roads that are susceptible to storm surges or floods.

Dispensing and treatment centers could include the national hospitals and the preexisting system of public health clinics. The availability of physicians, pharmacists, and other medical personnel might limit the number of dispensing sites that can be opened. Alternatively, volunteers could be organized to assist the health community in case of a disaster.

The NPS program will continue to work closely with representatives from the Pacific Islands to enhance and prepare their communities to receive, distribute, and dispense NPS assets. NPS program is aware of the unique challenges that communities in the Pacific Islands face. The mission of the NPS program will be accomplished such that it will also address the Pacific Islanders' needs

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involving biological or chemical terrorism or a mass casualty situation. State and local responders under appropriate circumstances can utilize the NPS to increase their response capabilities and to more rapidly respond to the consequences of terrorism. Through training and education, the NPS will work with state and local officials to prepare their communities to efficiently and effectively receive, secure, and distribute NPS assets. As the threats to our communities change, the NPS program will continually assess and evaluate the program's formulary to respond to the changing needs.

References

1. U.S. Department of Health and Human Services. *Operating Plan for Anti-Bioterrorism Initiative*, Washington, D.C., 1999.
2. Federal Emergency Management Agency. *Federal Emergency Response Plan*, Washington, D.C., 1999.
3. Rotz LD, Khan AS, Lillibridge SR, et al. Public health assessment of potential biological terrorism agents. *Emerg Infect Dis* 2002;8(2):225-229.
4. Kaima, Rhyne C. The Pacific emergency health initiative: a pilot study of emergency preparedness in Oceania. *Australian Journal of Emergency Medicine* 2001(13):157-164.

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Conclusi

The NPS p to improve

A fellow's not down till he lies
In the dust and refuses to rise

Edgar Guest in the poem 'Defeat'