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Vaccine deaths yet to show ‘causal links’

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World Health Organization maintains pentavalent vaccine Quinvaxem is safe despite six deaths in two months



A baby is vaccinated at a center for preventive health in Hanoi. At least six infants have died after getting shots of the pentavalent vaccine Quinvaxem since November last year, but WHO and national authorities maintain there is no link.

As the world celebrated Christmas several weeks ago, Nguyen Thi Thanh Thuy almost lost her three-month-old daughter Nguyen Thu Truc.

The baby had been administered a popular vaccine used nationwide under an expanded national immunization program. Local health authorities have suspended three batches of the vaccine but continued to insist, even after several deaths, that the product is safe.

At least six babies have died and three others suffered serious complications in Vietnam after receiving Quinvaxem since November.

According to the Vaccine Resistance Movement, the vaccine has also been responsible for deaths of at least five children in Sri Lanka, eight in Bhutan and at least three in Pakistan over two years after its launch in 2006.

Thuy, a resident of Binh Dinh Province's Quy Nhon Town, said her daughter had a fever and cried loudly before losing consciousness several hours after taking the pentavalent vaccine Quinvaxem.

"Luckily, the provincial hospital is nearby and doctors rescued her in time," she said.

On the same day, two other babies who had also taken Quinvaxem earlier in the day were also admitted to the hospital. Both were saved.

Deputy director of the Binh Dinh Health Department, Le Quang Hung, said the infants had reacted to the vaccine and that it was rare. He said local health authorities had sealed the batch of vaccines and sent it to the Ministry of Health for further tests.

But Nguyen Huy Nhat, a two-month-old baby in Thanh Hoa Province was not so lucky as the babies in Binh Dinh taking Quinvaxem.

According to the Thanh Hoa Center for Preventive Health, Nhat took Quinvaxem and oral polio vaccine at around 9:30 a.m. on November 12, 2012.

The family took him to a local health station at around 4:30 p.m. the same day, after he began crying a lot and his breathing became rapid and his lips turned pale.

He was transferred to Thanh Hoa Children's Hospital on November 13 where he was diagnosed with breath failure and complicated heart disease. He died later the same day.

Although the hospital concluded that he died of heart disease, the coincidence of his death after taking Quinvaxem has sparked alarm, especially following the three cases in Binh Dinh and several more cases in other provinces.

'Third world' product

Quinvaxem, listed as a prequalified medicine by the World Health Organization (WHO), has been distributed in Vietnam since June 2010 as part of a program run by the Global Alliance for Vaccines and Immunization through the UNICEF.

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The fully liquid drug immunizes children from five diseases – diphtheria, tetanus, pertussis or whooping cough, hepatitis B, and Hib (Haemophilus influenzae type b).

Vietnam has so far administered 13 million doses of the vaccine to children between two and four months old, according to figures from the health ministry.

The country previously used DPT, another combination vaccine that protects children from diphtheria, tetanus, and pertussis.

Nguyen Tran Hien, director of the National Institute of Hygiene and Epidemiology and chairman of the National Extended Vaccination Program, said the rate of complications from DPT is 1.03 per million, and the death rate is 0.6 per million, while corresponding rates for Quinvaxem are 0.69 and 0.17 per million.

He said the ministry has asked the WHO to have another independent agency test the involved batches and advised the producer, Berna Biotech Korea Corporation of South Korea, to review production and distribution of the vaccine in Vietnam.

According to Hien, the batch includes 400,000 doses and more than 200,000 have been used in the northern region.

He said the vaccine is no longer used in South Korea because the country has shifted to a new generation product with higher purity and less possibility of reactions.

But he also said Quinvaxem is an affordable one for Vietnam because it costs around VND77,000 (over three US dollars) a dose, while new alternatives produced in the US and Belgium cost several times more.

“It is difficult for us to afford between four million and five million doses a year. It is even more difficult to buy the latest version of the vaccine that is about six times more expensive. Anyway, Quinvaxem is still recommended by the WHO,” he told Vietweek.

Safety reaffirmed

Asked for comments on recent deaths after taking Quinvaxem, the WHO has maintained there is no relevant link.

“To date, based on the review of the available information, WHO believes that no causal link to a potential vaccine quality problem has been established,” WHO Vietnam said in an email to Vietweek on Tuesday.

“We have official notification from Ministry of Health that there have been deaths of six children following receipt of this vaccine. The investigation into these deaths is

ongoing. Each death reported needs to be thoroughly examined to assess whether it is really related to administration of vaccine and if so, what exactly is the cause,” it said.

According to WHO, deaths following vaccination are rare and often coincidental events and the frequency of those events depends in particular on the actual infant mortality in the population studied and number of days following vaccination.

“To WHO’s knowledge only one country has suspended the use of the vaccine. This precautionary suspension followed a similar observation of coincidental deaths shortly after the vaccine was introduced. Upon review of the cases, no link with vaccination could be identified,” it said, without naming the country.

WHO said the responsible national authorities of each individual country make decisions on whether or not to recommend suspension of the use of a particular vaccine.

“They are not obliged to, nor do they always inform WHO. However, WHO continues to monitor these situations as they occur,” it said.

In previous coverage of the vaccine, Vietweek had mentioned an article in the British Medical Journal in which a group of pediatricians, professors, health activists and a former Indian health secretary cautions against the introduction of the five-in-one vaccine that combines antigens against five diseases in a single shot.

The article accused the WHO of “an elaborate cover-up,” changing its own criteria for classifying adverse effects “to say the vaccine was not responsible for the deaths in Sri Lanka.”

Vietweek has asked WHO Vietnam to comment on this allegation, but had not received a response as of press time.

Making sure

Nguyen Van Binh, director of the health ministry’s Preventive Health Department, said to make sure, the ministry is going to send samples from the suspect batches to an independent laboratory in the Netherlands.

The vaccine was introduced globally in 2006 by the Netherlands-based biopharmaceutical company Crucell.

“So far, there is no evidence showing links between the quality of the vaccine and the complications, but, at the same time, there is no evidence proving that there is no possible link,” he said.

Binh said the health ministry has suspended all Quinvaxem batches suspected of causing reactions, but is also recommending that parents have their children vaccinated because it is important to protect the latter's health.

On Tuesday, health minister Nguyen Thi Kim Tien signed an instruction on monitoring children after they are vaccinated.

She asked relevant agencies to offer "complete consultancy" to the family of the children about relevant benefits and risks, conduct examinations to identify contraindications and prepare enough drugs and equipment for the treatment of complications after vaccination, the government website reported.

The Pasteur Institute and other agencies will have to strictly monitor the quality of vaccine and vaccination services; and issue more instructions on safe vaccination procedures, it said.

According to the health ministry, the proportion of serious reactions to vaccination in Vietnam is 0.5-0.9 per every one million doses. However, there have been nine cases of serious reactions in more than one month after taking Quinvaxem and tuberculosis vaccines.

Kim Nga, a woman in HCMC who is five months pregnant, said she will take her baby (after it is born) to major hospitals in the city and get the latest, safer vaccines.

"But I don't think poor people in rural areas can afford these vaccines. They just have their children taking the vaccines like Quinvaxem that are supplied for free at communal medical stations."

By Lien Chau - Khanh An, Thanh Nien News (The story can be found in the January 25th issue of our print edition, Vietweek)