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POLICY FORUM

Smallpox Vaccination: National Security and Individual Risk

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Last year's dramatic season finale of *ER* brought smallpox into the living rooms of many Americans, highlighting the role of emergency physicians as first responders in the event of a bioterrorist attack.

Emergency physicians, more so than members of other specialties, are expected to respond to natural and man-made disasters in part because the Code of Ethics of the American College of Emergency Physicians (ACEP) puts forth a duty to respond to out-of-hospital emergencies and disasters as one of the central tenets of the emergency physician's relationship with society.¹

The ACEP reacted to the fictional TV series, *ER*, suggesting in a press release that real-life physicians are not adequately trained to respond to a smallpox outbreak. This may soon change, and it will begin with physicians around the country receiving the smallpox vaccine.

In September 2002 the Centers for Disease Control and Prevention (CDC) released its most up-to-date Smallpox Response Plan and Guidelines.² These guidelines along with later supplements were set forth to serve as the basis for all states' emergency response plans in the event of an actual smallpox outbreak.

All US states and territories were then asked to submit their individual guidelines for responses to a bioterrorist attack, including plans to vaccinate emergency responders prior to an actual smallpox case. The CDC announced on December 12, 2002 that it would offer the smallpox vaccine in January 2003 to about 450,000 designated emergency responders based on the plans submitted by each state, and to the 500,000 military and other government personnel designated by the Departments of Defense and State. The Bush administration has said "emergency, health care workers and other personnel will be asked to *volunteer* to receive the smallpox vaccine" [emphasis added] as part of Smallpox Response Teams.³ On January 24, 2003 this vaccination program "sputtered to a start" with 4 out of the 20 eligible doctors in Connecticut receiving the vaccine.⁴

According to recent teleconferences between the press, the CDC, and the Department of Health and Human Services (DHHS), the government expects to offer the vaccine to another group of about 10 million people made up of health care workers, police, firefighters, and other emergency responders in the spring of

2003. The vaccine will be made available to the public at large in 2004, or earlier for those who choose to enroll in clinical trials.

This will take place even in the absence of a single case of smallpox but amidst valid, thoughtful criticism. Various organizations (American Hospital Association, American Public Health Association, Institute of Medicine, ACEP, Service Employees International Union, American Federation of State, County and Municipal Employees) have raised a host of objections to the government's plans, which will directly affect emergency physicians.⁵⁻⁸ The American Medical Association took a stance in favor of the June 2002 Advisory Committee on Immunization Practices' recommendations to the CDC to vaccinate a specific group of health care workers and emergency responders but has not voiced an opinion on the CDC and DHHS's current plan of staged, mass vaccination.⁹ Of real concern to the public, and to health care workers especially, are the serious adverse reactions that, in the past, have affected 1,000 people for every million vaccinated. Another 14 to 52 people had life-threatening adverse reactions, with 1 or 2 deaths per 1 million people vaccinated.¹⁰

For a various reasons there will likely be more adverse reactions to the smallpox vaccine now than in the past. Because smallpox vaccination of the American public was discontinued in 1972, there is near-zero immunity to the vaccinia virus among today's unvaccinated population and an unknown residual immunity in previously vaccinated individuals.¹¹ More people today have contra-indications for the vaccine than in the past. There are more immuno-compromised individuals, (cancer patients, organ transplant recipients) including an estimated 300,000 people in the United States who do not know they are HIV-positive, and a higher incidence of eczema (another contraindication for the vaccine).¹¹

In the face of possible mass vaccination over the next year, many groups have raised questions about compensation for individuals who receive the smallpox vaccine and experience mild to fatal adverse reactions.⁵⁻⁷ Under section 304 of the Homeland Security Act, individuals can sue the federal government for compensation but they would have to prove negligence on the part of an individual or entity that administered the vaccine.¹² Outside of this narrow and unlikely case, doctors and others who receive the vaccine, experience adverse effects, and seek compensation will have to get assistance from their own health insurance plans and the state's workers' compensation plan.¹² Compensation will differ from state to state or from one insurance plan to another, and the payments will put an additional strain on already tight health insurance and state budgets.

Although the idea of a "no-fault" compensation fund like the Children's Vaccine Injury Fund has been suggested, the Secretary of the Department of Health and Human Services, Tommy Thompson, has said "there is no legislation being drafted or has ever been discussed" that offers broader federal compensation.

With a worrisome number of adverse reactions expected, the ACEP points out that "putting even a small number of MDs and RNs out of work on a short-to-middle-term basis without proper safeguards or compensation, could destabilize our entire emergency care system." Groups have asked for the government to offer reinforcement to the health care system and a more staggered vaccination plan, which would permit health care workers more time to recover from adverse reactions, minimizing understaffing crises in hospitals.⁵⁻⁷ Thus far no such amendments to the federal plan have been made public.

Although the choice to receive the vaccine is voluntary and only advised by the government for the designated emergency responders, the question "how voluntary is voluntary" has been raised. Cheryl A. Peterson, RN, a senior policy fellow at American Nursing Association, suggests that being vaccinated might become a condition of employment in high-risk situations such as working in a major urban hospital emergency room.¹³

Will there be repercussions for doctors who refuse to receive the vaccine? Would a doctor have to disclose a reason for vaccine refusal, explaining, for example, that the doctor or a family member is HIV-positive, or undergoing chemotherapy, or just doesn't want to take the risk?

Although the IOM and many other professional health organizations support some type of precautionary smallpox vaccination plan, they are calling for more cautious and prudent decision making by the federal government. Many of their concerns are not being addressed as the CDC dodges questions from the press. In a recent teleconference, for instance, the CDC refused to talk about the number of hospitals that chose not to participate in the government's plan.

Dr. Julie Gerberding, director of the CDC, responded to concerns expressed in the recent IOM review of the CDC's plan by saying "we respect the input... but the point is the program needs to go forward."¹⁴ When asked by *Los Angeles Times'* reporter what was behind the recent pleas for a slower vaccination process, Dr. Gerberding responded "We do not appreciate a groundswell of requests to delay or stop this program.... This is an issue of homeland security and an issue of national defense."¹⁴

It is also an issue that has become highly politicized, with homeland security rhetoric usurping public health considerations. The IOM, an independent organization and a branch of the National Academy of Sciences, points out that the current safety monitoring arrangement for the vaccination program is made up of 2 government organizations, the CDC and the Department of Defense. Of particular concern is "a perception that the scientists overseeing the actual data on safety... are not actually independent of those setting or overseeing policy."¹⁵

The Bush administration appears to be moving ahead as planned. As of January 28, 2003, 35 states and 1 county had requested the shipment of the smallpox vaccine.

The CDC has already shipped out at least 98,600 doses.¹⁶ It will now be up to emergency responders to decide whether to receive the vaccine for the public good, and at their own risk, without being told what the likelihood is of a smallpox attack. And doctors, many of them emergency physicians, will be among the first to make that difficult decision.

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