

# Rx Response After Action Review:

## 2009 H1N1 Outbreak

### Overview

The 2009 H1N1 influenza outbreak provided the first opportunity to test Rx Response's overall ability to respond to an event of this type (prior activations occurred in response to natural disasters). This document seeks to capture lessons learned and identify new opportunities to improve the Rx Response program's overall level of pandemic preparedness specifically and make recommendations for improving public health's response mechanisms generally.

- In preparing this review, the Rx Response Support Team made an effort to acknowledge both areas of strength and as well as those in need of further attention. Our view is that, overall, Rx Response was successful in its response to the 2009 influenza pandemic outbreak.
- The outbreak arose in a manner significantly different from that anticipated (based on avian flu assumptions). To ensure the program benefits fully from the team's experience during the recent crisis we have sought to fully capture the critical lessons learned.

This document examines three areas:

- I. Successful aspects of Rx Response and public health pandemic response effort;
- II. Challenges in the response effort; and
- III. Opportunities for improving overall readiness for any future pandemic or other long-term public health threats.

The body of this report captures the most pertinent, high-level observations that Rx Response believes would be of interest to the Coordinating Body. Please see the appendices for more granular and / or administrative observations.

### Presentation of this Report

This report is presented to the Coordinating Body as part of Rx Response's pandemic after-action review.

- In the event the Coordinating Body wishes to proceed with additional documentation on after-action findings for future provision to external stakeholders (e.g. government partners, etc), we will be pleased to prepare additional documentation.
- Finally, it is important to note that the 2009 A H1N1 novel influenza strain remains a threat to the US, particularly given the potential for a "3<sup>rd</sup> wave" over the next few months. In light of the ongoing threat posed by this virus, we recognize the need to expedite preparations and strengthen resilience wherever possible.

## Pandemic Response Successes

### **1. Government transparency and inter-agency coordination and communication increased public confidence and allowed more efficient response.**

1. Policymakers in the public health and security communities have collaborated closely and coordinated efforts and have been overall forthright in communications to the public. While the US government has recently been criticized in the public media with respect to shortfalls in vaccine production vis-à-vis the stated / predicted amounts, the government's overall approach has helped lessen concerns as well as the psychological impact of a fearful public by managing expectations of both the general public and the private sector.
2. Jeffrey Levi, PhD, executive director of Trust for America's Health, a non-profit health advocacy group in Washington DC, said that although there were some difficulties with the vaccine production expectations, the government was transparent throughout the process and that they adjusted their message to the public when shortcomings were discovered. He noted that the constant dialogue between the federal government and the American public "has reflected an honest attempt to reflect the current state of knowledge."<sup>1</sup> Walter R. Dowdle, MD, former Deputy Director of the CDC, seconded the notion that the US government took appropriate actions to remain transparent throughout the decision-making process to protect public health. In a recent interview, he said "I feel the US did a highly credible job in making early vaccine production and purchasing decisions, assessing and reassessing needs, adjusting high risk definitions, and modifying vaccine recommendations, all as knowledge of the novel H1N1 continued to emerge."<sup>2</sup>

### **2. Rx Response leveraged its trusted position among its private and public sector partners to successfully advocate for effective solutions on a number of challenging issues, as well as created new outreach opportunities.**

1. Rx Response provided critical guidance to states and recommended against polling for antiviral inventory levels at pharmacies. Rx Response instead recommended resources that could provide more valuable and meaningful information to state managers. As a result, states gradually but steadily began turning to these sources (for example, its regional distributor, or BARDA for the national-level picture), thereby lessening the burden on pharmacies.
2. Rx Response assisted ASTHO and NACDS in formulating operational framework guidance for state public health departments to engage pharmacies in the administration of H1N1 vaccine.
3. Rx Response participated in discussions between NACDS and AHIP that were aimed at resolving billing challenges associated with the administration of H1N1 vaccine. While a complicated issue,

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<sup>1</sup> CIDRAP News, "House Committee Probe Pandemic Vaccine Decisions"  
<http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/nov1809adjuvant.html>, November 18, 2009

<sup>2</sup> CIDRAP News, "Health Officials, Experts Reject 'False Pandemic' Charges"  
<http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/jan1310vaccine.html>, January 13, 2010

the successful effort represented a prime example of joint cooperation among the private-sector biopharmaceutical industry partners to serve the public's best interests.

4. Rx Response advocated for and later participated in the implementation of the CDC "Dashboard Project" to track countermeasure levels across the biopharmaceutical supply system. This project represented unprecedented rapid cooperation between private-sector and public health entities to quickly develop a solution that met all stakeholder needs.
5. Rx Response's outreach efforts to its public and private-sector partners over the past year proved highly successful and strengthened Rx Response's position as a trusted source of accurate and timely information. The program's ability to serve as an efficient go-between for these partners gave Rx Response an expanded voice in influencing emergency protocols and procedures impacting the US private-sector biopharmaceutical supply system. See Appendix I for a full list of examples.

### **3. Government and private-sector success in learning and implementing lessons from past emergencies and influenza concerns - such as H5N1 - led to financial and educational investments that paid significant dividends during the H1N1 response.<sup>3</sup>**

1. Preparations for massive vaccine development were launched within days of the identification of the novel H1N1 influenza outbreak in Mexico on April 26, 2009, leading to the most rapid completion of influenza vaccine in history.<sup>4</sup> In a November 18, 2009 statement to the US House of Representatives Committee on Appropriations, Dr Nicole Lurie, Assistant Secretary of Preparedness & Response (ASPR) at HHS, commented on the strong contributions the private sector was making to the government's national response efforts, saying: "The private sector demonstrated a firm commitment to working through complex issues of vaccine administration, billing processes, and other policy issues that would facilitate a successful vaccine campaign with the goal of providing easy access to the 2009 H1N1 influenza vaccine for every person in the United States who wants it."<sup>5</sup>
2. In addition to the rapidity of vaccine production, the vaccine has so far proved to be incredibly safe. Although a few batches of vaccine have been recalled,<sup>6</sup> CDC Director Thomas Frieden has noted federal officials' high levels of confidence in the vaccine's safety, due to it being produced

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<sup>3</sup> This led WHO Director General Dr. Margaret Chan to proclaim that "no previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning" (WHO, "World Now at the Start of 2009 Influenza Pandemic," [http://www.who.int/mediacentre/news/statements/2009/h1n1\\_pandemic\\_phase6\\_20090611/en/index.html](http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html), June 11, 2009).

<sup>4</sup> On May 22, HHS announced a \$1 billion USD program to fund vaccine development. On May 25, HHS ordered French drug maker sanofi-aventis to begin large-scale production of a vaccine for the H1N1 flu. At the July 9, 2009 Flu Summit, National Institute of Allergy and Infectious Diseases Director Anthony Fauci stated that a US nation-wide network of vaccine research laboratories was testing the candidate vaccines for safe doses and how to implement them.

<sup>5</sup> November 18, 2009, Statement by Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response.

"Safeguarding our Nation: HHS Response to the H1N1 Outbreak," <http://www.hhs.gov/asl/testify/2009/11/t20091118c.html>

<sup>6</sup> The batches that were recalled were due to lower than expected levels of antigens. Although the potency was seemed potentially sufficient to achieve immune response, manufacturers recalled them in a precautionary show of commitment to product safety and effectiveness.

by the same manufacturers using the same methods as the seasonal flu vaccine, which also has an excellent safety record.<sup>7</sup>

3. A series of emergency declarations<sup>8</sup> pushed forward “fast-track” response mechanisms that increased government’s capacity to confront the challenges of responding to the H1N1 pandemic.
4. The timely PREP ACT declaration reduced one of the largest barriers to private sector participation in response efforts – liability concerns for participants in countermeasures delivery.
5. The US federal government was quick to disperse supplemental funds to states for combating H1N1.<sup>9</sup> These funds accelerated state and local -level capacity to respond to the outbreak.
6. Federal educational efforts such as [www.flu.gov](http://www.flu.gov), frequent CDC webcasts, and public-service commercials and campaigns, have been crucial in managing public expectations during the pandemic, as well as enhancing the country’s overall capacity to handle pandemic response.
7. Multiple public and private sector entities (including the US federal Departments of Homeland Security (DHS), Health & Human Services (HHS), Occupational Safety & Health Administration (OSHA) and the US Chamber of Commerce) published updated pandemic-related guidance instructing businesses and organizations on appropriate preparedness and response measures that can be implemented to mitigate operational risks during a pandemic.
8. Several manufacturers successfully produced H1N1 vaccines using adjuvants or virus-like particles (VLPs). While these products have not been approved by the FDA for distribution and use within the United States to date, adjuvanted vaccine was approved for the European Union market. In general, these types of technological advances move beyond traditional egg-based vaccine production (including new cell-based technologies) and show promise in improving antigen yields in the future, which could mean more vaccine being available sooner.

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<sup>7</sup> Thomas Frieden , CDC Press Briefing, October 27, 2009, <http://www.cdc.gov/media/transcripts/2009/t091027.htm>

<sup>8</sup> On April 26, 2009, Acting Department of Health and Human Services (HHS) Secretary Charles Johnson declared a Public Health Emergency for novel H1N1; this declaration was renewed by new HHS Secretary Kathleen Sebelius several times: July 24, 2009; October 1, 2009; December 28, 2009 ([www.flu.gov/professional/federal/index.html](http://www.flu.gov/professional/federal/index.html)). More recently, on October 23, President Barack Obama declared a national emergency, clearing the way for healthcare systems to expediently implement their disaster plans.

<sup>9</sup> This was evidenced on July 13, 2009 when HHS committed \$884 million USD to purchase additional supplies of two key ingredients for potential H1N1 vaccine to further prepare the nation for a potential resurgence of the 2009 H1N1 virus. HHS also appropriated \$350 million USD in federal funds to help states and territories step up pandemic preparedness efforts, and President Obama announced on September 2 that his administration has appropriated \$7.65 billion USD to HHS for the 2009 H1N1 influenza outbreak, including an additional \$2.7 billion USD to procure H1N1 flu-related drugs and supplies.

## II. Challenges Confronted in Response Efforts

### **1. Prior planning measures that linked organizations' activation & escalation criteria to "global triggers" complicated response efforts because they did not accurately reflect the realities of the situation.**

1. The outbreak unfolded in a manner inconsistent with prior assumptions regarding geographic point of origin, as well as the timeframe in which the virus would become globally widespread.
2. US federal government pandemic planning assumptions (upon which the Rx Response pandemic plan drew heavily) lacked relevance during this outbreak. Specific assumptions that turned out to be inaccurate included surveillance, advance notice, overseas initial outbreak, and likely US and foreign government actions at each phase.
3. WHO triggers based on "spread" rather than "severity" caused confusion for both government and private sector stakeholders. The private sector in particular had looked to the WHO for guidance on the appropriate level of response in their organizations, with WHO alert phases serving as triggers for plan activation and escalation in many corporate plans. Given the mild-moderate severity of disease for most who fell ill, the level of response in plans indicated by the WHO-based pandemic levels may have been inappropriate.
4. Dependence on US government alert systems also proved challenging in 2009. HHS pandemic severity phases were pulled from the Pandemicflu.gov website after they proved mismatched to the realities of the H1N1 situation. Rx Response interactions with private-sector companies at that time suggested that this action confused private sector firms that linked continuity plans to HHS phases. An alternative pandemic system has yet to be put in place, leaving many businesses unsure how to align internal pandemic response efforts with government triggers.
5. The rapidity of these events left many private sector companies in a challenging position. A premium was quickly placed on accurate and timely information, and intra-sector consultation with other private-sector companies and external consultation with the government ramped up significantly.
6. Rx Response also linked levels of effort to WHO and HHS phases. The 2009 H1N1 outbreak proved to be geographically widespread but also, for the most part, mild. As a result, implications for the US private-sector pharmaceutical supply system were much smaller than anticipated, compared to the high level of the WHO alert.
7. Historical case information was of limited relevance. The Rx Response Pandemic Plan was heavily H5N1 focused, as this particular strain was deemed likely to be the "next big threat". However, this outbreak showed that any novel pathogen can become a threat extremely quickly and react in unpredictable ways.
8. Rx Response (like many other organizations and government agencies) assumed a potential epidemic would originate in South or Southeast Asia, or the Middle East. The outbreak's emergence in North America surprised many, upending both planning and timeline assumptions.

**2. Planning only for a worst case scenario (for example, an 1918-like influenza pandemic) does not fully explore the issues that arise in less dire situations. Intermediate triggers for scalable responses should be identified and incorporated into plans.**

1. Rx Response's original triggers for activation focused largely on external sources (for example, the WHO or HHS), or an acute determination by the Coordinating Body that the biopharmaceutical supply system had broken down. There was no documented consideration or flexibility for activating during an episode of acute media / public attention and fear. As a result, the program was left without an explicit mandate to respond to a 'mild' case of influenza pandemic – since the biopharmaceutical supply system was intact and able to meet legitimate prescription demand.

**3. The nature of state-by-state response makes it difficult for regional or national firms to participate efficiently in response efforts.**

1. With 50+ disparate state-level response efforts occurring simultaneously during a nationwide pandemic response, varying levels of response policies and efficiency were observed at the state level. Pre H1N1 planning using the worst case planning assumptions prioritized critical infrastructure workforce.<sup>10</sup> The priority groups for H1N1 were altered dramatically<sup>11</sup> Better communication to the critical infrastructure community about the change should have been accomplished.<sup>12</sup>
2. Rx Response noted a broad recognition - both within government and the private sector - that establishing a parallel secondary supply system alongside the existing private-sector distribution network creates redundancies and is therefore potentially inefficient. Many public officials lack a clear understanding of supply chain operations, inventory monitoring, and procurement channels. Moreover, distribution of biopharmaceutical products remains complicated. Each state currently has distribution policies to the local level for Strategic National Stockpile (SNS) assets, however, concerns remain that inter-state coordination and local implementation could be difficult<sup>13</sup> This is true both for deciding where to send biopharmaceutical product and for determining how (and where) this product will be dispensed or administered.
3. Some confusion remains regarding appropriate trigger points for releasing antiviral product from federal and state stockpiles into the marketplace – a function technically outside the original mandate of the SNS program.<sup>14</sup>

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<sup>10</sup> Department of Homeland Security and Department of Health and Human Services, "Guidance on Allocating and Targeting Pandemic Influenza Vaccine", October 17, 2007, <http://www.flu.gov/individualfamily/vaccination/allocationguidance.pdf>

<sup>11</sup> Center for Disease Control and Prevention, "2009 H1N1 Vaccination Recommendations," <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>

<sup>12</sup> From recent discussion at Institute of Medicine Forum, January 13, 2010

<sup>13</sup> Trust for America's Health, "Pandemic Flu: Lessons from the Frontlines", June 2009 p.9, <http://healthyamericans.org/report/64/pandemic-flu-frontlines>

<sup>14</sup> The Strategic National Stockpile is the United States' national repository of antibiotics, vaccines, chemical antidotes, and antitoxins. Its original mandate was to protect the American public from a public health emergency due to a biological, chemical or radiological/nuclear attack by providing vital medical product that the marketplace would otherwise be unable to supply to a concentrated region of the United States in a very timely manner (initial response within 12 hours). The pandemic has had the opposite issues: identifying "chronic" shortage of countermeasures and delivering them to areas of need with minimal disruption on the normal supply system has been a challenge.

#### **4. Increased communication about vaccine development, approval and production process to the response community and the public in general is needed.**

Even though vaccine was developed and approved in only 5 months from the identification of a novel H1N1 influenza virus<sup>15</sup>, vaccine demand outstripped supplies in the initial vaccination campaigns and led to reports of heightened anxiety among the general US public.<sup>16</sup>

#### **5. The FDA's drug shortage program did not adequately provide timely information regarding antiviral shortages to clinicians, pharmacies, distribution centers, local, state and federal health officials.**

#### **6. Financial challenges to robust response emerged, especially at the state and local level.**

1. Deep budget cuts, combined with a national economic recession, made some states reluctant to allocate scarce resources to purchasing and stockpiling additional antiviral product prior to the pandemic declaration, even with a substantial federal subsidy.<sup>17</sup>
2. Disagreements lingered regarding the determination of fees (and payers of those fees) for dispensing/administration services provided along with "free" SNS product,<sup>18</sup> as well as state by state differences as to whether stockpiled product was used to provide care to the uninsured or underinsured even when the normal supply system was able to fulfill the legitimate prescription demand.

#### **7. The following general Rx Response observations are areas of on-going concern related to potential future public health responses.**

1. Ambulatory care, emergency departments and hospital bed capacity have emerged as the focal areas predicted to create the largest immediate strains to the system as a result of a surge in sick patients. A recent report released by Trust for America's Health (TFAH), based on the CDC Flu Surge modeling program and using statistics from the 1968 flu pandemic, estimated that if there was a severe H1N1 or other viral outbreak, 15 states would exceed their current available

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<sup>15</sup> FDA Approves Vaccines for 2009 H1N1 Influenza Virus, September 15, 2009

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm182399.htm>

<sup>16</sup> Michael Shear and Rob Stein, Rob. "Why Such a Shortage of Swine Flu Vaccine?," *The Washington Post*. October 27 2009

<sup>17</sup> Trust for America's Health, "H1N1 Challenges Ahead," October 2009, page 7,

<http://healthyamericans.org/reports/h1n1/TFAH2009challengesahead.pdf>

<sup>18</sup> Although the costs for antivirals released from the Strategic National Stockpile are publicly paid for (<http://www.bt.cdc.gov/stockpile>), private sector dispensers may be permitted to charge a dispensing fee for each prescription filled.

hospital bed capacity during the fifth week of the outbreak, and an additional 22 states would reach a hospital bed utilization rate of at least 80%.<sup>19</sup>

2. Production of countermeasures for as-yet unidentified future emerging threats could potentially benefit from faster production processes, such as cell-based vaccine development.

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<sup>19</sup> This report used the CDC's FluSurge program and used statistics that were compiled after the 1968 flu pandemic. The models estimated that the pandemic would last for eight weeks and would reach its peak in severity by the fifth week. Healthy Americans, "H1N1 Challenges Ahead," <http://healthyamericans.org/reports/h1n1/TFAH2009challengesahead.pdf> , October 2009

### III. Opportunities for Improvement

#### **1. Recommendation: Rx Response undertake additional actions to (1) clarify “worst case” scenario impacts during a more severe pandemic scenario and (2) incorporate insights into existing plans.**

1. The Rx Response Biopharmaceutical Supply System Workshop held on September 9, 2009 provided substantial guidance and clarification regarding the potential threats that a pandemic might pose to the pharmaceutical supply system, enabling Rx Response to develop and capture appropriate response actions in the plan. The lessons learned from this workshop should be communicated to Rx Response’s partners in an effort to mitigate anticipated threats to the biopharmaceutical supply system.
2. Once updates have been made to the Rx Response Pandemic Plan, Rx Response should hold a more in-depth pandemic exercise that involves all Rx Response participants in the Fall or Winter of 2010.

#### **2. Recommendation: With insights from #1 in hand, Rx Response should continue efforts to bring government and private-sector focus and solutions to these issues.**

1. Rx Response should continue to leverage its position as a trusted go-between for its private and public-sector partners to explore possible reforms to the infrastructural, legal, and procedural impediments identified in this document.
2. Rx Response should advocate that under such an influenza situation – which is less than worst-case, from a virulence perspective - federal, state and local governments can capitalize on the efficiency of the biopharmaceutical supply system’s infrastructure in order to streamline both the distribution of product and the timely flow of related information. Incorporating these tried-and-true networks into government’s response efforts will ensure that fewer inefficiencies and redundancies will form in the distribution process, thereby getting medical products to patients in need in a timely fashion.
3. To be most useful for businesses, any severity index would need to include morbidity as well as mortality estimates. The 2009 H1N1 experience might also serve as a reminder that any single system should not serve as the only or primary trigger for an organization’s pandemic response, and that local, or organizational triggers can prove most effective when modifying business practices to address a pandemic threat.
4. Rx Response should leverage its contacts at DHS and HHS in an effort to participate in any planning committees responsible for establishing a nation wide, universally accepted, set of pandemic response implementation triggers, should this initiative be launched. If the federal government does not plan to address this issue, Rx Response could take the lead on organizing a forum for discussion
5. Related to this, Rx Response should push to participate as part of the private-sector biopharmaceutical supply system in any discussions conducted with government on the possible changes to the vaccination prioritization system. Rx Response can serve as an influential voice in these discussions for the need to immunize critical private-sector employees involved in

pandemic response. Another option is to have the Healthcare Sector Coordinating Council lead the effort on the private-sector's behalf, with Rx Response members providing valuable inputs / concerns.

6. To aid the efforts of the above two, Rx Response should conduct workshops with the Coordinating Body members to draw out, capture, and document Rx Response member concerns and recommendations.

**3. Recommendation: Rx Response should continue to fully support the establishment of information-sharing and situational awareness building vehicles such as CDC Dashboard.**

1. Rx Response should engage in public-private sector efforts that explore the potential for leveraging resources established for H1N1 influenza response moving forward.
2. Rx Response believes that such information-sharing mechanisms should be permanent resources for public health response efforts, rather than utilized on an ad hoc basis for a specific event.

## **Appendix I: Granular / Technical Rx Response Observations**

### **Pandemic Response Successes**

#### **1. The Coordinating Body model of organization allowed Rx Response to function as intended. Flexibility in plans was essential to effective response.**

1. Coordinating Body representation on internal Rx Response conference calls was strong and members actively contributed to conference call discussions.
2. For example, HDMA and NACDS passed along and responded to information requests while also identifying potential opportunities for Rx Response to engage and add value.

#### **2. The Rx Response Support Team maintained desired service levels throughout activation period.**

1. Rx Response leadership kept the program on course at key decision points and delegated where appropriate.
2. The Rx Response Support Team surged efforts to support Rx Response's activation and successfully maintained situational awareness reporting for nearly two weeks. These reports captured information that was relevant to recipients and frequently cited by recipients as valuable.
3. Control Risks continues to present a scalable solution to Rx Response's internal staffing needs. The firm successfully expanded internal service delivery capacity, freeing up key Support Team resources to focus on analytical and operational tasks.
4. Control Risks continues to present a scalable solution to Rx Response, with additional consultants available in Washington, DC, across the US, and world-wide, as needed. For example, during the recent outbreak, Control Risks was able to furnish Rx Response with daily internal reports on conditions in Mexico City.

#### **3. InfoCenter platform successfully served as the virtual HQ for Rx Response.**

1. InfoCenter proved suitable for capturing and communicating information, as well as managing internal response efforts.
2. During the initial 30 days of H1N1 response, approximately 56 external users logged in to the system and a far greater number of recipients received the daily situation reports. This was the most robust engagement tempo so far observed during any Rx Response activation.

#### **4. Rx Response's outreach efforts over the past year proved highly successful to Rx Response's public and private-sector partners alike, by strengthening Rx Response's position as a trusted source of accurate and timely information.**

1. Rx Response received timely notification of a number of Medicaid and other emergency health policy changes stemming from the pandemic response, which the team communicated onward.
2. Rx Response created accounts for, and distributed situation report notifications to, all National Alliance of State Pharmacy Association (NASPA) state representatives, thereby enhancing ties to a valuable group of contacts with whom we did not previously enjoy direct access.
3. Rx Response successfully leveraged its new relationship with NASPA to create a comprehensive state-by-state guide to pharmacies interested in registering for both H1N1 vaccine and antiviral administration.
4. Rx Response helped assuage both public and private-sector fears of antiviral shortages by communicating that the biopharmaceutical supply system was working as normal and that any end-user shortages were most likely due to “end of flu season” low inventory levels, hoarding, or other localized and temporary causes.
5. Rx Response responded to or redirected (as appropriate) a number of federal and state information requests. Eleven states submitted information requests regarding the availability of Tamiflu<sup>™</sup> and Relenza<sup>™</sup>. Rx Response played a similar role when Tamiflu oral suspension became in short supply and information on workaround solutions (including compounding the drug) was in high demand.
6. Rx Response leveraged its relationship with seasonal vaccine manufacturers to fulfill information requests on perceived seasonal vaccine shortages. The spike in H1N1 vaccine demand generally created uncertainty over seasonal vaccine supply – and led to Rx Response’s utilization as a trusted resource of this information.
7. Rx Response hosted a Biopharmaceutical Supply System Workshop in September 2009 that provided benchmarking information to manufacturers and distributors on pandemic preparedness and response. The workshop also brought in outside perspectives (including CDC representation) that allowed audience members better insight into the issues the biopharmaceutical supply system and public sector face during a pandemic situation.
8. The modest virulence of the first two waves of H1N1 created an environment where Rx Response could simulate and refine its processes for creating appropriate information-sharing and emergency preparedness and response measures. The “lessons learned” from this experience with H1N1—reflected throughout this report and from other Coordinating Body discussions—has readied the Rx Response Program to respond to a more virulent pandemic or public health emergency in the future.
9. The outbreak resulted in significant opportunities for the Rx Response program to engage with state emergency operations centers, state departments of health, and pharmacy representatives. This exposure led to approximately 147 new, valid requests for InfoCenter access.

## Challenges in Response Effort

### **1. Rx Response experienced some “glitches” in both InfoCenter and general work processes.**

1. The “Notifications” function did not work as expected from the emergency page of InfoCenter, although “General Notifications” from the non-emergency InfoCenter page worked properly.

*NOTE: This has since been fixed.*

2. Profile journals were not used by the Support Team as established in the Pandemic Plan. This was partially due to the fact that multiple shifts were not needed for the response effort, as well as the fact that the team was minimally staffed, with a few individuals spanning the same multiple roles day by day.
3. Training materials, which were to be developed prior to the onset of any novel influenza threat, were not in a finished state.

*NOTE: Rx Response has since developed a series of workbooks for any surge support that Rx Response might need during an emergency.*

4. Rx Response participants and partners frequently sent requests and information to Rx Response Director Erin Mullen via email, instead of utilizing InfoCenter-based solutions (e.g. Discussion Board and Situation Report submissions), as encouraged during program presentations and literature. For example, only one of the 11 information requests received from state officials was done through InfoCenter – the rest went directly to Erin.

### **2. Rx Response pandemic planning did not take into account the voracious appetite Coordinating Body members and other stakeholders displayed for situational awareness information at the immediate outset of the crisis.**

1. Plan-housed schedule assumptions for Rx Response Coordinating Body & Crisis Owners and Communicators meetings proved inadequate, particularly at the beginning of the crisis, when there were significant unknowns and uncertainty.
2. The most intense period of activity during the several weeks Rx Response spent in active engagement came during the first 72 hours following the major media uptake of the issue.

### **3. Rx Response members will continue to draw their own lessons from recent events and may implement changes that may, in turn, impact their capabilities to support Rx Response.**

1. The implication for Rx Response is that, in the future, any disaster response requiring highly-specialized biopharmaceuticals produced by a small number of manufacturers will continue to represent a distinct risk to the US biopharmaceutical supply system and therefore may have a significant impact to the Rx Response program.

## Opportunities for Improvement

### **1. Recommendation: Rx Response should identify and remediate those administrative and technical processes determined to have lacked effectiveness during the recent crisis.**

1. The Rx Response Pandemic Plan required significant updates to incorporate salient lessons learned during the 2009 H1N1 outbreak. These changes included (but may not be limited to):
  - A new structure for measuring the specific impact of an outbreak on the US private-sector biopharmaceutical supply system was developed following the realization that high-level national or international pandemic phase status ultimately bore little relevance to the status of the US biopharmaceutical supply chain. Proposed triggers have been developed that focus on flexibility and logic and are more specifically relevant to program interests. The proposed revision is included as Appendix I below.
  - Regardless of actual impact on the biopharmaceutical supply system, Rx Response realized that the program must be prepared to activate in the face of public media pressure to respond to a perceived shortage, or other inability of the biopharmaceutical supply system to meet demand. This is a new acknowledgement that Rx Response's level of effort is partially defined / determined by external factors.

*NOTE: This has since been completed.*

- Information (factual knowledge and assumptions) regarding specific potential threats (e.g. H5N1) should have been captured in dedicated appendices, rather than in the main section of the Pandemic Plan document to increase flexibility and ease of use.

*NOTE: This has since been completed.*

- The plan did not reflect the potential desire of Coordinating Body and member companies to meet daily (or more frequently) in the early days following an outbreak's emergence. The purpose of this interaction is to obtain actionable and reliable information at a time when media reporting may not be reliable.

*NOTE: This has since been completed.*

- The plan did not reflect that news media websites update much more frequently (and less reliably) than government websites and that information reported in the press must be validated using real-time government communications methods (e.g. CDC media calls). The sources that Rx Response relied on for accurate information (both electronic media and conference calls) should be updated in the plan to reflect the experience of the recent H1N1 outbreak.

*NOTE: This has since been completed.*

- An initial high level of activity for the Support Team should be provided for in the plan-- particularly during the Alert and Engaged phases when a high-degree of flexibility is required to respond to changing conditions. The plan should recognize that significant effort is required at the onset of an event, as well as when major events occur that require additional monitoring and communication effort.

**2. Recommendation: Rx Response management team should continue to evaluate existing staffing requirements to ensure correct alignment both during activation and non-activation periods.**

1. Rx Response Director Erin Mullen was able to maintain consistent leadership throughout the crisis—a testament to her dedication to mission. Erin does, however, remain a single point of failure in the sense that her role would be difficult to replace without notice.

*NOTE: Rx Response's ongoing Resilience project is putting in place scalable checks and redundancies to mitigate against this risk.*

2. The staffing alignment selected for the 2009 outbreak did not include mobilization of all roles in the Pandemic Plan. However, the staffing model adopted was appropriate to the requirements placed on Rx Response. In the event of a more severe outbreak scenario, roles and responsibilities would likely need to be organized more formally.

*NOTE: Support Team Workbooks developed since the 2009 H1N1 outbreak have formalized many of the roles identified in the Pandemic Plan.*

3. Rx Response should continue to cultivate resources that can be activated during a crisis to support the core Support Team. These responsibilities may include (but are not limited to):

- ✓ Situation Report Updates
- ✓ Emergency Admin Page for Non-Administrator Submission Approval
- ✓ Alert Emails
- ✓ User Access Requests
- ✓ Rx Response Voicemail
- ✓ News Monitoring
- ✓ Call Identification and Schedule Development
- ✓ Handling/Documenting Information Requests
- ✓ Emailed Sit Rep Drafting and Approval
- ✓ Meeting/Awareness Notifications
- ✓ Tracking Lessons Learned and After Action Items

**3. A number of InfoCenter improvements should also be implemented and documented in the Rx Response Pandemic Plan in the near term.**

1. The emergency notifications function within InfoCenter has already been upgraded.
2. Rx Response should consider adding a "Support Team Schedule" to identify who is working and when, as well as a "Responsibilities Breakdown" chart.
3. A daily Conference Call Log should be completed in InfoCenter and emailed to all Support Team members in a clear format that provides times, subjects, call-in details and other relevant information on all calls.
4. The Coordinating Body Pandemic and Support Team task lists should be completely populated in InfoCenter.

5. Instructions should be added to the InfoCenter Administrator Guide for locating items in the Recycle Bin and Site Collection Items Recycle Bin and restoring them.

*NOTE: This has since been completed.*

6. Instructions should be added to the InfoCenter Administrator Guide for changing an emergency's name.

*NOTE: This has since been completed.*

7. Instructions should be added to the InfoCenter Administrator Guide for emailing notifications with attachments using [alerts@rxresponse.org](mailto:alerts@rxresponse.org) or [admin@rxresponse.org](mailto:admin@rxresponse.org) email accounts.
8. The possibility of creating an attachments feature to notifications originating from InfoCenter should also be explored.
9. Holding statements for some of the above scenarios could be created or revised in order to more quickly address recurring actions undertaken by the Support Team.
10. Plans should be updated to include a step to create a "Lessons Learned" action item in the Support Team task list to capture lessons learned and after action items as well as add a discussion topic in Emergency Page.
11. During a pandemic scenario, Situation Report subject headings should be reconsidered and revised as appropriate to make the reports more pandemic-specific. Some suggestions may include:
  - a. "Government Status" could be changed to "Government Actions".
  - b. An "International Situation" section could be added.
  - c. A "Government Guidelines" section could be added.
  - d. "Shelter Openings" and "Special Needs Shelter Openings" sections could be removed.
12. Inaccurate, invalid, and unreachable email addresses should be followed up on immediately and managed to prevent receiving repeated bounce-back emails.
13. In the area of partner training, Rx Response could better prepare participants to utilize InfoCenter tools (including the admin and alerts email addresses) when sharing information, as these tools are designed to mitigate single points of failure and ensure a prompt response. These reminders should be embedded in all external Rx Response communications, especially in the emailed Situation Report notifications. Draft statements to cut and paste should be included in the plan with a template in notifications.

## Appendix II: Rx Response Program's Level of Response

The following chart was presented during the July 2009 Coordinating Body meeting, and represents a Coordinating Body-approved revision of Rx Response's new response "triggers" for activation. The goal of these revisions was to institute more flexible triggers, allowing Rx Response to nimbly respond to the reality of each unique situation (as it related to the functioning of the US-based private-sector biopharmaceutical supply system), rather than relying on confusing and potentially antiquated government-based triggers.

Rx Response Plan Section	Old Structure	New Structure
Section A - Engagement & Analysis	<b>Trigger:</b> <i>WHO Phases 1-3</i>	<b>Biopharmaceutical Supply System Level:</b> <i>No Identified Threat / Impact</i>
Section B - Response	<b>Triggers:</b> <i>WHO Phase 4</i> <i>WHO Phase 5</i> <i>WHO Phase 6</i>	<b>Biopharmaceutical Supply System Levels:</b> <i>Potential Identified Threat / Impact</i> <i>Significant Threat / Impact</i> <i>Reduced Identified Threat / Impact</i>
Section C – Performance Evaluation	<b>Trigger:</b> <i>Inter-wave &amp; post-pandemic stages</i>	<b>Biopharmaceutical Supply System Level:</b> <i>Post Pandemic</i>