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Smallpox vaccine: Mandating risk to ward off an old enemy?

By **Jay C. Weaver, JD, EMT-P**, Boston Public Health Commission Emergency Medical Services; Adjunct Faculty, Northeastern University, Boston.

By implementing a national smallpox vaccination program on Dec. 13, 2002,¹ President George W. Bush launched the first vaccination campaign undertaken in the interest of national security rather than public health.² He also sparked public debate about a program that bears potential safety and risk implications for medical professionals, emergency personnel, and the public.

Under this program, the federal government initially will require immunization only of those individuals most likely to come under biological attack, such as military personnel and embassy personnel serving overseas.³ Later, the government will administer vaccinations on a voluntary basis to medical professionals and emergency personnel.⁴ The president also suggested in his address that smallpox vaccine soon will become available to all Americans who insist on immediate immunization.⁵

These developments carry tremendous legal implications. In the months to come, courts undoubtedly will struggle to define the circumstances under which the government may compel smallpox vaccination. At the same time, individuals excluded from the initial round of vaccinations likely will sue to demand protection. The chosen method of vaccine distribution already has generated controversy in both the medical and legal communities.⁶ These issues will become even more compelling should a smallpox outbreak actually occur.

New Concerns About an Old Disease

Before it was eradicated, smallpox was a highly infectious and sometimes fatal viral infection. Characterized by fever and a rash that causes scarring and pitting, it has been mentioned frequently in recent years as a potential weapon of terrorism.⁷

Outbreaks of smallpox have occurred from time to time for more than 3000 years.⁸ Prior to the 18th century, epidemics occurred so frequently that practically

everyone in the world eventually contracted the disease.⁹ Most of these outbreaks involved variola major, or “the speckled monster,” as it was known in England.¹⁰ By the end of the 19th century, however, a milder form of the disease, variola minor, had spread from South Africa to Florida, throughout the United States, into Latin America, and back across the Atlantic to Europe.¹¹

The earliest attempt to combat smallpox consisted of a practice known as “variolation.” By intentionally exposing healthy individuals to the pus or powdered scabs of minimally ill smallpox patients, Asian physicians in the 1600s discovered that they could create immunity without the serious effects of the naturally occurring illness. This practice later proved successful in slowing the spread of smallpox in Europe and the American colonies.¹²

The real breakthrough in smallpox prevention occurred nearly a century later, however, after rural farmers observed a link between exposure to a bovine

illness and smallpox immunity. English physician Edward Jenner demonstrated in 1796 that the injection of a healthy individual with fluid extracted from the cowpox lesion on a milkmaid’s hand created immunity against smallpox. From this experiment, the modern practice of vaccination arose.¹³

In 1967, the World Health Organization (WHO) launched a 10-year global smallpox vaccination campaign. The last infection from person-to-person contact occurred in Somalia in 1977, and WHO declared the disease eradicated three years later.¹⁴ Vaccination of civilians promptly ceased everywhere, and by 1990, the United States had stopped vaccinating its military personnel, as well.¹⁵

Even as the process of vaccination was winding down, WHO warned that the continued storage of smallpox virus in research laboratories could lead to another epidemic.¹⁶ An expert committee recommended in 1980 that laboratories destroy their variola stocks or transfer them to one of two “reference laboratories” located in Russia and the United States.¹⁷ The WHO executive board later recommended the destruction of all smallpox samples, but concern that this would forever preclude additional smallpox research led to several extensions of the compliance deadline. The most recent deadline, which called for the elimination of all smallpox samples by the end of 2002, has been suspended indefinitely in response to the Sept. 11 terrorist attacks and recent anthrax incidents in the United States. Fearful that terrorists already have obtained the variola virus and smallpox soon might be employed as a bioweapon, WHO has decided that existing samples should be retained, at least temporarily, for use in developing more effective vaccines.¹⁸

Other reasons exist for the growing concern about the potential misuse of existing variola stocks. After defecting in 1992, a former deputy director of the Soviet Union’s civilian bioweapons program, Ken Alibek, revealed that the Soviet government had produced smallpox virus in large quantities for use in bombs and intercontinental ballistic missiles, and that Russia has attempted to create more virulent and contagious strains of variola.¹⁹ Even today, Russia maintains an industrial facility capable of producing tons of smallpox virus annually.²⁰ Dwindling financial support and security problems at Russian laboratories have raised concerns that some of this material might fall into the hands of terrorists.²¹

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Equally troubling is a recent Central Intelligence Agency (CIA) assessment that four nations — Iraq, North Korea, Russia, and France — possess covert stocks of smallpox virus.²² Only two facilities — the Centers for Disease Control and Prevention (CDC) in Atlanta, and the State Research Centre of Virology and Biotechnology in the Russian city of Koltsovo — have received authorization to maintain stocks of smallpox virus.²³ All other nations reported by 1983 that they no longer possessed such material.²⁴ Yet an official at the CIA's Weapons Intelligence, Nonproliferation, and Arms Control Center recently described the quality of information regarding these undisclosed variola stocks as ranging from “medium” to “very high.”²⁵

The same intelligence review also concluded that the man accused of masterminding the Sept. 11 attacks, Osama bin Laden, recently devoted money and personnel to the procurement of bioweapons, including smallpox. While a Bush administration intelligence official said that there was “no reason” to believe that bin Laden had succeeded in acquiring lethal pathogens, the attempt alone underscores the potential for bioterrorism in the future, as well as the urgent need to prepare defenses against it.²⁶

The Disease and its Management

When it existed, smallpox had no specific treatment and was prevented effectively only through vaccination.²⁷

The more severe and common form of the disease, variola major, produced a two- to three-day prodrome of fever, malaise, headache, and backache.²⁸ Severe abdominal pain and delirium sometimes accompanied these signs.²⁹ A milder form of the disease, variola minor, produced a lower fever, a less extensive rash,³⁰ and fewer constitutional symptoms.³¹

Smallpox derives from a Latin word for “spotted.” Its name refers to the raised rash that served as the true hallmark of infection. This rash appeared first in maculopapular form, then progressed to papules, vesicles, pustules, and finally, by about the 14th day, to scab lesions. Smallpox rashes generally arose first on the oral mucosa, face, and forearms, before spreading to the trunk and legs. Lesions created by smallpox rashes have been described as feeling like “firm round objects embedded in the skin.” As the scabs separated from the dermis, they left behind pitted scars.³²

Beyond the skin, mucosa, and reticulum cell hyperplasia, other organs seldomly were affected.

Secondary bacterial infection occurred only rarely. Death, which generally resulted during the second week of illness, probably resulted from toxemia associated with circulating immune complexes and antigens.³³ Overall, the disease carried a mortality rate of approximately 30%, though a rare hemorrhagic strain of the disease carried a mortality rate of approximately 96%.³⁴

Transmission during the smallpox era always involved some type of person-to-person contact. Animals and insects could not spread the disease. Infection generally occurred via the direct deposit of infective droplets onto mucosal membranes or into the alveoli as a result of close, face-to-face contact with an infected individual. Indirect spread through fine-particle aerosols occasionally was reported, however.³⁵ Infected individuals sometimes became contagious with the onset of fever, but the most contagious period coincided with the onset of rash. Infected individuals ceased to be contagious once the scabs fell off.³⁶

Because smallpox can spread so rapidly, emergency department (ED) personnel must learn to become diligent in their detection and reporting of the disease. According to Donald A. Henderson, the public health expert who led the fight to eradicate smallpox,³⁷ “[t]he discovery of a single suspected case of smallpox must be treated as an international health emergency and be brought to the attention of national officials through local and state health authorities.”³⁸

Suspected smallpox patients must be isolated immediately to limit the exposure of nonimmune individuals. These patients should receive care only from personnel who have received the smallpox vaccine and have demonstrated an immune response. Health care providers should observe universal precautions and should wear protective garments to maximize the likelihood of containment within the designated isolation area. Bedding and linen used by infected patients should be autoclaved. Contaminated surfaces should be cleaned with disinfectants such as hypochlorite or quarternary ammonia. Unless the entire facility has been restricted to smallpox patients and vaccinated individuals, negative air-pressure rooms with high-efficiency particulate air filtration should be employed.³⁹

Definitive treatment for smallpox does not exist. Antiviral agents have not proven effective. Management of future smallpox outbreaks, therefore, will consist of supportive care, combined with occasional antibiotic therapy for secondary infections when indicated.⁴⁰ The CDC has reported that vaccination

may prevent or lessen the severity of symptoms when administered within three days after exposure. Vaccination administered four to seven days after exposure may afford a lesser, yet still significant, measure of protection.⁴¹

Vaccination: Effectiveness and Controversy

Vaccination represents the only proven method of preventing smallpox. Because the new vaccination program seeks to protect Americans only against a potential threat, however, and not against an existing disease, its implementation has sparked significant controversy.⁴²

Vaccine approved for use in the United States does not contain variola virus. Rather, it consists of live vaccinia virus, an orthopoxvirus that stimulates the production of antibodies that fight smallpox.⁴³ The federal government claims to have enough of this vaccine to protect every American who might need it. Eventually, the government hopes to replace vaccinia with a safer, reformulated vaccine.⁴⁴

While the vaccine held by the United States government contains no variola, and therefore cannot cause smallpox, it is by no means a benign formulation. For every million recipients of the vaccine, one or two die, usually as a result of progressive vaccinia, postvaccinal encephalitis, or eczema vaccinatum.⁴⁵ Other complications include fever, malaise, and swollen arms and glands. One out of three recipients feels sick enough to stay home at least one day from work or school. One in every 1000 sustains an allergic rash, a widespread vaccinia rash, or “inadvertent inoculation” — spreading of the vaccinia virus from the injection site to other parts of the body through injudicious touching.⁴⁶

Researchers have identified several groups that are likely to develop postvaccination complications. At-risk groups include individuals with a history of eczema or other forms of chronic dermatitis; any one with a compromised immune state, including those infected with HIV, those suffering from AIDS, leukemia, or lymphoma; and those taking immunosuppressive medications. The CDC does not recommend the routine pre-exposure vaccination of pregnant women or children younger than 1 year of age. Should any of these individuals have a genuine risk of contracting the disease — as, for example, when a bioterrorist attack with variola actually has occurred, as opposed to simply being threatened — the clinician

will have to balance the potential benefits of immunization against the relative contraindications of the vaccine. Vaccinia immune globulin (VIG) has proven effective in limiting some postvaccinal complications. The government currently possesses only limited supplies of this preparation, however.⁴⁷

The Bush administration has touted vaccinia as a “safe vaccine.”⁴⁸ At the same time, some experts have denounced it as “the most dangerous of all immunizations.”⁴⁹ This divergence of opinion has left the public confused over the wisdom of accepting vaccination. Many Americans feel that the vaccination itself poses a greater threat to their health than a bioterrorist act that might never occur.⁵⁰ Still, a poll conducted in November 2001 suggested that more than half of all Americans would want to be vaccinated if given the opportunity.⁵¹

Even health care professionals cannot reach a consensus regarding the utility of smallpox vaccination. Two of the most prestigious teaching hospitals in the nation, Grady Memorial Hospital in Atlanta and Virginia Commonwealth in Richmond, announced less than a week after the president unveiled his vaccination plan that they would not inoculate their staffs.⁵² A June 2002 poll revealed that 91% of the members of the Association of State and Territorial Health Officials opposed any plan that would entail vaccination of the public before the onset of a biological attack.⁵³ Some health care and emergency workers who will have the opportunity to become inoculated ahead of the general public seem eager to accept vaccination, while others have stated publicly that they will refuse it.⁵⁴

Leadership of the nation’s largest health care union, the 1.5 million-member Service Employees International Union, wrote the Bush administration on Jan. 16 to urge more research into protections for workers and patients before vaccinations begin.⁵⁵ On the same day, the American Federation of State, County, and Municipal Employees (AFSCME), AFL-CIO urged a delay in implementing the vaccination plan until the program addresses concerns including the use of safety-designed needles to protect those administering the smallpox vaccine and safeguards to prevent employers from improperly coercing employees to receive the vaccine.⁵⁶

Debate has erupted, too, over the method the government has selected for distributing the vaccine. The president’s plan establishes a four-phase inoculation process for the nation. The first phase — mandatory vaccination of military personnel — began at Walter

Reed Army Medical Center in Washington, DC, on Dec. 13, 2002. The second phase began in January 2003, when the Bush administration encouraged 429,000 civilian emergency workers to accept voluntary vaccination within a period of about 30 days. The government will then extend the program to a broader group of about 10 million health care workers. Finally, in late spring or early summer of 2003, vaccination will become available to any American who insists on receiving it.⁵⁷

The incremental nature of this vaccination program represents a compromise between those who favor universal immunization and those who have advocated a “wait-and-see” approach.

At present, the CDC has no plans to respond with blanket vaccination even in the event of a genuine smallpox outbreak. Instead, smallpox response teams will employ “ring vaccination.” Public health officials will attempt to contain the spread of the disease by identifying and isolating those who have been infected, and by tracing and vaccinating all contacts of those individuals.⁵⁸ Some authorities have criticized such measures as ineffective.⁵⁹

Adding to the confusion is the fact that a substantial number of Americans cannot be certain of their immune status. Prior to 1972, state and federal governments required inoculation of military recruits, immigrants, American tourists traveling abroad, and most children attending public schools. Few of these individuals have received additional smallpox vaccinations since that time. Studies have shown that smallpox immunity diminishes over time, but the precise rate of decrease has not been established. Individuals who received vaccinations during the smallpox era, therefore, may remain somewhat resistant to the disease, or they may not have retained any immunity at all. This uncertainty makes the choice between accepting and rejecting voluntary inoculation even more difficult than it otherwise would be.⁶⁰

Legal Implications for EDs and Practitioners

The Bush administration’s smallpox vaccination program calls for state health departments to establish vaccination clinics under the guidance of the CDC.⁶¹ The number and location of these clinics will be determined by the states, subject to CDC approval.⁶² Some of these schemes may call for the utilization of EDs as vaccination sites, and for this reason ED administrators should possess a working knowledge of the vaccination

process and its associated liability risks. Even in states where public pre-exposure vaccinations will be administered solely by state public health personnel, EDs eventually may need to vaccinate their own employees. In any event, EDs must be prepared to administer smallpox vaccinations in the event of an actual bioterrorist attack.

Even now, with the national vaccination program just gaining momentum, the potential for legal action looms. The military already has begun inoculating its personnel, and this alone may create fertile ground for lawsuits. Unlike civilian medical and emergency personnel, who for now are being asked to accept smallpox vaccinations selectively and voluntarily, members of the armed forces deployed to high-risk regions must submit to compulsory vaccination unless a medical contraindication exists.⁶³ During the 1990s, hundreds of U.S. military personnel who refused vaccination against anthrax were court-martialed, discharged, or forced to resign.⁶⁴ This raises a significant legal issue: Can the federal government mandate smallpox vaccinations? Faced with an imminent biological attack — or, worse yet, in the aftermath of a smallpox outbreak — would the president have the power to order inoculation of the entire American population? If this happens, and the president lacks the necessary constitutional authority, EDs and personnel who participate in the smallpox vaccination program could risk civil liability by administering vaccine to unwilling recipients.

In a line of decisions dating back to the 1905 case of *Jacobson v. Massachusetts*, the U.S. Supreme Court has held that state governments possess the power to compel vaccinations as a means of protecting the public health. In *Jacobson*, an individual who had run afoul of a local ordinance mandating smallpox inoculation disputed the authority of a government entity to impose such a requirement. The appellant objected to the regulation on a number of grounds, the most innovative of which pertained to the very nature of vaccination. Introducing disease to a healthy population in the form of a vaccine, he argued, constitutes a violation of liberty, and potentially of the right to life as well. The Court rejected all of these contentions, holding that “a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” and, moreover, that state authorities must “not permit the interests of the many to be subordinated to the wishes or convenience of the few.”⁶⁵

The *Jacobson* ruling comported with previous high court decisions establishing the authority of the states to promulgate regulations for the protection of the health and safety.⁶⁶ This so-called “police power” encompasses the enactment of reasonable quarantine laws and “health laws of every description.”⁶⁷ The court has held that compulsory vaccination is a proper exercise of this power,⁶⁸ and, furthermore, that the various legislatures — rather than the courts — should determine whether compulsory vaccination constitutes an appropriate method of controlling an infectious disease.⁶⁹ The passage of time and the eradication of smallpox have not diminished *Jacobson’s* significance. To the contrary, courts in various jurisdictions have relied on *Jacobson* dozens of times in recent years.⁷⁰

One might argue that a distinction exists between the smallpox vaccination programs of the past, which served to control the spread of an existing disease, and the recently initiated smallpox prevention program, which has been launched as a defense against a nonexistent illness. Indeed, members of the Bush administration have made no secret of the fact that this program may prove more useful as a deterrent to bioterrorism than as a public health measure.⁷¹ Still, the utility of such a program in protecting the nation’s health in the face of a potential epidemic — whether naturally occurring or man made — cannot be disputed, and for this reason the courts likely would view it as a “health law” that falls within the purview of state police power.⁷²

So far, the President has ordered mandatory vaccination only for members of the armed forces. This represents a valid exercise of his constitutional power as commander in chief.⁷³ Whether the president possesses the authority to compel the general population to submit to inoculation remains less clear.⁷⁴ Since each state possesses the power to require vaccination of its citizens, and since the federal government cannot compel states to enact or enforce a federal regulatory program,⁷⁵ the imposition of a federally mandated vaccination plan may require congressional action — something that by itself may be viewed as an attempt by Congress to overstep the bounds of its pre-emption power.⁷⁶ Thus, the federal government may have to rely on each state to enact the necessary legislation. The structure of the CDC’s Smallpox Response Plan reflects this reality, in that the CDC plans to mobilize local and state public health resources in the event of a smallpox outbreak, rather than assuming direct federal control.⁷⁷ Regardless of the source of the order,

however, one may reasonably conclude that the government — at one level or another — possesses the authority to mandate vaccination, and that ED personnel who administer smallpox vaccine as agents of the government have little to fear in the way of liability on constitutional grounds.

Should smallpox vaccination become compulsory, a number of Americans surely will resist because of their religious convictions. Decisions in numerous jurisdictions upholding childhood vaccination as a prerequisite to public school attendance suggest that religious objection will provide no defense to a constitutionally enacted universal vaccination requirement. In *Cude v. State*, for example, the Arkansas Supreme Court upheld the right of the state to compel childhood vaccinations over the religious objections of parents, reasoning that “anyone has the right to worship God in the manner of his own choice, but it does not mean that he can engage in religious practices inconsistent with the peace, safety, and health of the inhabitants of the state.”⁷⁸ Similarly, in *Anderson v. State*, the Georgia Court of Appeals held that a person’s right to religious freedom ceases where it “overlaps and transgresses the rights of others” to defend against dangerous illnesses. “Liberty of conscience is one thing,” the *Anderson* court commented. “License to endanger the lives of others by practices contrary to statutes passed for the public safety and in reliance upon medical knowledge is another.”⁷⁹

A handful of judicial decisions have recognized parental religious objection as a valid defense to childhood vaccination requirements, but nearly all of these decisions arose from the interpretation of a single controversial New York statute.⁸⁰ Unlike the compulsory vaccination statutes of virtually every other state — which do not by their language provide religious exemption from compulsory childhood vaccination — New York Public Health Law § 2164(9) expressly exempts from vaccination those who object for religious reasons. For many years this statute required “bona-fide membership in a recognized religious organization” to qualify for exemption from the state’s vaccination mandate.⁸¹ In 1987, however, the Eastern District of New York announced that this provision violated the First Amendment,⁸² and the state legislature subsequently amended the statute to extend protection to anyone who evidences “genuine and sincere religious beliefs which are contrary to the practices” required under the law.⁸³ Courts in three other jurisdictions — Florida, Michigan, and Wyoming — have ordered

government entities to respect religious objections to school-related immunization requirements, but these cases are distinguishable in that each decision turned not on the merits of religious objection, but rather on the relevant government entity's lack of statutory authority to issue the regulation.⁸⁴

Despite the reluctance of the courts to acknowledge religious exemptions to compulsory childhood vaccination, some jurisdictions have held that the government may not inquire into the sincerity of the parents' religious beliefs. In *Department of Health v. Curry*, for example, the Florida District Court of Appeals recognized the validity of a statute requiring the immunization of school-aged children, while at the same time holding that the statute did not authorize inquiry into the depth of the parents' religious convictions.⁸⁵ Similarly, the Massachusetts Supreme Judicial Court held in *Dalli v. Board of Education* that the state could not constitutionally require conformity with the "tenets and practice of a recognized church or religious denomination" as a condition of religious exemption from vaccination.⁸⁶ On the other hand, the Supreme Court of New York held in *McCartney v. Austin* that a father did not have the right to withhold polio vaccination from his son simply because he believed the vaccination law to be unjust.⁸⁷ More recently, the New York Family Court held that a father had illegally withheld measles vaccination from his son where the evidence showed that the objection was rooted more in distrust of the vaccine and in science than in religious objection.⁸⁸

Individuals may not circumvent mandatory vaccinations laws simply because they do not believe in the efficacy of vaccine.⁸⁹ Nor are they free to avoid compulsory vaccination laws because they feel that the vaccination itself will harm them or their children.⁹⁰ As the Supreme Court noted in *Prince v. Massachusetts*, "the family itself is not beyond regulation in the public interest."⁹¹

Even if the patient accepts vaccination willingly, ED practitioners should bear in mind that inoculation carries the same malpractice liability risks as any other medical procedure. EDs therefore must ensure that personnel who perform these vaccinations possess the requisite credentials under state and federal law. In a 1966 Washington case, *Barber v. Reinking*, a practical nurse placed a 2-year-old boy across her lap and injected him with polio vaccine. The boy moved suddenly, and the needle broke off in his buttock. After two hours of unsuccessful exploratory surgery at a community hospital, the wound was sutured with the

needle tip still embedded in the boy's muscle. Nine months later, the needle was extracted by personnel at another hospital, and the boy's mother brought a malpractice action against the nurse and the physician who had ordered the vaccination. The trial court instructed the jury that "[i]t is the duty of one who undertakes to perform the service of a trained a graduate nurse to have the knowledge and skill ordinarily possessed, and to exercise the care ordinarily used in like cases, by trained and skilled members of the nursing profession practicing their profession in the same or similar locality and under similar circumstances. Failure to fulfill either of those duties is negligence."⁹²

The potential for negligence is especially high when administering smallpox vaccinations because the procedure differs significantly from an ordinary injection. In the words of the CDC, "it is not a shot as most people have ever experienced."⁹³ Rather, the practitioner dips a bifurcated needle into the vaccine vial, causing one drop of the vaccine — which constitutes the recommended dosage for an adult patient — to adhere between the prongs. The practitioner then punctures the skin over the deltoid or triceps muscle with the needle 15 times within a few seconds, thereby depositing the vaccine and causing a drop of blood to appear. Because the vaccine contains a live virus, standard infection control precautions must be observed at all times, including the disposal of the needle in a suitable biohazard waste container. The practitioner must cover the wound with a dressing suitable to prevent inadvertent inoculation at other sites, and arrangements must be made for follow-up observation of the site, which is necessary to ensure immunity and to rule out complications.⁹⁴

With smallpox vaccinations emerging from a 30-year hiatus, America's health care providers must learn how to administer it all over again.⁹⁵ If practitioners receive inadequate training, or if they do not perform the procedure appropriately, patients may leave the clinic thinking they have protection against the disease, when in fact they do not. If one of those patients later dies from smallpox, liability might be traced back to the improperly administered vaccination. This would not be all that difficult to prove, since a properly performed vaccination leaves telltale signs, including bleeding, blistering, and scarring.⁹⁶

As with any vaccine, health care providers administering smallpox vaccine must remain cognizant of the proper dose. In *Caron v. United States*, parents brought a medical malpractice claim under the federal

Tort Claims Act against the Air Force physician who had given their daughter oral polio serum and a pair of vaccinations— one against diphtheria, pertussis, and tetanus, and another against typhoid. The physician administered the typhoid vaccine in a dose suitable for an adult, causing subsequent development of grand mal seizures and mental retardation. All of the physicians who testified agreed that the dose of vaccine administered by the defendant approached the sublethal range, and the trial court found for the plaintiffs.⁹⁷ The First Circuit affirmed.⁹⁸

Another type of error likely to create liability for those who administer smallpox vaccinations is the failure to provide appropriate warnings. This is uniquely important in the setting of smallpox inoculation because of vaccinia's potential to infect others. In one study conducted during the smallpox era, the risk of transmission to susceptible contacts was 27 infections per 1 million vaccinations. Before the U.S. military discontinued routine smallpox vaccinations in 1990, six transmissions reportedly originated from a single recruit.⁹⁹

To minimize the likelihood of inadvertent inoculation, vaccinated individuals must receive detailed instructions regarding methods and significance of contamination prevention. The CDC does not recommend covering the vaccination site with an occlusive dressing, as this may cause maceration. Rather, the site may be left uncovered, or it may be covered with gauze until the scab has separated on its own. Bandages should be changed every one to two days to prevent fluid buildup.¹⁰⁰ To prevent the spread of vaccinia to others, soiled materials should be washed in hot water and detergent and, when possible, bleach.¹⁰¹ Failure to provide this information could result in a malpractice action by anyone who becomes ill as a result of contact with the unguarded vaccination site.

For EDs that elect to vaccinate their employees, questions remain, too, about compensating those who become ill as a result of the immunization process. In *Guillory v. St. Jude Medical Center*, the Court of Appeal of Louisiana held that a hospital technician was entitled to worker's compensation after developing encephalomyelitis triggered by hepatitis vaccinations administered by her employer. Because the hospital had requested the technician to take part in a hospitalwide inoculation program, the illness in that case constituted a "compensable occupational disease by accident during the course and scope of her employment."¹⁰²

Similarly, in *City of Austin v. Smith*, a Texas appeals court held a municipality liable under workers' compensation law to a firefighter who became incapacitated from swine flu vaccination. Inoculation in that case was voluntary, and the evidence showed that the firefighter wished to receive vaccination for his individual protection. The city did not offer vaccination at the same time to every member of the public, however, but instead gave priority to individuals who "because of their occupations, would be critical to the community in the event of a swine flu epidemic." The jury concluded from this and other facts that the city desired its firefighters to receive the vaccinations, and that the vaccination — along with the associated incapacitation — resulted from an injury occurring during the course and scope of employment.¹⁰³ These decisions suggest that ED employees who become ill as a result of participation in the national smallpox vaccination program would fall under the coverage of state workers' compensation laws.¹⁰⁴

Smallpox vaccination today carries a greater risk than it did when the disease occurred naturally.

While hospitals possess the ability to provide supportive care today than they did during the smallpox era, susceptible patients exist today in far greater numbers. One individual already has died as a result of this dangerous combination. A 19-year-old recruit who had undiagnosed HIV when the military vaccinated him against smallpox in 1984 developed progressive vaccinia and AIDS, from which he died.¹⁰⁵ This experience underscores the need for practitioners to obtain a thorough medical history and perform an adequate physical examination as a means of ruling out contraindications to vaccination.

Guarding Against Liability

The only true safeguards against malpractice liability are accurate diagnosis and appropriate disease management. These challenges will prove especially difficult when treating patients infected with smallpox. Smallpox has not occurred naturally in the United States since 1949,¹⁰⁶ and as a result, virtually none of today's ED practitioners have witnessed it personally.

To ensure the timely containment and effective treatment of smallpox, ED practitioners must familiarize themselves now with its signs and symptoms.

Practitioners have an obligation, too, to provide accurate information to their patients. This obligation includes warnings, where appropriate. Practitioners

must take special care to instruct vaccination recipients in the proper care of their inoculation sites. Failure to do so could result in the spread of vaccinia, either to another location on the recipient's body or to some other person, for which the practitioner might incur liability. Whether traditional rules of informed consent would apply in the face of compulsory vaccination remains to be determined. Normally, health care providers must provide their patients with sufficient information about the risks associated with a procedure to enable a reasoned decision. This requirement may be rendered moot, however, should applicable law prohibit the patient from refusing the procedure.

Some patients should not receive smallpox vaccinations, of course. In the past, legislators left health care providers with little discretion regarding compulsory inoculation. Statutes tended to require universal compliance, even among individuals who felt they would suffer greater harm from the vaccination than from the disease it was intended to prevent.¹⁰⁷ Today, though, with so many more Americans likely to suffer adverse effects from vaccination,¹⁰⁸ contraindications are being taken more seriously.¹⁰⁹ New compulsory vaccination policies reflect these concerns by exempting those at high risk for complications.¹¹⁰

Among the most difficult decisions ED personnel may face involves the vaccination of pregnant women. Vaccination during pregnancy may cause fetal vaccinia, and is therefore not recommended.¹¹¹ At the same time, however, unvaccinated pregnant woman are unusually susceptible to hemorrhagic smallpox — a condition that proves almost universally fatal.¹¹² A number of jurisdictions already have recognized causes of action for acts committed against victims not yet born.¹¹³ Thus, a practitioner who administers the vaccination risks liability to the fetus, while failure to administer the vaccination may create liability to the mother.

The Homeland Security Act of 2002, signed into law by President Bush last November, effectively eliminates the individual liability of health care workers who administer smallpox vaccinations. Under this statute, any individual licensed or otherwise authorized by state law to administer smallpox vaccine is treated as an employee of the U.S. Public Health Service with regard to liability arising from smallpox inoculations.¹¹⁴ As a federal employee, these individuals would receive indemnification by the U.S. Government under the federal Tort Claims Act, which allows claims against the government but precludes personal

liability claims. Thus, an individual who becomes incapacitated by smallpox as a result of an improperly performed smallpox vaccination could bring a negligence action against the federal government, and potentially against the ED in which the vaccination was performed, but he could not sue the health care provider who administered the vaccination.¹¹⁵

Conclusion

Smallpox may have been eradicated, but concerns about the recurrence of this disease linger. While legal issues pertaining to smallpox vaccination pale in comparison to the likely effects of a terrorist-induced smallpox epidemic, they deserve consideration nevertheless. Now that a national smallpox vaccination program has been launched, ED personnel must be prepared to participate. Even practitioners who do not administer the vaccine could be affected, since they may be called upon to treat complications arising from inoculation. Liability provisions of the Homeland Security Act should go a long way toward alleviating the concerns of those involved, but individual and institutional liability can be further minimized through education, training, and preparation of relevant personnel.

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5. Which of the following patient groups has the greatest risk of contracting hemorrhagic smallpox, a condition that almost always proves fatal?
 - A. Infants
 - B. The elderly
 - C. Pregnant women
 - D. Males
6. The Supreme Court has held that the regulation of public health generally falls under the “police power” of which government body?
 - A. The federal government
 - B. The government of each state
 - C. The president
 - D. Congress
7. As of Jan. 1, 2003, which of the following groups were required by law to accept smallpox vaccinations?
 - A. Firefighters, police officers, emergency medical technicians, and other “rescue workers”
 - B. Members of the armed services deployed to high-risk areas
 - C. Citizens of certain states
 - D. All Americans, except those who objected on legitimate religious grounds

8. Which of the following best describes the smallpox vaccine currently administered in the United States?
 - A. Live smallpox virus
 - B. A synthetic compound that can cause smallpox-like symptoms in some people
 - C. Deactivated smallpox virus
 - D. A live, smallpox-like virus that is capable of causing illness

Answers: 5. C; 6. B; 7. B; 8. D.

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