
**Meeting of the States Parties to the Convention
on the Prohibition of the Development,
Production and Stockpiling of Bacteriological
(Biological) and Toxin Weapons and on Their
Destruction**

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Item 5 of the provisional agenda

**Standing agenda item: cooperation
and assistance, with a particular focus
on strengthening cooperation and
assistance under Article X**

**Identifying and addressing barriers to the emergency sharing
of international public health and medical assistance**

Submitted by the United States of America

I. Introduction

1. The timely provision and acceptance of emergency international public health and medical assistance is critical to both the security and health of communities. Article VII of the Biological and Toxin Weapons Convention (BWC) requires States Parties to assist any Party that has been exposed to danger as a result of a violation of the Convention. In addition, all 170 States Parties to the BWC are also States Parties to the World Health Organization's (WHO) International Health Regulations (IHR) (2005), which obligates States Parties to collaborate during the response to potential public health emergencies of international concern. Because an attack with biological weapons may not immediately be recognized as a deliberate act, the synergy between these undertakings is particularly important.
2. The 2012 Meeting of States Parties noted the value of identifying and addressing specific impediments to the provision or receipt of international assistance in response to an attack or unusual disease outbreak. Identifying impediments and means of overcoming them is essential to achieving the goal established by the 2011 BWC Review Conference of finding ways to strengthen implementation of Article VII, and, as many of these impediments are also applicable to natural outbreaks or other health-related emergencies requiring international response, it is also important from both public health and humanitarian perspectives.
3. Over the past decade, the United States of America has gained valuable experience in both providing and receiving international public health and medical assistance through

real-world events such as Hurricane Katrina, the Deepwater Horizon oil spill, the 2009 H1N1 influenza pandemic, and the 2010 earthquake in Haiti, as well as simulations and exercises – notably the USA National Level Exercise 2011. While the provision of assistance in several of these cases was not directly related to a disease outbreak, the response to these events nevertheless helped to identify important issues that would also affect response to a major biological incident. The USA Government, particularly the USA Department of Health and Human Services (HHS), has received an increasing number of requests from international partners for medical countermeasures and public health personnel to help respond to disease outbreaks and catastrophic emergencies abroad. This is a trend that is likely to continue into the future.

4. This paper describes USA experiences and related efforts to identify and overcome the legal, regulatory, and logistical challenges impeding the ability of governments to both provide and receive international assistance during public health emergencies. While the categories of challenges faced in providing and receiving assistance are similar, the specific laws and processes needed to facilitate each are distinct. Moreover, the policy and political considerations for countries receiving assistance are likely to be very different from those of providing countries. Therefore, this paper examines the issues separately, first dealing with those relevant to providing assistance, followed by those relevant to receiving assistance.

II. Providing international assistance

1. Providing international public health and medical assistance: USA examples

5. Over the past five years, the United States of America has responded to and provided international public health and medical assistance related to several major international public health emergencies. During the 2009 H1N1 influenza pandemic, the USA received international requests for vaccines, antiviral drugs, diagnostic test kits, and other public health and medical assets. By the end of 2010, the USA had provided diagnostic test kits to 147 countries, deployed 820,000 antiviral drug treatment courses to countries throughout Latin America and the Caribbean, and donated nearly 17 million doses of 2009 H1N1 influenza vaccine to the World Health Organization.¹ After the devastating January 2010 earthquake in Haiti, the USA deployed personnel from multiple departments and agencies to help respond to the disaster. HHS alone deployed over 1,100 medical personnel, who treated 31,300 patients and performed 167 surgeries in the month following the earthquake.² A little more than a year later, HHS deployed subject matter experts to the USA Embassy in Japan following the tsunami and Fukushima nuclear disasters. USA experts provided radiological technical expertise and assisted with public messaging and risk communications in support of the Government of Japan and American citizens living in Japan.

¹ “An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness,” accessed online at: <http://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

² Statement from the USA Department of Health and Human Services, accessed online at: http://www.hhs.gov/haiti/20100301haiti_statement.html

2. Providing international public health and medical assistance: identified challenges and policy responses

A. Receiving and adjudicating requests for assistance

6. From the above experiences, the United States of America has identified a number of critical challenges, including the need to develop and implement a process to receive and adjudicate foreign requests for assistance. The USA experience during the 2009 H1N1 influenza pandemic demonstrated that a potential or actual pandemic or other international disease outbreak may be accompanied by multiple requests from international partners for public health and medical assistance, ranging from medical countermeasures and personnel to funding, information sharing and technical assistance. Responding to these types of requests requires navigating multiple obligations set forth in bilateral and multilateral agreements and partnerships. Furthermore, requests may be received by one or more USA departments and agencies, providing a challenge for ensuring a centralized, coordinated process to respond. As a result, the United States of America has considered how decision-makers and technical experts might evaluate and coordinate responses to requests from international partners for certain assets (for example, medical countermeasures and public health and medical personnel), and during certain events, such as an influenza pandemic.

B. Policy preparedness: legal, regulatory and logistical obstacles

7. In order to conduct international assistance missions, countries must overcome a host of legal, regulatory and logistical challenges. While these issues will be specific to the legal systems of both the providing and receiving countries and must therefore be evaluated on a case-by-case basis, the United States of America has identified the following general considerations for the international deployment of medical countermeasures or public health and medical personnel: (a) recognition or waiver of medical credentials, licenses, and professional certifications of personnel by the recipient country; (b) liability protections for medical providers or those who manufacture, donate/distribute or administer medical countermeasures; (c) regulatory clearance to import and/or use medical products in a host country; and (d) mission funding.

8. Although the unique nature of each response makes it difficult to develop solutions for each of these areas in advance, the USA has taken steps to identify issues, analyze relevant domestic laws that aid or constrain a response, and provide a menu of potential tools to overcome the challenges. In addition, the USA is working with international partners through bilateral and multilateral fora to identify and address these legal, regulatory and logistical challenges and develop joint solutions to the international provision of public health and medical assistance. These fora include the USA-Canada Beyond the Border (BTB) Initiative, the trilateral North American Plan for Animal and Pandemic Influenza (NAPAPI) and the multilateral Global Health Security Initiative (GHSI). In addition, the USA is working with the WHO to address specific challenges encountered during the 2009 H1N1 influenza vaccine deployment such as donor liability issues, regulatory requirements and funding for transportation. In addition, the United States of America seeks to use BWC meetings as a forum to promote coordination and cooperation on international public health and medical assistance.

C. Response operation

9. Successful execution of international assistance missions requires that international operational plans and deployment mechanisms be created and exercised in advance of emergency situations. International deployments of both medical countermeasures and personnel present certain unique operational considerations, including (a) selecting personnel with appropriate skill sets for international deployment, including language

skills, health and fitness considerations, etc.; (b) customs and border issues, including having passports/visas and the ability of personnel or goods to lawfully enter the host country; and (c) transport and/or logistical support for deployments of greater distance and complexity.

III. Receiving international assistance

1. Receiving international public health and medical assistance: USA examples

10. In August 2005, the USA States bordering the Gulf of Mexico were devastated by Hurricane Katrina. Nearly 80 percent of the city of New Orleans was flooded after levees failed. In the wake of the storm, the international community rushed to provide aid to the United States; 151 countries, political entities, and organizations offered \$854 million in monetary aid, in addition to offers of personnel, medical supplies, and forensic teams.³ The United States of America did not have a mechanism in place to receive the generous aid being offered. However, in subsequent years, we worked to develop plans and methods that enable receipt of international assistance. When the Deepwater Horizon oil rig exploded in April 2010, spilling nearly five million barrels of crude oil into the Gulf of Mexico, receiving foreign assistance still provided challenges for the USA Government, particularly related to logistics, USA regulations, and reimbursement.

11. In 2011, the USA held a National Level Exercise (NLE 11), designed to simulate a catastrophic earthquake in the New Madrid Seismic Zone, affecting seven USA States. Federal, State, local, international, nongovernmental, and private sector partners participated to identify strengths and weaknesses of existing USA preparedness plans for communications, emergency operations center management, citizen evacuation, mass care, critical resources logistics, medical surge and recovery. The exercise included 81 hypothetical offers of assistance, of which 29 were accepted by the end of the simulation. As with real-world examples, key resources often had to be declined due to legal, logistical, and regulatory constraints.⁴ In one hypothetical case, for example, a Canadian medical team was unable to deploy into the United States of America, in part because of difficulties related to the import of that team's medical caches, which included large numbers of medical supplies that were not approved for use in the United States of America.

2. B. Receiving international public health and medical assistance: identified challenges and policy responses

A. Receiving and adjudicating offers of assistance

12. Similar to the challenges described above for receiving and adjudicating requests for assistance, the USA Government has also found it necessary to create a system to cope with offers of assistance during domestic catastrophes. Following Hurricane Katrina, the International Assistance System (IAS) was created among USA Government agencies responsible for domestic response, foreign affairs, and foreign aid. The IAS "Concept of Operations" describes the policy and processes for: (a) deciding whether to accept or

³ The Federal Response to Katrina: Lessons Learned. Accessed at: <http://library.stmarytx.edu/acadlib/edocs/katrinawh.pdf>

⁴ National Level Exercise 2011 (NLE 11) Functional Exercise Final After Action Report (AAR). Accessed online at: http://asdwasecurity.files.wordpress.com/2012/04/nle-11-aar-final_v022812.pdf

decline formal offers of assistance to the Federal government, (b) procuring resources not available in the United States, and 3) receiving and distributing assistance once provided.

13. At the onset of a large-scale disaster, before the IAS is activated, the default USA policy is to request that all nations that wish to assist should provide funding to appropriate NGOs working in the affected area. For assistance that does come to the Federal government, the IAS distinguishes between two flows of assistance: “push” and “pull.” “Push” assistance includes all unsolicited offers of assistance, while “pull” requests are those for which the USA has identified and requested additional resources or assets needed to respond to the disaster. The IAS also provides for consideration of the degree of oversight or inspection the proposed assistance would require and whether it can be readily used by those involved in the disaster response. For example, products like blankets and tarps have few regulatory restrictions but may not be needed (or “pulled”) by the IAS due to the nature of the emergency or already available resources. On the other hand, more complex forms of assistance, such as pharmaceuticals or personnel, may encounter legal and regulatory barriers that delay their entry or simply make them impossible to use under the particular circumstances. The IAS incorporates input from throughout the USG in both making these determinations and, if assistance is accepted, reviewing the assets and providing regulatory approvals, and expediting customs clearance and technical expertise if necessary.

B. Legal, regulatory and logistical obstacles

14. Countries must also be prepared in order to rapidly accept and distribute international assistance. While the categories of challenges may be similar to those described above for providing assistance, receiving assistance requires unique legal, regulatory and logistical solutions. Such challenges may include: (a) ensuring the recognition of or waiving medical credentials, licenses, and professional certifications of incoming personnel, (b) assuming liability or providing liability protections for medical providers or those who manufacture, distribute or administer medical countermeasures, (c) providing emergency regulatory approval, or waivers to approval, for the import and use of medical products, and (d) plans to distribute or incorporate assistance once received.

15. For example, while countries providing assistance will seek legal protections for incoming goods and personnel, recipient countries must not only weigh these demands but must also have the legal means of providing such protection if a decision is reached to provide them. In the USA, certain types of protections, like indemnification, can only be provided by Congress. Moreover, in federalist systems like the USA, it may be necessary to provide assistance directly to a State or provincial authorities, which may not be capable of assuming significant liability. As a further example, while providers must overcome barriers to transporting countermeasures to recipients, it may be the recipient’s responsibility to plan and fund the distribution once the asset is received. Past responses have been delayed by provider’s requirements that recipients have adequate distribution plans.

I. Recommendations and conclusions

16. States Parties will undoubtedly continue to experience catastrophic public health disasters with both national and international health and security implications, and will likely continue to reach out to the international community for public health and medical assistance. All States Parties providing or receiving international assistance, such as medical countermeasures and medical and public health personnel, will need to work across sectors within their governments to identify and address logistical, legal, and regulatory barriers to the sharing of international assistance.

17. Well in advance of a possible receipt of a requests for international assistance related to a biological attack or unusual disease outbreak, States Parties should explore the development of centralized, coordinated processes for assessing requests for assistance in the context of their unique statutes governing the asset(s) in question as well as their bilateral and multilateral agreements and partnerships. Furthermore, States Parties should identify mechanisms for funding the procurement and transport of assets and examine potential liability arrangements for the provision of assistance. States Parties may also identify export/regulatory requirements that may impact potential deployment.

18. States Parties receiving assistance should explore processes and procedures for deciding whether to accept or decline offers of assistance to their national government and/or when to request assistance to supplement their own domestic response efforts. In addition, States Parties should examine their capacities for receiving and distributing assistance once provided, for example, considering whether regulatory mechanisms are available which allow for the use of potentially unlicensed products or whether liability provisions under domestic law will adversely affect access to countermeasures.

19. States Parties should consider working across sectors and leveraging existing bilateral and multilateral partnerships, and creating new ones, to better coordinate plans and develop joint solutions to the exchange of assistance during public health and medical emergencies. The BWC provides a forum for discussion of such coordination and the sharing of experiences in this critical area.
