

June 25, 2012

Vaccinating children against anthrax

After the shattering terrorist attacks of Sept. 11, 2001, it became an article of faith in the United States that no amount of emergency preparation could be too much. Medicine swept to the forefront of the nation's defenses as officials poured billions of dollars into vaccines and antidotes, in case the next assault should come from bioterrorism instead of hijacked jets out of the blue.

Now, the government is wondering whether it's possible to go a step too far as it considers conducting anthrax vaccine studies on children.

The ethical dilemma: Should children be experimentally vaccinated against a threat that might never come? Or should the country hold off until an attack, meantime leaving children unprotected against life-threatening bacteria for which adults have a vaccine?

President Barack Obama's administration has turned to a commission to help find an answer. In May, the Presidential Commission for the Study of Bioethical Issues signaled it was leaning against the pediatric studies at first blush, while pressing ahead with its inquiry. This followed a vote in the fall of 2011 by another advisory group, the National Biodefense Safety Board, to recommend that the studies proceed if outside experts determined they could be done safely and ethically. A decision is expected by the end of the year.

A week after the 2001 terrorist attacks, when Americans were in a state of high anxiety over the prospect of another imminent blow, a killer struck by sending anthrax spores through the mail. Five people died, 17 were sickened and mailrooms in official Washington and beyond were locked down by people in biohazard suits.

Years later, the killings were blamed on a disturbed federal scientist who committed suicide as authorities closed in, not on terrorists from afar. But the episode demonstrated the ability of an attacker with access to anthrax to distribute it widely and in lethal form — for the price of a postage stamp, no less.

In one doomsday model drawn by the government, an anthrax attack theoretically exposed more than 7 million people, nearly 2 million of them children. But as time passes without a terrorist attack of any sort, it's become harder to put the fear of doomsday in the population.

“Respectable members of the public do not believe in the threat,” nor do they believe the vaccine works, Dr. John S. Parker, chairman of the biodefense safety board, told the presidential commission (<http://bioethics.gov/cms/meetings>). “But it's clear to me that the facts speak louder.”

“If there is an anthrax release,” he said, “we must strive to have the same degree of surety of the vaccine's safety in children as it is in adults.”

More than 1.2 million adults, most in the armed forces, have received the anthrax vaccine but no one knows the proper dose, the safety or effectiveness in children. It is a particularly painful vaccine, causing more than the usual local redness, sometimes sparking fever and altogether drawing more complaints than the flu shot.

The usual risk-benefit calculations that are considered in devising treatments for childhood diseases don't apply in this instance because, absent an attack or highly unlikely accidental exposure, no child will benefit. This isn't the mumps.

The Alliance for Human Research Protection appealed to the government to come down against such trials, contending they would be a "reckless deviation from the precautionary principal of medical ethics" to subject healthy children to a vaccine studied for a merely theoretical threat.

To be sure, not all would be lost if an attack happened without a protocol for childhood vaccines in place. Powerful antibiotics can deal with immediate exposure and a vaccine administered later can defend against spores that linger in a dormant state. But proponents say the chaotic aftermath of an attack is not the time to be scrambling to immunize children from unleashed pathogens.

Dr. Michael R. Anderson, a fellow of the American Academy of Pediatrics, says if Washington were dusted with anthrax, adults would quickly get half a milligram in the arm from the national vaccine stockpile. But the child "down at the day care center — we have no idea what to give."

Health officials estimate 300 children would be needed for an initial trial and perhaps 1000 for a follow-up.

In an initial, informal sounding of the commissioners, four indicated their opposition to the trials, three were in favor and one wouldn't say.

At least two more public meetings are expected, in August and November, with the commission's report likely by the end of the year — after the Nov. 6 presidential and congressional elections. It so happens that timing might keep the issue from becoming yet another political football.

In his now-defunct campaign for this year's Republican presidential nomination, Texas Governor Rick Perry stumbled when conservative critics reminded voters that he had signed an order requiring Texas girls to be vaccinated against the sexually transmitted human papillomavirus to protect them from cervical cancer.

A rival pronounced it flat out wrong "to have innocent little 12-year-old girls be forced to have a government injection through an executive order," proving that when it comes to public health policy, nothing is immune from politics — even immunizations.
— Cal Woodward, Washington DC

DOI:10.1503/cmaj.109-4238