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By Rick Jurgens Valley News Staff Writer - Feb 11, 2016

Lebanon — Upper Valley parents and health care providers continue to respond to the refrigeration lapses that compromised vaccines and prompted a revaccination program for more than 800 young patients at Alice Peck Day Memorial Hospital.

The vaccine problems were announced in letters to parents of children who had received care at the hospital's Robert A. Mesropian Center for Community Care. The letters, which were sent out Jan. 11, disclosed that unsafe temperatures in storage refrigerators during a 14-month period that ended in October 2015 might have rendered some vaccines ineffective, leaving some children vulnerable to otherwise preventable diseases.

The letters assured parents that the compromised vaccines had not harmed recipients, and recommended that those children who were determined to be at risk get revaccinated at no charge. Customized revaccination plans developed by pediatricians were included in the letters sent to those families.

The compromised vaccines at APD included those aimed at preventing diphtheria, tetanus, pertussis, hepatitis A and B, human papillomavirus, measles, mumps, rubella, polio and rotavirus and providing resistance to bacteria that cause meningitis and pneumonia, according to the hospital.

News of the compromised vaccines and plans for revaccination evoked a range of reactions from parents of the affected children.

Lebanon resident Emma Wunsch, whose 7- and 5-year-old daughters are patients at the APD clinic, said she didn't blame the hospital for the vaccine problems. Even after hearing about the vaccination problem, she recommended her pediatrician at the APD clinic to a friend who just had a baby, she added.

"It wasn't their fault," Wunsch said. "Things malfunction."

But Heather Tufts, of White River Junction, was less pleased about receiving notice that her 8-month-old daughter would require another shot of DTAP, a combination vaccination that raises immunity to diphtheria, tetanus and whooping cough.

Tufts said she was "pretty mad about it," especially because her daughter hates shots. "She screams. She's inconsolable for hours."

The revaccination program is off to "a pretty strong start," APD Chief Executive Sue Mooney said. As of Feb. 8, about 250 patients had been revaccinated, hospital spokesman Peter Glenshaw said.

Before launching the program, the hospital reviewed the files of about 3,500 pediatric patients, vaccine inventory and storage records, and the temperature histories in the vaccine storage refrigerators, which have been recorded around the clock since September 2014, Mooney said. That enabled the hospital to determine which vaccines had been affected by so-called temperature excursions — temperatures outside the ranges recommended to ensure their strength and effectiveness — and which patients received those vaccines.

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A pediatrician then assessed whether each patient needed revaccination and developed a customized plan for everyone who did, she said. A pediatrician analyzed the timing of the original and follow-up vaccinations required to provide immunity, and scheduled necessary revaccinations and follow-ups accordingly.

Mooney previously said she had not been directly involved and didn't know when the hospital became aware that, in addition to the record-keeping issues that surfaced in early August, some vaccines might have been compromised.

But she defended the hospital's decision to wait until January to alert parents and patients to the problem. It took time to collate and analyze the records and develop individual response plans, she said in interviews. The hospital was "advised by outside experts that the right answer was to revaccinate and we felt as though putting out any sort of information and being unprepared to revaccinate was not in the best interest of our patients," she added.

New Hampshire's Immunization Program has a \$26 million budget and purchases the vaccines used by Alice Peck Day and 300 other providers in a statewide immunization program that reaches 330,000 children, according to the state Department of Health and Human Services.

But the revaccination effort, which will entail no charges to patients, won't be underwritten by the state, Mooney said.

"APD is paying for the replacement vaccines," she said. "The state is not incurring additional expenses."

Mooney said that hospital had not yet estimated the program's cost.

One critic of the hospital's response to the compromised vaccines is Laura Condon, of Bedford, N.H. She follows vaccination issues as state advocacy director for the National Vaccine Information Center, which opposes mandatory vaccination programs, and as a director of the New Hampshire Vaccine Association, a nonprofit that acts a funding vehicle for the state's immunization program.

APD should have included in its announcement the information that, at least in some cases, a blood test might be an alternative to revaccination, she said.

Condon was referring to titer tests, which, according to the National Institutes of Health's National Library of Medicine, use blood samples to determine "whether a previous vaccine helped your immune system protect you against the specific disease."

A two-page insert in the hospital's Jan. 11 mailing that posed the question of whether there was "any alternative to revaccination" didn't mention blood tests. Instead, it said only that the U.S. Centers for Disease Control and Prevention "recommends revaccination in this situation as the safest and most effective way to ensure protection from these vaccine-preventable diseases."

And that is the general approach suggested by the CDC's Advisory Committee on Immunization Practices. "Vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated," the panel said in recommendations published in 2011.

Mooney defended omitting mention of titer testing in the hospital's mailing. The hospital wanted to make clear that revaccination was the best option, she said.

A mention of the testing alternative "felt like it was going to make the communication less clear," she added.

Mooney said the pediatricians who reviewed the details of each case in which a child might have received a compromised vaccine "advised me that there was probably less than a handful of patients that they thought might be worth having a conversation with about titers."

Those families received "a more individualized communication ... in addition to the letter," Mooney said. If testing seemed appropriate, the hospital picked up the tab, she said.

Cori Anderson, a special instructor in biology at Dartmouth College and the mother of a 1-year-old boy who required revaccination at APD, dismissed the value of titer testing as a general alternative.

"The labor cost of having to do that with 800 and some children" wasn't justified, she said, especially since "the scientific evidence is overwhelmingly supporting that even if you get a double dose or extra vaccine, there is really no harm to the child."

But Condon, the vaccine activist, said it seemed to her that the hospital had prioritized "the money issue over the safety and health of the children."



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The CDC Advisory Committee acknowledges that testing sometimes can obviate the need for additional vaccines for some diseases, but "commercial serologic testing might not always be sufficiently sensitive or standardized for detection of vaccine-induced immunity ... and research laboratory testing might not be readily available."

The vaccines were compromised in what amounted to the second refrigeration-related problem that surfaced at APD in about a six-month period.

The first problem was identified on Feb. 10, 2015, when state inspectors made a routine but unannounced visit to the hospital and found that a log sheet for recording daily temperatures in a specimen refrigerator in the medical surgical unit only had two entries for January. The inspectors notified the hospital in an inspection report dated Feb. 12, 2015.

After the uncompleted log sheets were discovered, hospital officials reminded staff and clinical leaders in the medical surgical unit that daily temperature checks were required, and hospital managers were assigned to monitor compliance. The top medical-surgical nurse was assigned to make monthly updates to the hospital's Quality Council on the refrigeration temperature monitoring, according to a plan of correction signed by Mooney.

Mooney said that the cited refrigerator was used to store urine samples until they were sent to a laboratory, and that the hospital had only been monitoring temperatures when something was stored.

There was little to compare that issue with the temperature problems in the vaccine program, which occurred when "a new (monitoring) program was instituted statewide," she added.

The February inspection also found other deficiencies at APD, including unchanged filters on blanket warmers, a torn patient bed, a rusted laboratory cart, five areas with unsecured sharps containers, an absence of documentation showing some scheduled emergency drills occurred, improperly marked glucose containers, and unsecured medical records and patient information.

Mooney said the findings were included in the state inspectors' report in which the hospital otherwise performed well.

"We did quite well on that survey and the state was not in any way, shape or form unhappy with what they saw when they came here," Mooney said.

State Department of Health and Human Services spokesman Jake Leon said officials of the Health Facilities Administration, the unit that inspects hospitals, "did not recall the specifics of the conversation that they had with Alice Peck Day" after the February 2015 visit.

Leon said that particular conversation "would have reflected the fact that the hospital corrected the deficiencies in the time frame that they said they would correct them" and that "they were in substantial compliance with the regulations for a critical access hospital."

A critical access hospital is a small facility that qualifies for higher reimbursement for providing care to patients covered by Medicare.

At least one 5-year-old caught up in the revaccination kerfuffle emerged in good spirits. Wunsch, the Lebanon mother, said that while her daughter "was not happy about the shot" required to ensure that she was protected from diphtheria, tetanus and pertussis, she was pleased to receive a lollipop, a sticker and the assurance that she would not need another such shot until she is 10.

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