

Hospitals and the Novel H1N1 Outbreak: The Mouse That Roared?

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With so much effort directed during the past few years toward pandemic influenza preparedness, especially toward H5N1 avian influenza, the rapid emergence of a novel H1N1 (nH1N1) influenza strain was met with a certain matter-of-fact acceptance by hospital and health care planners in April 2009. Emergency planners have long parroted the phrase “not if, but when,” and so it became immediately clear that “when” had reared its head again. Yet, as mortality rates and epidemiology became clearer, the sense of urgency declined in many health care–related agencies, organizations, and facilities. As pandemics go, this seemed to be a mouse among lions.

Hospitals and health care systems that had invested time and effort in pandemic and all-hazards preparedness efforts swiftly applied a combination of strategic and tactical response plans. Those that were not as well prepared struggled to make sense of the dizzying array of issues, recommendations, and response requirements surrounding this rapidly evolving event. All worked hard to coordinate efforts within the broader context of the community mitigation and public health strategies that were being implemented. The events of spring 2009—the first wave of the pandemic—have served as a “pandemic reality check”¹ and a wake-up call to those responsible for health care sector planning that time is running out to develop operational plans for pandemic influenza. Despite relatively low morbidity and mortality of nH1N1, the predicted numbers of cases possible in a nonimmune population could overwhelm health care resources, even if optimal communications to the public about when to seek care is delivered in a timely manner. Discussions about adjusted standards of care that were academic last year are more urgent, while the public appears to be less receptive to discussions about reallocation of scarce resources.

HOSPITAL RESPONSES

To a varying degree across the country, hospital emergency departments (EDs) and primary care practice settings were visited by large numbers of patients in the early weeks of the nH1N1 outbreak. Some communities, for example, New York City and areas in south Texas and southern California, were much more significantly affected, in part owing to the disease burden in the community, the degree of testing for influenza in the community, and the interest of the mass

media in exploring issues related to this outbreak. Even in those communities not harboring significant numbers of confirmed cases of the novel influenza strain among its population, however, there was a surge in demand for ED services (Fig. 1) (Z. Corrigan, executive director, Northern Virginia Hospital Alliance, personal communication, June 24, 2009). Much of the demand for patient care was related to patients who presented with influenza-like symptoms (the “worried ill”) and those seeking reassurance or testing (the “worried well”). There is strong precedent for this sort of occurrence, particularly when a new, emerging infectious disease frightens the public and results in their seeking medical attention and advice. The default result is often patients seeking care and counseling at the hospital ED.^{2,3}

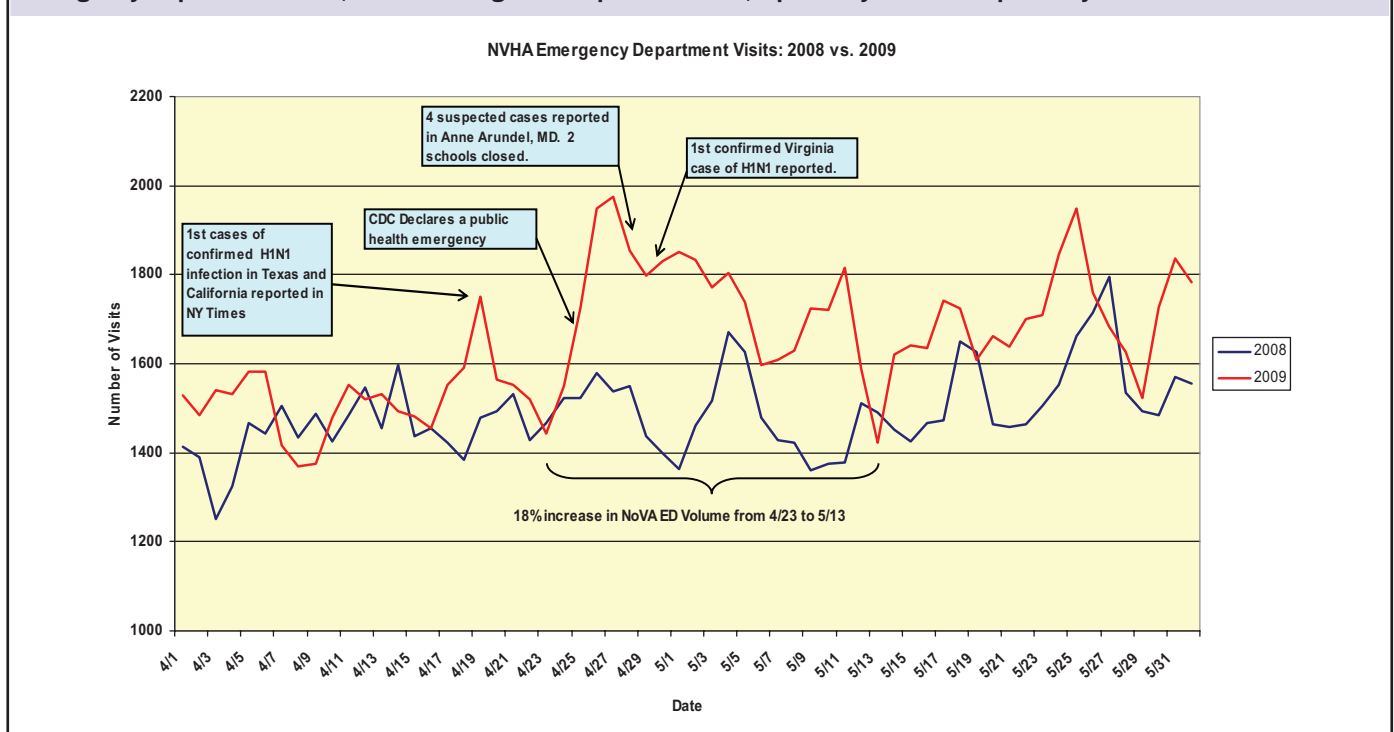
The surge in demand for health care services was not sustained, however, because testing and treatment were de-emphasized relatively early in the epidemic and activity faded with summer’s arrival. The burden on inpatient services was minimal in most areas, lessening the overall effect on hospital operations as elective surgery volumes were generally not affected; however, the spring wave prompted many hospitals to implement an incident management system to coordinate the many elements involved in the response. This required the convening of a “command group,” often the hospital or health care system emergency preparedness coordinator, members of the emergency management committee responsible for the key elements of emergency operations plan implementation, and key administrative leaders (who may or may not be as engaged in the day-to-day and month-to-month activities of such committees). In particular, infection control and the EDs played key roles in instituting and modifying organizational plans to meet the event demands, and those that had established plans and working relationships between these groups were able to often quickly reach consensus on tactics. The role of such a command group was to provide the leadership required to tease through the many issues brought up in the context of this outbreak and provide a cogent, transparent response plan to meet those planning objectives. The following sections highlight some critical issues.

Surveillance Capabilities

To know what impact the nH1N1 outbreak had on hospital, and specifically ED (ED) and laboratory, resources, an ongo-

FIGURE 1

Emergency department visits, Northern Virginia Hospital Alliance, April–May 2008 vs April–May 2009.



ing tally of ED patient visits, screening tests for influenza, and inpatient admissions of cases with febrile respiratory illness was required at minimum. This information was often facilitated by electronic medical records (in those settings in which they are in place) and the ability to electronically build screening questions into the ED triage process and adjust them to the evolving situation (eg, travel history, symptoms). The significant demand for diagnostic evaluation, specifically by patients and their health care providers, had a significant impact on hospitals during this initial phase of the nH1N1 outbreak. The use of influenza antigen testing was quickly determined to be an insensitive means of assessing true infection, and the option for definitive testing using real-time polymerase chain reaction modalities was not immediately available in most health care settings.^{4,5} It is unlikely with the fall resurgence of the virus that diagnostic testing will play a major role in the ambulatory care setting, given the limitations of rapid antigen testing.

Exposures and Exposure Tracking

In addition, “internal” surveillance efforts had to include a clinical reporting mechanism for identifying staff exposures to potential influenza patients. Regular reporting of such data contributed to the ongoing efforts to provide situational awareness to the health care system or hospital leadership, and was often coupled with reporting of other key data points. Particularly given the issues related to worker safety, such exposure tracking efforts were of significant importance. Of note, analysis of nH1N1 transmission among health care

providers demonstrated that inconsistent adoption of recommended personal protective measures may have contributed to nosocomial transmission of nH1N1 influenza from patients to health care workers.⁶ It is important to note how difficult maintaining compliance with respiratory protection guidance is in the tumultuous ED setting, where clinicians are often attending to numerous patients in parallel, and the ability to prepare for bedside patient encounters are frequently rushed, particularly when the motivation of providers to be compliant was often lacking due to the relatively low crude mortality rates.

Logistics Support and Key Resource Availability

The response to any surge event requires the mobilization of resources and the initial response to the H1N1 outbreak was no different. Critical resources were identified as those needed to protect the health care workforce, specifically personal protective equipment (PPE) such as masks, gowns, gloves, and goggles. Augmentation of engineering controls, including the use of “air scrubbers” to circulate air through a HEPA filter machine, were used to supplement existing negative pressure room capabilities (in short supply in most hospitals) in some facilities, and temporary negative pressure triage areas were created for suspicious cases in others. Signage was rapidly created to reinforce mask use for patients and staff. The coordination of such resources under the auspices of a respiratory protection plan and an infection control plan were critical. Other resources that were identified as being in short supply, particularly early in the event, included the influenza

antigen detection kits used to perform the screening test on patients suspected of being infected. A robust logistics procurement plan was necessary to meet the needs of the ED, outpatient clinics, and even community practitioners, who may limit referrals to the ED by performance of screening tests in the office setting. Hospitals often received requests for masks and PPE supplies from their clinic partners that normally would not use these supplies in quantity or at all. Despite their best efforts, many institutions, even those that had stockpiled N95 masks, saw their stocks being used up at extremely rapid rates, often during periods during which few true-positive cases were being seen.

Antiviral Treatment

Hospital pharmacies and community pharmacies alike did not have significant stocks of antiviral medications on hand, in part because of a history of ambivalent support for their use in treating seasonal influenza, and the decreased sensitivity of circulating seasonal H1N1 strains to oseltamivir.⁷ The release of 25% of the Strategic National Stockpile to those states with confirmed cases was not particularly helpful in some areas, as in the absence of Centers for Disease Control and Prevention (CDC) guidance for preferred methods of distribution and use, state and local plans for distribution of the Strategic National Stockpile were inconsistent, and often not appropriate for limited distribution of pharmaceuticals. In addition, there was confusion related to shifting guidelines for antiviral administration. This was partly a function of the “exploding” communicability of nH1N1 disease across the United States. Increasing numbers of cases were confirmed to be positive and patients desired treatment; however, this contrasted with a more nuanced public health strategy for targeted treatment of individuals at higher risk for complications.

This fall, antiviral treatment and prophylaxis will be aimed at individuals with high-risk medical conditions or age categories. Unfortunately, more than 30% of the United States population meets high-risk criteria, and available antiviral supplies are inadequate to provide all high-risk individuals with medication absent illness or exposure. The goal for communities is to ensure that these at-risk individuals can be identified and obtain early treatment (while symptoms are nascent) or prophylaxis to prevent them from avoidable morbidity and mortality. As ED and clinic volumes increase, there is a real risk that usual triage for severity of conditions will result in these individuals never getting seen for care or waiting so long that they abandon the effort to obtain appropriate medications in the early or incubation phase of illness. Their subsequent illness and/or complications will have a multiplier loading effect on health care facilities. Hospitals and clinics should make plans to provide telephone prescribing for established patients with at-risk conditions and determine other ways in which these needs may be met for patients without usual medical care. This may take the form of “flu centers,” drive-through screening and prescribing, or pharmacy prescribing, among other strategies.

Staff Education and Training

As in many prior biological events hospital staff demonstrated significant confusion and concern about the clinical management of this novel influenza strain, in large part exacerbated by the prominence the story was given in the mass media. After all, health care providers are subject to exposure to the same messages as the public, and can easily be swayed by persistent coverage, inappropriately correlating scope of coverage with severity of disease. Adding to this was the waterfall effect of targeted messaging to health care staff from professional societies, mass media, viral media, and social networks; who was saying the right thing? By the time many advisories filtered down to the ED fax machine or were included in the daily incident action plan, they were outdated, creating difficulty for institutions that were not ready to make changes rapidly to their policies and processes. Moreover, there was a significant need for just-in-time training to support infection control practices including fit testing, treatment recommendations, and workplace administrative procedures. Facilities and systems should ensure that clear chains of information management are in place and that there is a priority system for information communication because not every update warrants an immediate change in practice and notification to all stakeholders. Scheduled daily updates are preferable, with urgent changes only as required for life-safety issues.

Communications

A cohesive communications strategy, focusing on both internal, hospital-focused communications (as stated above with regards to staff education and training) and working with the media and community partners on an external communications plan, played a huge role in the initial response to the H1N1 outbreak. The meteoric media response at the outset of the outbreak was difficult to keep pace with, often taking away precious time and resources from the planning process. Supporting the media effort was and will always be, however, a fundamental aspect of incident response. Internal communications relied on timely interpretation and filtering of a multitude of information sources, with frequent updates to staff required. Staffs tend to trust those sources of information they know best, particularly credible sources within their facility. Coordinating access to identified hospital experts as part of a media relations plan was also important and often the only way to provide credible recommendations to the viewing and listening public regarding what to do, how to act, and when it is or is not appropriate to present for evaluation at hospital EDs.

WHAT ARE THE IMPLICATIONS FOR THE COMING MONTHS AS SEASONAL INFLUENZA AND SUBSEQUENT WAVES OF THE PANDEMIC FLU STRAIN RETURN?

A number of items will require prioritized planning for health care organizations readying themselves for a continued and possibly more severe response to the nH1N1 influenza pan-

demic and seasonal influenza this fall, as detailed in the following sections.

Media Relations

Given the persistence of this novel influenza strain into the summer months in North America, it is increasingly clear that coordination with the media will play an important role in setting the tone for the community response to increased numbers of clinical cases, and the potential for increased virulence, with the return of seasonal and novel influenza this winter. Establishing open lines of communication with the print, electronic, and viral media will serve both parties—the health care community and the media. Health care organizations, both public and private, will be able to reiterate the important messages related to diminishing disease transmission, including those related to nonpharmaceutical interventions, personal protective infection control measures (eg, frequent hand washing, proper cough etiquette), and other important community mitigation strategies, while the media will be meeting its mission of reporting on issues of importance to the public.⁸

Staffing and Resource Solutions

Numerous studies have estimated the likelihood of staff absenteeism during a pandemic event^{9,10} and have detailed the infection control practices needed to prepare for an event.¹¹ Given the probability that staffing shortages will exist if the subsequent waves of pandemic are more widespread and/or virulent and the impact this will have on health care service delivery, steps must be taken to address these shortages and what preventive measures can be put in place to reduce the impact. Mitigation strategies will include more robust staff education and training, particularly around the use of PPE. Adoption of transparent workplace decisions regarding patient load requirements and other matters related to an eroded staffing pool will be important, as will the implementation of human resources policies that support the health care worker in this constrained environment. This must also include measures to retain staff during an emergency, particularly those in the lower tiers of employment who provide support services, not necessarily clinically related, a cohort of staff that is relied upon for proper facility function.

Adoption of practical strategies for personal protective measures must balance the known epidemiology of the nH1N1 influenza strain against the tradeoffs of different levels of respiratory protection and their availability. Noncompliance with PPE usage by health care workers is well documented, despite expert advice to the contrary and the conduct of health care delivery in high exposure risk environments.¹² These challenges must be recognized, and attempts to improve adherence to these protocols must be emphasized. Given that surgical masks are more readily tolerated than N95 masks, some consideration must be applied to the human factors decisions regarding PPE use. Few institutions stock adequate N95 masks to enable use for all patient encounters during influenza season.¹³ Reuse of N95 masks

versus the use of disposable simple masks must be balanced. Some simple masks provide excellent filtration of 3- to 5- μm particulate in bench testing and others are poor.¹⁴ Supply of N95 masks is delayed in many areas, and orders continue to pour in, many of which will not be filled until early winter. Complicating matters are inconsistent recommendations from the CDC, the World Health Organization, state health departments, and professional societies regarding adequate respiratory protection,^{15–17} evolving data about influenza transmission via the airborne route,¹⁸ and at least 1 regulatory challenge to standards differing from those of the CDC.¹⁹

Such factors must be given consideration, particularly when attempting to determine the best way to maximize staff protection. Health care worker and hospital staff compliance with recommendations for seasonal and nH1N1 influenza vaccine administration will be another important adjunct to these efforts. At the time of this writing, an H1N1 influenza vaccine is scheduled to become available in October in limited quantities, and more readily available soon after. Hospital administration will need to begin to prioritize who within its workforce shall receive access to this vaccine when it becomes available.

Government Guidance

Federal agencies working on pandemic influenza planning guidance, particularly the Department of Health and Human Services (DHHS), CDC, and the Department of Homeland Security, understand the implications that a severe resurgence of nH1N1 cases will have on the delivery of patient care. Efforts must be focused on the recognition that a spectrum of illness related to this influenza outbreak may stress the availability of key resources during the peak of the crisis. A mechanism for recognizing in real time that such stressors exist will be important, as will be the process for the allocation of scarce resources using sound ethical principles, under legal protections appropriate for the crisis conditions.^{20,21} Indicators that highlight the transition of conditions from conventional patient management to those under surge conditions may include both “saturation points,” such as hospital census, staffing availability, and critical resource availability (eg, ventilators), and the degree of disease burden in the community, as reflected in the daily number of ED visits and the daily number of admissions related to febrile respiratory illness.

Questions related to surge response and the operational issues related to the federal obligation (Emergency Medical Treatment and Active Labor Act [EMTALA]) requiring that all Medicare-participating hospitals with dedicated EDs perform a medical screening examination on all of the patients presenting to the hospital, regardless of their ability to pay, have recently been addressed by the Center for Medicare and Medicaid Services. In the worst-case pandemic scenario, an EMTALA waiver may be invoked under a joint Presidential declaration of disaster, with the Secretary of DHHS declaring a public health emergency. In the absence of such a waiver,

other options remain for EDs to manage surge under existing EMTALA requirements, including the establishment of alternative screening sites on the campus of the hospital, or at an off-campus, hospital-controlled facility. Communities that choose to set up influenza screening clinics at sites not under the control of a hospital can do so without the concern of having to meet EMTALA obligations for a medical screening examination.²²

WHAT ARE THE ISSUES THAT CONTINUALLY DROP TO THE BOTTOM OF THE PLANNING AGENDA, YET NEED ATTENTION NOW MORE THAN EVER?

A number of issues are vitally important to the long-term solvency of the health care sector, and may make or break any given hospital's chance of surviving a sustained pandemic event without experiencing financial collapse. Unlike the risk posed by the powerful hurricanes of the summers of 2005 and 2008, limited both by geography and duration, the greatest risk to hospitals in the setting of pandemic is the gale-force equivalent of an unrelenting demand on health care services in the setting of limited resources for weeks or months. As important as planning for these issues are, with rare exception, they remain mostly unfulfilled or incomplete elements of the comprehensive preparedness strategy needed to meet the challenges that a more severe strain of the novel H1N1 influenza may bring. Agreements with insurers and state medical programs for advance reimbursement during a pandemic, when elective surgery volumes may fall precipitously, are needed now, and should be a priority for state health and hospital association planners.

Continuity of operations planning, including consideration given to business interruption procedures may prove useful in the coming winter. Although such efforts are often geared to the catastrophic disaster event,²³ even mild disease in the community could result in significant disruptions to hospital business. In particular, school closures will affect hospital staffing significantly. So, too, will minor disruptions to the supply chain because hospitals continue to rely on just-in-time delivery schedules.

The emphasis in prior surge capacity planning documents and articles has been on the generation of inpatient care capacity.^{24–26} As witnessed in spring 2009, outpatient capacity may be a key constraint. Just as we have designed systems to be scalable and flexible to provide unconventional inpatient care (including use of alternate care sites), we must plan for all ambulatory care facilities (clinics, urgent care centers, and hospitals) to be able to maximize their capacities and minimize bottlenecks. This will include adaptive strategies that incorporate the use of clinic telephone systems, waiting areas, diminished paperwork, and rapid refill and prescription systems, to name but a few.

To accomplish this, there must be better cooperation and agreement between hospitals and public health about the operation of flu centers and alternate care sites in the com-

munity, including their location, governance and legal authorities, scope of operations and level of care delivered, resource and pharmaceutical support, and most important, staffing. These sites may have a care spectrum requiring vastly different supplies and staffing and there may be conflicting need for these sites among emergency management, public health, and health care.

Efforts focused on developing such an alternate care system, in which care is stratified among a number of levels of care beyond that delivered in the hospital—home health care, community-based care including the means for virtual (telephone or Web based) or real-time triage, and out-of-hospital care in designated alternate care sites—will be critically important to a successful community response. Such efforts will only be successful with meaningful engagement of the hospital community in converting such plans into actionable solutions. A working multiagency coordination group must be operationalized^{27–29} and able to make decisions about these types of sites on the spot during an event, using the little planning time remaining to ensure that plans for a spectrum of alternate care sites are in order.

Finally, although crisis standards of care have received significant attention^{30,31} in the past few years, most hospitals lack operational frameworks for clinical care committees to prioritize hospital operations during an event and do not have written guidance for triage decisions, tools, and teams. These frameworks have been described but must be in implementable form this fall and winter. Hospital coalitions must determine how they will provide the most consistent standard of care possible if usual care cannot be provided, and these systems must incorporate the following:

- A process by which the state codifies an adjusted standard of care and provides recommendations for triage
- Situational awareness from facility to state level
- Regional resource monitoring, requesting, and allocation agreements between partner facilities/coalitions
- State or regional plans to adopt triage tools for specific scarce resources (eg, ventilators)
- Legal protections for health care workers making triage decisions consistent with the above plans
- Participant and public stakeholder participation in the creation, adoption, implementation, and revision of such plans

Concern exists that even well-established plans may conflict with political decisions, and with decisions made in neighboring regions and states. Dialogue with political stakeholders and between states and bordering regions before discovering resource deficiencies is critical to ensure consistency when possible and clarity of differences when not possible. Indicators and triggers must also be defined and data systems tuned to be able to reflect them. These indicators may need to include outpatient volumes and other indicators not generally considered in surge capacity planning.

The Institute of Medicine³² generated a report in September 2009 at the request of DHHS, Office of the Assistant Secretary for Preparedness and Response, which summarizes key issues and action items around standards of care in a disaster situation, and stakeholder facilities and agencies may wish to review this report to ensure that their plans are consistent.^{20,33}

CONCLUSIONS

Hospitals in the United States have made many gains in the recent past in preparing for disaster in their community, and many communities have been tested along the way. What remains to be seen is how the hospitals will fare if one and all are stressed by waves of nH1N1 influenza cases in addition to seasonal influenza later this year. Have we taken the time and devoted adequate planning to outpatient surge capacity? Have we come up with realistic, operational plans for standards of care and triage in the setting of a disaster? Time is running out to answer these questions.

In the coming weeks, despite its relatively low pathogenicity, will nH1N1 be the mouse that roared?

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