



U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response

FY 2013 BUDGET YEAR IN REVIEW

An overview of ASPR's
budget and accomplishments

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ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE



U.S. Department of Health and Human Services
The Office of the Assistant Secretary for Preparedness and Response (ASPR)

Fiscal Year 2013 Budget Year in Review

A disaster or other public health emergency can happen at any time with little or no warning. Every disaster holds the potential to impact health. As Hurricane Sandy demonstrated, emergencies can overwhelm the resources of a state or community, even those that are seemingly well-prepared to respond to and recover from disasters. That is why the mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) is so important.

ASPR works to protect people's health when disaster strikes by building strong, healthy communities that are able to withstand adversity and become resilient. ASPR brings together the worlds of policy, science, and emergency management. We drive national and global policy on health preparedness and ensure that evidence-based practice is the foundation of our strategies. We work with industry to ensure that the nation has the vaccines, drugs, and medical supplies it will need during a public health emergency. When states ask for assistance during and after a disaster, we are ready with a federal health response tailored to meet their needs.

During 2013, ASPR demonstrated bold and effective leadership in public health emergency pre-

paredness, response, and recovery. ASPR collaborated with local, state, and federal partners around the country to respond to and recover from natural disasters and other public health emergencies. ASPR was integral to the development and approval of ground-breaking medical treatments. ASPR worked within HHS and with private industry to test and stockpile vaccines against a new influenza strain that emerged in China. Furthermore, ASPR accepted new responsibilities for policy development and leadership on national and global health security. ASPR carried out its mission while improving the efficiency and quality of our work and the management and development of our workforce.

“Community and state preparedness is essential to the health security of all Americans. Events in the last few years have demonstrated how critical it is for health systems across the country to be ready and able to respond quickly and effectively.”

Nicole Lurie, MD, MSPH
Assistant Secretary for
Preparedness and Response

HELPING COMMUNITIES RESPOND TO AND RECOVER FROM HURRICANE SANDY

Less than one month into fiscal year (FY) 2013, the East Coast of the United States was blasted by Hurricane Sandy. This deadly, destructive, and costly hurricane devastated the Northeast, including New York City and the New Jersey coast. Families, neighborhoods, businesses, public services, emergency responders, hospitals, and other health care providers were tested by the hurricane. Even today, the recovery continues.

ASPR's Office of Emergency Management (OEM) coordinated a comprehensive response to Hurricane Sandy that included health and medical support from nearly 2,300 National Disaster Medical Service (NDMS) personnel, more than 450 Public Health Service Officers, and 50 other HHS employees. In the face of power outages and historic flooding, local health care systems in New York and New Jersey worked to meet a surge in demand for health care. More than two dozen teams of doctors, nurses, paramedics, veterinarians, and support staff assisted them. Teams deployed in advance of the hurricane and were providing medical care within just a few hours of the hurricane's landfall.



DMAT Responders help with Hurricane Sandy Response to augment staff at facilities to help patients get the care they need.

OEM/NDMS provided emergency medical care in temporary facilities set up next to hospital emergency departments and in fields near closed or overwhelmed hospitals. They also supported door-to-door checks on vulnerable people and facilitated access to critical prescriptions so that homebound residents did not have a significant interruption in their regular regimen of medications. ASPR also made the Emergency Pharmaceutical Assistance Program available to help thousands of residents without any form of insurance to replace medicines and limited durable medical equipment that had been lost or damaged in the storm.

ASPR/OEM's Division of Recovery coordinates health and social services recovery planning and operations, before and after incidents, within HHS and across the federal government. During 2013, ASPR supported recovery field operations in Louisiana following Hurricane Isaac and in New Jersey and New York following Hurricane Sandy. After Hurricane Isaac, ASPR's recovery staff provided intermittent onsite support in Baton Rouge. They worked with primary and supporting agencies and organizations and with federal, state, tribal, and local partners to conduct joint assessments of disaster-related recovery needs and priorities, develop a recovery support strategy, and coordinate federal health and social services recovery efforts. In response to Hurricane Sandy, ASPR deployed recovery coordinators to New Jersey and New York soon after the hurricane's landfall. They remained onsite for five months working with regional, state, and local partners.

Research is an important part of response and recovery, too. In 2013, ASPR's Office of Policy and Planning awarded \$5 million in grants to nine or-

ganizations to inform long-term recovery decisions in communities affected by Hurricane Sandy. The grantees are exploring factors that help these and other communities build resilience into their recovery. The organizations are conducting a broad range of health care related recovery research. This research includes identifying community and individual-level resilience factors and determining how to foster resilience for affected individuals. Key populations being studied include at-risk populations such as older people, or those who may become at-risk, such as people living in high rises. Some other researchers are assessing health care system response and recovery issues, and developing models to predict the post-disaster functioning of New York City communities.

The grants require researchers to share their findings with each other and the impacted communities. In 2014, ASPR is convening researchers, receiving interim findings from these grantees, and awarding additional grants. These investments will help not only the people and communities harmed by Hurricane Sandy but also future disaster responders and survivors.

DEVELOPING INNOVATIVE COUNTERMEASURES AGAINST INFLUENZA AND OTHER THREATS

Our nation continues to face potential health threats from things such as pandemic influenza, emerging infectious diseases, and man-made threats from chemical, biological, radiological, and nuclear (CBRN) agents. ASPR's Biomedical Advanced Research and Development Authority (BARDA) contracts with pharmaceutical and biotechnology companies to develop, manufacture, and procure tools known as "medical countermeasures" (MCMs) against natural and man-made threats.

BARDA works within HHS and across the federal government with other agencies that are involved in researching and developing candidates for MCMs. ASPR's HHS partners include the National Institutes of Health (NIH)—which funds basic research—the Centers for Disease Control and Prevention (CDC)—which manages the Strategic National Stockpile of MCMs—and the Food and Drug Administration (FDA), which helps ensure that products are safe and effective and that MCMs are available for emergency use in certain cases before they are licensed. HHS' coordinated and strategic approach to developing new countermeasures—called the "Public Health Emergency Medical Countermeasures Enterprise,"—creates a pipeline of MCMs to support U.S. health security.



Next-Generation Portable Ventilator developed through BARDA partnership with private sector

From 2004-2013, ASPR/BARDA procured 12 new CBRN MCMs leveraging the authority granted during the *Project BioShield Act of 2004* and the Special Reserve Fund. ASPR/BARDA is committed to acquiring another 12 CBRN MCMs by the end of 2018.

During FY 2013, ASPR/BARDA invested more than \$1.3 billion in MCMs. BARDA's start-up and initial investments in MCMs culminated in achieving sev-

eral major milestones in 2013. Five first-in-class MCMs received FDA approval during FY 2013, and a sixth was approved a month after the close of the fiscal year. These MCMs are:

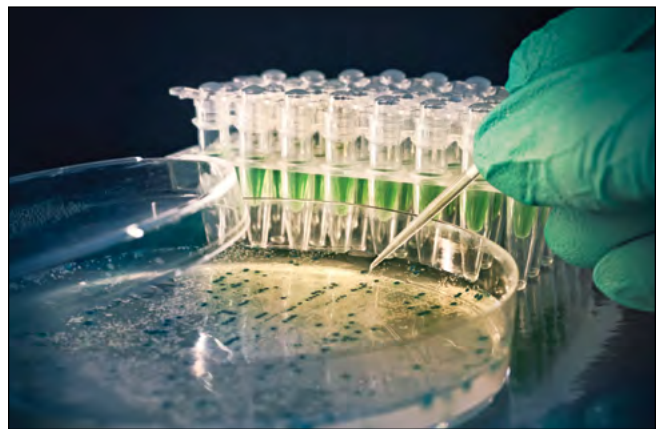
- Flucelvax—the first cell-based influenza vaccine in the United States, which is manufactured by Novartis in a state-of-the-art manufacturing facility that won the International Society for Pharmaceutical Engineering 2013 Overall Award and Best-in-Class Award for Process Innovation;
- FluBløk—the first U.S. recombinant-based influenza vaccine, which results from recombining genetic material and is manufactured by Protein Sciences Corporation;
- Aura—a next generation portable ventilator manufactured by Covidien that FDA approved an all-hazard MCM;
- Raxibacumab—a new FDA-approved antibody drug to treat anthrax in adults that is manufactured by Human Genome Sciences and Glaxo-SmithKline (GSK), which is the first product approved under the FDA Animal Efficacy Rule;
- HBAT—an antitoxin for botulism that is produced by Cangene; and
- QPAN—a new vaccine, with adjuvant, for H5N1 influenza, which is manufactured by GSK.

While reaching these important milestones, BARDA also increased the number of MCMs in the nation's development pipeline from 130 to 155. The MCMs in advanced stages of development include new products to treat thermal burns, antibiotics, chemical antidotes, and antiviral drugs for other health threats. Under Project BioShield, BARDA

also added to the Strategic National Stockpile three new MCMs for Acute Radiation Syndrome and chemical attacks, thereby enhancing national preparedness.

PREPARING FOR H7N9: A POTENTIAL PANDEMIC INFLUENZA

Another particularly important event last year was the rise of a new strain of avian influenza in Asia. The flu strain, identified as H7N9, emerged in China and has killed more than 100 people. Although H7N9 has not reached the United States, HHS determined that this strain poses a significant threat of a potential flu pandemic. Using a standard process whenever a novel strain of influenza emerges, ASPR/BARDA, NIH, and CDC moved ahead promptly and methodically to develop, manufacture, test in human clinical studies, and stockpile a vaccine to protect public health should the virus emerge in the United States or become a pandemic.



Identifying and incubating promising research or discoveries to better fuel the medical countermeasure pipeline.

In preparation for responding to pandemic diseases, BARDA established a fill-and-finish manufacturing network in 2013. This network—which covers the final steps in manufacturing a vaccine—boosts U.S. domestic capacity to quickly manufacture an influenza vaccine and make it available to

the public. The network has increased our nation's capacity to produce a vaccine domestically by an estimated 20 percent.

IMPROVING COMMUNITIES' HEALTH CARE PREPAREDNESS FOR DISASTERS

Building a strong network of health care partners is critical to emergency response and national health security. Community health care systems that work efficiently and effectively on a daily basis are better prepared to respond to a disaster or mass casualty incident. Hospitals are a critical component in a community's response and recovery from emergencies, but they cannot respond to a large-scale emergency independent of their local partners.



Emergency responders train on handling a mass casualty event.

ASPR's Hospital Preparedness Program (HPP) is a critical component of community resilience and public health. In 2013, HPP distributed more than \$330 million in grants to better prepare states and local communities for emergencies. Using HPP funding, communities are building health care coalitions that coordinate how their health care systems prepare and respond to disasters. Com-

munity health care coalitions leverage all of the health care assets in the community to better respond to a community's unique health care needs. States and local communities use HPP resources and guidance to plan for coalition-wide responses, to train staff for large-scale events, and to conduct coalition-wide emergency drills so the entire health care system is ready to respond and can recover more quickly when faced with a disaster. In many cases, because of these investments and planning, states and local communities are able to respond without needing to request federal support at the time of the disaster.

One of the most notable examples of these preparations was showcased in April 2013 during the Boston Marathon. The Boston Healthcare Preparedness Coalition, which receives HPP funding, meets bi-monthly to review upcoming events, discuss potential hazards, and fine-tune response protocols. When two bombs exploded during the 2013 Boston Marathon, killing three and injuring more than 250 people, hospitals in the area had just a few minutes to activate command centers and assemble trauma teams. The planning funded and supported by ASPR's HPP meant that the hospitals and other coalition partners were ready and able to act quickly to save lives and mitigate injuries.

Just days later, an ammonium nitrate explosion occurred at a fertilizer facility in West, Texas. Fifteen people died, and more than 160 others were injured. Throughout the night of the explosion and for several days later, the Texas Department of State Health Services remained in constant contact with ASPR Regional Emergency Coordinators and HPP Field Project Officers. The state deployed

response assets and acted based on training funded and supported by OEM/HPP.

With this HPP-sponsored preparation, Texas emergency managers found that:

- They could communicate better with one another than in previous emergencies.
- Local hospitals and health departments effectively coordinated their response with the regional and state medical operations centers.
- Medical surge—the ability to provide adequate medical evaluation and care during events that exceed the normal limits of the infrastructure—was coordinated and synchronized to meet the increasing need for medical and hospital care as a result of the explosion.
- Responder safety and health was coordinated successfully, so that responders were protected from the physical and chemical hazards at the explosion site.

SUSTAINING FEDERAL MEDICAL READINESS AND DISASTER RESPONSE

As described above with respect to Hurricane Sandy, ASPR/OEM provides states and communities health and medical support during public health emergencies. Sometimes, communities and states are able to respond without needing federal assets. At other times, they may request federal assistance. When called upon, OEM and NDMS provide assistance.

Several thousand intermittent federal employees from across the United States are part of NDMS. They form more than 90 medical, veterinary, and mortuary support teams. NDMS deploys teams with its own medical supplies to provide patient

care quickly. NDMS maintains more than 300 caches of communications, medical, veterinary, and pharmacy equipment and supplies that are prepositioned nationwide. In FY 2013, funding for preparedness and emergency operations was \$28 million, and funding for NDMS-related activities was \$50 million.

In addition to disaster response around the nation, ASPR's NDMS teams provide medical support for events called "National Special Security Events." In FY 2013, these events included the Presidential Inauguration, the State of the Union address, and Independence Day festivities on the National Mall in Washington, D.C. This support also extends to irregular events like state funerals. For these events, OEM/NDMS teams provide medical care and are on standby for disaster medical care as part of the overall contingency planning.

During FY 2013, OEM/NDMS achieved several improvements. They reduced response times from 2-3 days after previous disasters to being deployed before landfall of Hurricane Sandy and responding within a few hours. In addition, OEM reconfigured existing equipment and supply caches to develop a new Mobile Lifesaving Kit. This new kit allows responders to be fully capable of stabilizing pediatric and adult patients while deploying more rapidly than with larger kits.

ADVANCING HEALTH RESILIENCE THROUGH RESEARCH, STRATEGY AND COLLABORATION

From each disaster response and recovery, emergency health planners learn more about what worked well and what requires improvement. They also are able to examine how different groups of people, including those deemed most at-risk, are

affected by a disaster. During FY 2013, ASPR's Office of Policy and Planning (OPP) continued to lead ASPR's coordination of policy and planning for public health emergencies within HHS and the federal government and with states, communities, tribes, and territories. In addition, ASPR's OPP leads important collaboration with other countries on pandemic influenza and emerging infectious diseases. OPP's FY 2013 funding was about \$16 million.

ASPR continually seeks improvements and innovation in response and recovery to protect health and increase resilience. For example, during and after Hurricane Sandy, OPP collaborated with the Centers for Medicare and Medicaid Services (CMS) to assess disaster-induced health care system stress and monitor the impact on people who are dialysis-dependent. During disasters, loss of power and health facility closures can lead to problems for communities and people with special health needs like dialysis. The information from these studies is helping us to better understand how to plan for and mitigate potential health problems for these patients in future disasters. Building on the success of these studies, OPP then partnered with CMS and the City of New Orleans to conduct a successful first-in-the-nation emergency preparedness pilot exercise. This exercise assessed how federal health data could assist a local health department in developing actionable information to identify and conduct outreach to medically-vulnerable individuals who rely on electricity-dependent medical devices and may need life-saving assistance in an emergency.

ASPR/OPP also continued its focus on the behavioral health impacts of disasters. For every emergency event, OPP and its partners made resources

available to communities to address the behavioral health effects on civilians and responders, and to help ensure that guidance and information are shared among all stakeholders. OPP revised the HHS framework for addressing behavioral health during disasters, collaborated with other HHS agencies to draft the Department's first human services concept of operations, partnered with the National Institute of Mental Health on a new grants program in this area, and hosted an inter-agency meeting on assisting survivors following emergencies.



Providing disaster behavioral health of mental health, substance abuse, and stress management services to disaster survivors and responders.

During 2013, ASPR also partnered with CDC to outline a strategy for ensuring that our country stockpiles necessary MCMs and continues to modernize its biosurveillance capabilities. ASPR and CDC identified Strategic National Stockpile requirements through 2020 and recommended approaches to meet those requirements.

When people can use knowledge, products, or technologies resulting from certain research not only to protect public health but also to harm it,

that research is called dual-use research of concern. During 2013, ASPR's OPP led an HHS review committee on dual-use research of concern to ensure that U.S. funds are used only for research that protects health. OPP also collaborated with our partners in North America and around the world to build global preparedness for pandemic influenza, emerging infectious diseases, and CBRN threats to human health. The U.S. government also used a policy framework developed by ASPR/OPP after the H1N1 pandemic to respond to a request from the World Health Organization to assist other countries with H7N9 in Asia and a novel coronavirus in the Middle East.

IMPROVING EFFICIENCY AND MANAGEMENT TO SUPPORT ASPR'S MISSION

ASPR could not achieve its mission without an extraordinary, committed workforce. In addition to scientists, emergency management planners and responders, and policymakers, ASPR's staff includes dedicated people who work on operations, information technology, communications, legislation, contracts, grants, human resources, budgeting, and finance.

During 2013, ASPR made significant improvements in how it conducts business and manages resources. For example, ASPR exceeded its goal for awarding contracts to small businesses. ASPR also substantially increased its public outreach—particularly through social media like Twitter. ASPR was timely and thorough in using funding made available to it for FY 2013 and collecting reimbursements from other agencies. Further, ASPR continued productive work on updating its strategic plan to continue making lasting transformation in public health emergency management.

These accomplishments are only part of the story. To learn more about ASPR's work to protect our nation's health security, how to prepare for disasters, and how to build resilient communities:

- Visit our website at www.phe.gov;
- Find us on Facebook under <https://www.facebook.com/phegov>; or
- Follow us on <https://twitter.com/PHEgov>.



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