

The Smallpox Vaccination Plan: Challenges and Next Steps

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Witness:

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Testimony:

Good morning, I am William Schuler, President and CEO of Portsmouth Regional Hospital, of HCA, Hospital Corporation of America. I would like to take this opportunity to thank Chairman Gregg, Ranking Member Kennedy, and others on the Senate Health, Education, Labor and Pensions Committee for providing me this opportunity to discuss with you the implications and concerns raised by the Federal Government's smallpox vaccination plan from the perspective of a community hospital.

Portsmouth, HCA and our trade association, The Federation of American Hospitals, fully support the Administration's decision to provide voluntary smallpox vaccinations for healthcare workers. We particularly applaud the Chairman, the Ranking Member and others on the Committee for their continued advocacy of voluntary vaccinations. There seems to be widespread recognition that proper implementation and safeguards will produce an environment where our nation's hospitals can provide the safest patient care and work setting for our patients, our employees and their families.

We believe that advanced voluntary vaccinations will provide the best protection to our providers in an identified smallpox outbreak, and will strengthen the ability of nurses, doctors and others throughout the nation to deliver the care that would be needed—care that would likely stretch for weeks and months following a smallpox epidemic. By vaccinating these core caregivers, we enable them to step forward with the assurance of their own immunity to provide this vital care.

Portsmouth's Role in Vaccinations

Portsmouth Regional Hospital, a 209-bed full service facility, is the seventh largest hospital in New Hampshire. In 1998, we served as one of the four facilities in the country chosen by the US Department of Justice to participate in Operation TOPOFF, a nationwide exercise to test healthcare preparation for mass casualties.

Under the President's smallpox vaccination plan, the Department of Health and Human Services (HHS) will work with state and local governments to form volunteer Smallpox response teams comprised of healthcare workers and first responders. Understandably, much of the efforts have filtered to the hospital level. As I describe how this vaccination plan is proceeding, I will highlight the critical issues facing a community hospital, how we are handling them, and where we feel further guidance and assistance is needed.

These issues include: 1) Staffing;

2) Treatment of vaccine-related adverse effects; 3) Communication, Planning and Funding;

4) Liability and Compensation; and 5) Regulatory Requirements.

Allow me to begin by describing the stages of the vaccination initiative:

Pre-Event Preparations

Stage I

Step 1 – One “pilot” clinic that will consist of a very small group of clinical individuals from two hospitals in the central region of the state, as well as five to seven members of the Public Health department vaccination team. (Imminent)

Step 2 – Five or six vaccination clinics at sites that have not yet been designated.

Approximately forty core, prescreened healthcare workers from Portsmouth Regional Hospital will be vaccinated at this time, twenty nurses and twenty physicians. (March)

Stage II – Vaccinations will be offered to all healthcare workers, EMS, First Responders, including Firefighters and Police. We are not aware of any policy or guidance from any level of government on this step or how many workers will be vaccinated. (End of summer if plan progresses)

Stage III – Vaccinations will be offered to General Public. Public would, at that time, receive vaccine from their primary care providers.

Post-Event Preparations

Community Clinics – A collaborative effort led by the state Office of Emergency Management (OEM), facilitated by a community team of Fire, Police, State Department of Health and Human Services employees, and hospital representatives. This team is charged with the formulation of a workable plan in which vaccination of an entire community, consisting of fifty to one hundred thousand people in our catchment area could be achieved in ten days following a smallpox outbreak in the United States.

At Portsmouth Regional Hospital, recruitment of volunteer physicians and clinical staff, including nurses, radiology technologists, respiratory therapists, and others began in our facility in mid-November, 2002. Physicians were the first to be invited to a classroom-style presentation by the Chief of Staff, Infectious Disease Physician, Infection Control Practitioner, Emergency Room Medical Director and myself. The physicians assumed the leadership role in the development and implementation of the voluntary vaccination plan. Educational booklets and volunteer rosters were distributed to the 150 physician attendees. Approximately twenty-five physicians volunteered immediately. A similar presentation was offered the following week to hospital nursing and ancillary staff, as well as staff from physician offices, local nursing homes and visiting nurse associations. An additional thirty clinicians were added to the volunteer roster. From our volunteer roster, we arrived at a core group of forty providers for Stage I vaccination, all from the hospital's Inpatient and Emergency Department staff. These volunteers were chosen because they had previously been vaccinated against smallpox, screened for contraindications and provided with additional educational resources. In March, we anticipate that this core staff will visit area clinics at staggered intervals to receive the vaccination.

Staffing

As the smallpox vaccination process proceeds into Stages II and III, Portsmouth faces increasing medical and staffing challenges. According to a study recently reported on by the CDC, 36% of adults receiving the vaccine for the first time will likely be sufficiently ill to miss work, school, or recreational activities or have trouble sleeping. Nationwide, this amount of absenteeism, superimposed on winter illnesses and a critical nationwide nursing shortage, will surely exacerbate an already tenuous staffing shortage. Provisions must be allowed for staggered vaccination schedules of clinical staff to ensure support of

normal hospital operations. Although our core team of forty staff has all previously received the smallpox vaccine without complications, we anticipate that approximately ten employees may require some time away from their duties. At this stage, we should be able to cover this level of absenteeism without impacting patient care. However, in future stages, as additional staff members are vaccinated, including those who have not had the vaccine before, these staffing issues will become of major significance.

According to the CDC guidelines, hospital responsibilities include not only program education, screening for contraindications, and identification of healthcare workers to be offered vaccine, but also daily vaccination site assessment and management, and evaluation of 'takes'. Such site assessment means that hospitals must provide daily staffing for a twenty-one day vaccine site assessment clinic. At this stage of vaccinations (Stage I) at Portsmouth, we would likely be able to absorb the financial and staffing burden. However, such a burden might not be so easily managed in a much larger hospital with a much larger pool of vaccinees.

Furthermore, in a Stage II setting, when a greater number of healthcare workers, EMT's, firefighters and police are vaccinated, the logistics for staffing, education, site care, assessment and record keeping will require state and federal support. They are not activities that a local community hospital can absorb with existing staffing. Consideration for extra funding to State Public Health departments would enable them to play a much greater role than we have seen to date in education, screening and post-vaccination site care, and will ease the vaccination-related staffing issues which are currently expected to be shouldered by the hospitals.

Treatment of Vaccine-Related Adverse Effects

If and when mass vaccination (Stage III) within the community occurs, it is important to recognize that community health care systems will be severely stressed. Using published rates of vaccine related complications, the 50,000 vaccinees in our designated service area could potentially lead to 5,000 office visits and up to 500 hospital admissions -- an untenable demand for a medical community and a 200 bed hospital like our own. We anticipate the need to coordinate a system where specialists would help in the evaluation of the more severe vaccine reactions, discussing and coordinating homecare for all but the most ill. This system has been discussed at a State level in theory only, but has yet to be developed. We will hardly be unique in this regard. Mass vaccination will create a volume of ill patients that in most communities will be unprecedented and profoundly difficult to manage.

Communication, Planning and Funding

Major issues remain regarding communication and division of labor. Communication between the State OEM and local emergency personnel has been sub-optimal. In the early stages of Community Clinic planning, local emergency personnel (fire and police) were not adequately informed about the CDC vaccination plans, or their responsibilities in such a plan. Initially, hospital and community responsibilities were stated to be quite limited. As planning unfolded, responsibilities originally assigned to the OEM were given to the hospital and community.

We have communicated this issue to State leaders, and have learned that the New Hampshire OEM, like many other states in the country, has received no additional

funding from FEMA. The New Hampshire OEM remains funded only through the Bioterrorism Grant and the New Hampshire Department of Health and Human Services. At a time when state and municipal budgets are already stressed, there is an understandable reluctance to take on additional responsibilities without funding. Furthermore, as is happening nationwide, New Hampshire is looking for millions of dollars in cuts from the Department of Health and Human Services in order to balance the State's budget. As a result, the state's OEM is relying too heavily on the staffing resources at a local hospital level for planning and initiation. In order to strengthen overall post-event planning, the State OEM requires additional funding, staffing, and resources.

Liability and Compensation

We, as a nation, must ensure that healthcare workers are protected from personal expense and lost wages as a result of adverse reaction to voluntary vaccination. Initially, hospitals and affiliated organizations, such as physician offices, had significant concerns about their protection from liability in the case of adverse outcomes from vaccination, or the rare, yet potentially devastating, inadvertent spread of the vaccinia virus to other healthcare workers or patients. We understand and appreciate the recent clarification of Section 304 of the Homeland Security Act that appears to have resolved many of these liability concerns. The guidance clarified that a hospital participating in the vaccination program is a covered entity, regardless of where its smallpox response team is vaccinated. The declaration goes a step forward by clarifying that all members of a participating hospital's team are covered, whether employees or not, such as non-employed medical staff.

However, further clarification of liability may be needed on the "scope of employment" issue. Specifically, it is not clear if the current guidance provides protection for vaccinated persons who inadvertently, and outside of the scope of one's employment, spread the infection caused by the smallpox vaccine outside the participating hospital. We look forward to working with the Congress and the Administration to achieve the full protection intended under Section 304.

Significant concerns also remain regarding first party compensation claims for health care workers and first responders. The only avenue to address compensation as a result of illness, under current law, would be through State Workers' Compensation Law, which provides coverage after three days of vaccine-related absence. However, since the vaccination is voluntary, and not a condition of employment, it remains unclear whether this would be an option for our employees. Furthermore, our hospital does not feel that our volunteer health care workers should be asked to absorb the first three days of absence from their own sick leave banks, nor should hospitals be responsible for payment of this sick time directly. In addition, not all private practice physicians subscribe to workers' compensation. Therefore, we would suggest that Congress develop an additional fund, similar to the National Vaccine Injury Compensation Program, to ensure that no volunteer health care worker goes without compensation due to smallpox vaccine-related complications. Providing such compensation would help us significantly in the recruitment of additional health care workers.

Regulatory Requirements

Finally, in a time of national emergency requiring the implementation of mass immunizations, health care resources will be severely strained. In these limited circumstances, certain aspects of current healthcare laws and regulations may not be in the best interest of the patients and health care workers in our hospitals.

For example, in response to anthrax exposures occurring in Florida, New York, Washington, D.C. and other states, some state departments of health issued directives regarding the handling of patients who feared they had been exposed to anthrax or other biological agents. One hospital was instructed to put a sign outside of the emergency department directing patients to an alternative site. In another instance, a state health department told asymptomatic patients who feared anthrax exposure that they did not need medical screening until laboratory results from source letters or packages were received. As you know, EMTALA requires hospitals to provide medical screening to all patients requesting medical treatment. In the event of mass vaccinations or potential smallpox exposures, hospital emergency departments could be overwhelmed by the “worried well.” Any hospital following the recommendations in the two examples above would have been subject to potential liability under EMTALA.

In addition, when hospitals are coping with mass vaccination clinics and the potential complications generated, the completion of the usual complement of hospital forms such as notices of HIPAA privacy rights and Advance Beneficiary Notices may not be possible or practical. We hope that the committee will consider how to mitigate the consequences of these regulatory dilemmas in a time of national crisis.

Conclusion

In closing, I would like to commend the Committee for its commitment to the safety and well being of first responders and their families. Portsmouth Regional Hospital, HCA and the Federation of American Hospitals look forward to working with the Committee to implement the Administration’s voluntary smallpox vaccination plan.

I would like to emphasize four key points--first, as the immunization program progresses to Stage II and Stage III, staffing shortages are likely to become particularly acute. Extra funding to State Public Health departments would enable them to play a much greater role than has been seen to date in education, screening and post-vaccination site care, and will ease the vaccination-related staffing issues which are currently expected to be shouldered by the hospitals. Second, further clarification on hospital liability as it pertains to “scope of employment” issues may be necessary. Third, Congress should consider developing an additional fund, similar to the National Vaccine Injury Compensation Program, to ensure that all volunteer health care workers have access to compensation in the event of smallpox vaccine-related complications. Fourth, although not the primary focus of today’s hearing, Congress may want to review the consequences, in limited national emergency circumstances, of regulatory issues such as EMTALA and completion of the paperwork requirements for HIPAA and Advanced Beneficiary Notices.

Thank you for providing me this opportunity to testify. I will be happy to answer any questions the Committee may have.