



Practice sting 2024-14

Practice sting Unclear guideline

This Practice Sting is particularly interesting for guideline developers, pediatricians and youth public health physicians

An unclear guideline can lead to confusion and therefore to incidents, as shown in the notifications below about vaccinating babies against rotavirus.

Notifications

1. A 6-week-old baby has been vaccinated against rotavirus by the pediatrician, while the mother has taken the immunosuppressant tacrolimus throughout the pregnancy. After the vaccination, the youth public health physician realizes that this is not in accordance with the Dutch RIVM guideline (National Institute for Public Health and the Environment). The baby had no serious side effects other than diarrhoea.
2. A pregnant woman with Crohn's disease continued to use infliximab during pregnancy. After birth, a blood level determination of infliximab was made on the child. No infliximab was detected in the blood. The pediatrician advises the youth public health physician to wait for the first 6 months before administering live attenuated vaccines. Vaccination against the rotavirus via the Dutch national vaccination program is then no longer possible.

Analysis

Since January 1, 2024, vaccination against rotavirus has been included in the Dutch National Vaccination program (RVP). The RVP guideline for *the Implementation of the National Vaccination Program* was then expanded with the Addendum *Vaccination against rotavirus for infants born from 1 January 2024 on*.

The guideline

Newborns are vaccinated against rotavirus twice within a maximum of 24 weeks after birth. The child receives the first vaccination when it is 6 to 9 weeks old and the second around 3 months. A serious side effect of the rotavirus vaccine is intussusception (sliding together of parts of the intestine), which leads to intestinal blockage. The guideline strongly advises against administering the rotavirus vaccine after 24 weeks, because after that age there is a peak in the spontaneous occurrence of intussusception.

The rotavirus vaccine is a live attenuated vaccine. These vaccines should not be given to people taking immunosuppressive drugs. Also, they may be contraindicated in newborns if their mother used these drugs during pregnancy or during the lactation period. In practice, this only concerns the rotavirus vaccine for babies. The MMR vaccine (mums, measles, rubeola), which is also a live attenuated vaccine, is administered for the first time after 14 months.

The addendum is not clear about the need for blood level determination of immunosuppressive biologicals in the child. On the one hand, the addendum recommends that a level determination be made when using an immunosuppressive biological, while on the other hand, the addendum states that level determination is not common. Furthermore, it is not easy for the reader to find out in the guideline whether this recommendation also applies to tacrolimus, a medicine that is produced via biological synthesis. The reader can find the answer to this question via the RIVM manual on *Vaccination in chronic inflammatory conditions* in the in England used guideline *Rotavirus vaccination program: information for healthcare professionals*. It states that maternal use of

steroids, cyclosporine, tacrolimus or azathioprine during pregnancy is not a contraindication to rotavirus vaccination in the child.

The notifications

In the first notification, contrary to what the notification reporter thought, action was taken in accordance with the guideline. Maternal use of tacrolimus during pregnancy is not a contraindication to rotavirus vaccination of a newborn. The youth public health physician who made the notification to the national reporting centre for the Prevention of Medication Incidents (VMI) had obviously not found the information in the guideline.

The second notification is a vaccination incident. An infliximab level was determined in accordance with the guideline. Infliximab was not detectable. The newborn could therefore have been vaccinated. The youth public health physician who made the notification does not know what the pediatrician's reason was for advising not to vaccinate.

Recommendations

For guideline developers in general

- Make sure guidelines are easy to read. This means that users can quickly find the information they need.
- Do not use terminology that is open to multiple interpretations.
- Provide clear information in the guideline.
- Do not refer to other guidelines/manuals, etc. for essential information for the user of the guideline.
- Always have guidelines read for clarity and implementability by the users of guidelines.

For pediatricians and youth public health physicians

- Study a new (version of a) guideline carefully. Implement a guideline into daily practice. This means:
 - Map out the consequences for daily practice. If necessary, adjust the healthcare institution's protocols accordingly or ensure that they are introduced.
 - If it concerns a multidisciplinary guideline, consult with all disciplines in the region for which the guideline has been drawn up.
 - If necessary, train colleagues in the new guideline and/or the protocol derived from it. With regard to the rotavirus vaccination guideline, these are in any case pediatricians and youth public health physicians and all healthcare professionals who work under the medical responsibility of these physicians.