VACCINATION POSSIBLE CAUSE OF SOLDIER'S ILLNESS AND DEATH

What can you say about the role of vaccinations in the death of Specialist Rachel Lacy?

Two panels investigated the case. The Smallpox Vaccine Safety Working Group (SVSWG), a subgroup of both the Advisory Committee on Immunization Practices (ACIP) and the Armed Forces Epidemiological Board (AFEB), reviewed four cases in the DoD program. The Clinical Expert Immunization Committee (CEIC), a group convened by the Health Resources and Services Administration of the Department of Health and Human Services, reviewed two of those four cases.

Both panels concluded that vaccinations may have triggered an illness that ultimately led to the death in April 2003 of SPC Rachel Lacy, a 22-year-old Army Reservist, who received several vaccinations at the time she was mobilized for deployment. The panels determined that evidence favored a causal relationship, but that the evidence was not conclusive. Each panel said that it was unable scientifically to identify a specific vaccination as the possible cause because several vaccinations were administered at one time.

What are the details of SPC Lacy's case?

Specialist Rachel Lacy died on April 4, 2003, while being treated at the Mayo Clinic in Rochester, Minnesota. She was a member of the US Army Reserve and had been called to active duty at the mobilization station at Fort McCoy, Wisconsin. Her death was a rare, tragic event that may have been related to vaccination.

Specialist Lacy was treated in a series of outpatient visits at Fort McCoy and nearby hospitals beginning in mid-March 2003. She was treated by several medical specialists, including pulmonology, neurology, and infectious disease.

She was a combat medic with the 452d Combat Support Hospital. This unit deployed for service in Afghanistan.

Specialist Lacy received five vaccinations on March 2, 2003, at Fort McCoy. In alphabetic order, they are anthrax, hepatitis B, measles-mumps-rubella, smallpox, and typhoid. The measles-mumps-rubella and smallpox vaccines are live-virus vaccines. The others are inactivated vaccines. She also received a tuberculin skin test on the same day. Other deploying soldiers in her unit and other military units received similar vaccinations.

As her condition worsened, a conference call brought together the civilian physicians treating her at the Mayo Clinic and a Sparta (Wisconsin) hospital, DoD clinical experts, the Minnesota Health Department, and the Centers for Disease Control & Prevention (CDC). Upon her death, these parties continued to collaborate in assessing the cause of

her death. The unusual nature of her case led her to be enrolled in the CDC Unexplained Death Program. CDC and DoD performed additional laboratory tests to better understand what happened. The two independent panels of civilian physicians coordinated by the Department of Health & Human Services reviewed SPC Lacy's medical records, lab results, and other documents.

Her death certificate lists the cause of death as "diffuse alveolar damage" (widespread damage to portions of her lungs). The death certificate also mentions that she had pericarditis and mentions some, but not all, of her recent vaccinations.

She did not have meningitis or encephalitis, nor evidence of vaccinia virus in spinal fluid.

The two expert panels concluded that vaccination may have triggered an illness that ultimately led to the death of Specialist Lacy. Neither panel could scientifically identify a specific vaccine.

Don't privacy regulations limit DoD in discussing personal medical information in this case?

Privacy regulations allow public disclosure if the next-of-kin agree.

During conversations between DoD officials and SPC Lacy's family, the family specifically requested that SPC Lacy's name be mentioned in explaining what happened. The family is interested in healthcare providers learning from their daughter's experience and we respect the family's wishes.

Will this finding of a likely association cause DoD to stop its vaccination programs?

No. DoD will continue its vaccination programs. We must protect our forces against infectious diseases, in locations where diseases circulate naturally, and when at highest risk of or having duties considered mission essential against biological attack using either anthrax or smallpox.

Which vaccine did the panels consider most attributable to this soldier's death?

No evidence pointed to one vaccine over the others. Live-virus vaccines have traditionally been considered more vigorous in the spectrum of adverse events that can follow vaccination, but there is no objective data to affirm this in the case at hand.

The medical literature includes a small number of case reports of autoimmune disease occurring after vaccination, but these cases cannot provide scientific proof of a cause-and-effect association. The medical literature also includes several studies showing some common vaccines (e.g., influenza, hepatitis B) to be generally safe in people with autoimmune diseases. Scientific knowledge is incomplete in this area, and more work is

needed to better understand rare events that happen after vaccination. DoD is committed to its ongoing collaboration with the CDC and other partners in evaluating adverse events after vaccination.

Which vaccines did Specialist Lacy receive; and did she receive them for the first time in March?

Specialist Lacy received, in alphabetic order, anthrax, hepatitis B, measles-mumps-rubella, smallpox, and typhoid. She had received multiple vaccinations previously, such as when she entered into military basic training. She had received hepatitis B, measles, and rubella vaccines earlier in life.

What were the key findings that led to a conclusion of a link?

This soldier had an unusual pattern of antibodies called anti-Ro antibodies that have been associated with lupus in some patients with the disease.

These antibody tests have to be interpreted with care, because most people who test positive do not go on to develop symptoms of lupus. Those people simply carry the antibody around for years and it doesn't cause a problem. A very small proportion of people who carry the antibody may experience some kind of "trigger" that sets in motion a lupus reaction. This lab finding leads some to conclude that the vaccines may have triggered her lupus; but as can be seen in Specialist Lacy's case, she had received multiple vaccinations in the past without any problem.

In retrospect, should this soldier have been vaccinated in the first place?

Specialist Lacy had received multiple vaccinations previously. She was healthy and medically cleared to receive the vaccinations that she received in March 2003. She provided all requested information during pre-vaccination screening procedures. Neither DoD nor the soldier knew any reason not to vaccinate her.

Do you think that this reaction could have been prevented?

We've asked ourselves that question. This soldier was properly screened and she received good compassionate care. Unfortunately, we do not see how her reaction could have been prevented.

Does this case have any bearing on your ongoing evaluation of pericarditis after smallpox vaccination?

Specialist Lacy's death certificate included mention of pericarditis, inflammation of the sack around the heart. One of the review panels (the Clinical Expert Immunization Committee, CEIC) noted that her inflammation was not like other cases of inflammation after smallpox vaccination. The CEIC noted that pericarditis developed late in this soldier's case and did not seem to be the main reason for her illness. Hence, this

soldier's case is unlike the series of myo-pericarditis cases seen following smallpox vaccination.

Have you seen other cases similar to Specialist Lacy's?

No, the clinical features of this case were unique and not like other people who experienced adverse events following vaccination. She developed a combination of symptoms, outcomes, and test results that are like no other patient we have encountered.

Did the panels recommend any changes in DoD policy?

This review process did not identify any changes to current screening processes that would be useful in preventing similar rare cases in the future.

From the beginning of our Smallpox Vaccination Program, we adopted the same screening and exemption criteria adopted by the CDC, FDA, and similar authorities. We regularly reevaluate our processes to see if we can make them better. After any serious adverse event following vaccination, we reassess our procedures.

Unfortunately, there is no useful test available that could have predicted the health problems this soldier developed after vaccination.

We considered whether a test known as an ANA test (it tests for anti-nuclear antibodies, which are proteins that bind to components inside of cells) might have been helpful in preventing this soldier's death. But this test produces false-positive results so often that it would not be a useful screening test for healthy populations, such as our deploying service members. False-positive test results indicate the presence of a condition when that condition does not really exist.

Why did you submit the case to two panels, instead of just one panel?

We involved both groups because each brought complimentary expertise to the review process. The strength of having two independent investigations would be better than having one. The Smallpox Vaccine Safety Working Group (SVSWG) has reviewed adverse-event information about the US smallpox vaccination program since the program's inception in December 2002. The Clinical Expert Immunization Committee (CEIC) is the successor to the Anthrax Vaccine Expert Committee (AVEC), an experienced review panel that reviewed adverse events reported after anthrax vaccination between 1998 and 2001.

Will DoD do anything different based on the findings of these panels?

DoD reemphasizes its message to all vaccinees to seek medical care if they experience medical problems after vaccination. DoD's 2-year-old Vaccine Healthcare Center

Network demonstrates DoD's commitment to better understanding rare and unusual adverse events after vaccination.

DoD asked the Armed Forces Epidemiological Board (AFEB) to review the long-standing tradition of administering simultaneous vaccinations. However, at this point, we know of no objective evidence sufficient to warrant a change in the immunization practices common in both military and civilian clinics.

At this time, we will continue our careful screenings, immunization procedures, and close monitoring for adverse events.

Why do you continue to vaccinate if this is a possible consequence of vaccination?

We know that the risk of infections makes it necessary to protect service members with vaccines. No vaccination is risk free. We have only to recall the devastating effect of disease on military forces during World Wars I and II, the impact of yellow fever on the construction of the Panama Canal, to know we must do all we can to protect the health of our service members.

How unusual are simultaneous vaccinations?

Administration of simultaneous vaccinations is a generally accepted practice and has been for many decades. One of the vaccines widely used in the United States to protect against Streptococcal infection contains 23 different components. For this vaccine one injection is the equivalent of receiving 23 simultaneous vaccinations.

In 2002, the Institute of Medicine (IOM) considered the safety of multiple vaccinations for infants, whose immune systems are less mature than adults' immune systems. The IOM concluded that such procedures are safe and that no change was needed in current national policies involving multiple immunizations.

To generate additional scientific evidence on the subject, DoD has additional evaluations underway of simultaneous vaccination of adults. DoD has automated medical records and a database that offers unique possibilities for the assessment of multiple vaccination safety in adults. We have sought independent civilian experts to assist our evaluations and we will share the findings in appropriate scientific forums.

How else does DoD evaluate vaccinations and the adverse events they may cause?

After every serious adverse event following vaccination, we reassess our procedures to ensure that we have included all of the necessary and appropriate steps in administering the program. After this soldier's death, because of the unusual characteristics of her case, we launched an extremely extensive investigation. The two panels whose findings we announced are part of that extensive investigation.

DoD and CDC collaboratively evaluate rare and unusual adverse events that follow vaccination through a network of specialty clinics. These clinics are called the Vaccine Healthcare Center (VHC) Network; it has centers at Walter Reed Army Medical Center (Washington, DC), Naval Hospital Portsmouth (Virginia), Wilford Hall Air Force Medical Center (San Antonio, Texas), and Fort Bragg (Fayetteville, North Carolina). For more information regarding the VHC Network, please visit their website at www.vhcinfo.org.