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Rotavirus vaccines WHO position paper: January 2013 – Recommendations

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ABSTRACT

This article presents the World Health Organizations (WHO) evidence and recommendations for the use of rotavirus vaccination from the WHO position paper on rotavirus vaccines – January 2013 recently published in the Weekly Epidemiological Record [1]. This position paper summarizes the WHO position on the inclusion of rotavirus vaccines in all national immunization programmes and recent developments in the field, in particular the potential of rotavirus vaccines to further reduce mortality by employing more flexible immunization schedules. The current document replaces the position paper on the use of rotavirus vaccines published in 2007 [2].

Footnotes to this paper provide a number of core references. In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes; they summarize essential background information on diseases and vaccines, and conclude with WHO's current position on the use of vaccines in the global context. This paper reflects the recommendations of WHO's Strategic Advisory Group of Experts (SAGE) on immunization. These recommendations were discussed by SAGE at its April 2012 meeting. Evidence presented at the meeting can be accessed at http://www.who.int/immunization/sage/previous/en/index.html.

Rotavirus vaccines should be included in all national immunization programmes and considered a priority, particularly in countries with high rotavirus gastroenteritis (RVGE)-associated fatality rates, such as in south and south-eastern Asia and sub-Saharan Africa.

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases with the scaling up of both prevention (promotion of early and exclusive breastfeeding, handwashing, improved water supply and sanitation) and treatment packages. WHO/UNICEF recommend that all children receive solutions of low-osmolarity oral rehydration salts (ORS) to prevent and treat dehydration due to diarrhoea. Breast milk is also an excellent rehydration fluid and should be given to children still breastfeeding along with ORS. In addition to fluid replacement, children with diarrhoea should continue to be fed during the episode. Food intake supports fluid absorption from the gut into the bloodstream to prevent dehydration and helps maintain nutritional status and ability to fight infection. Children should also simultaneously receive zinc treatment which reduces the duration and severity of diarrhoea episodes, stool volume and the need for advanced medical care [3,4]. Plans for introduction of rotavirus vaccines should consider the epidemiology of the disease by age, the coverage and actual age at vaccination and an evaluation of the estimated public health impact and potential risks. In addition, cost-effectiveness assessment, issues of affordability of the vaccine, financial and operational impact on the immunization delivery system, and careful examination of current immunization practices should be taken into account.

Introduction of rotavirus vaccine should be accompanied by measures to ensure high vaccination coverage and timely administration of each dose.

Following a review of new evidence on age-specific burden of rotavirus disease and deaths, timeliness of vaccination, and the safety and effectiveness of different immunization schedules, WHO continues to recommend that the first dose of rotavirus vaccine be administered as soon as possible after 6 weeks of age, along with diphtheria–tetanus–pertussis (DTP) vaccination, to ensure induction of protection prior to natural rotavirus infection.

Although early immunization is still favoured, the manufacturers' conventional age restrictions on the first and last dose of rotavirus vaccines may have prevented vaccination of many vulnerable children in settings where the DTP doses are given late (i.e. after 15 weeks for DTP1 or after 32 weeks for DTP 2 or DTP3). By allowing infants to receive rotavirus vaccine together with DTP regardless of the time of vaccination, immunization programmes will be able to reach children who were previously excluded from the benefits of rotavirus vaccines. Because of the typical age distribution of RVGE, rotavirus vaccination of children >24 months of age is not recommended.

RV1 should be administered orally in a 2-dose schedule at the time of DPT1 and DPT2 with and interval of at least 4 weeks between doses. RV5 should be administered orally in a 3-dose schedule at

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the time of the DTP1, DTP2, and DTP3 contacts, with an interval of at least 4 weeks between doses. With both vaccines, prematurely born infants should follow the vaccination schedules recommended for their chronological age.

Rotavirus vaccinations can be administered simultaneously with other vaccines in the infant immunization programme.

Apart from a low risk of intussusception (about 1–2 per 100,000 infants vaccinated) the current rotavirus vaccines are considered safe and well tolerated.

Proper planning and training of staff to conduct pharmacovigilance should take place before the vaccine is introduced. Countries should develop a strategy to inform relevant health staff that although the benefits outweigh the risks, a small potential risk of intussusception after rotavirus vaccination remains. Countries should also ensure that caregivers are adequately counselled to recognize danger signs of dehydration or intussusception that should prompt immediate medical consultation.

Given the background rate of natural intussusception and the large number of children included in national immunization programmes, intussusception cases are expected to occur by chance alone following rotavirus vaccination. It is important to establish the baseline incidence of intussusception at sentinel sites and to use epidemiological studies, such as the self-controlled case series method, to assess the safety of rotavirus vaccines [5].

Severe allergic reaction (e.g. anaphylaxis) after a previous dose, and severe immunodeficiency including severe combined immunodeficiency, are contraindications for rotavirus vaccination. Precautions are necessary if there is a history of intussusception or intestinal malformations, chronic gastrointestinal disease, and severe acute illness. Vaccination should be postponed in case of ongoing acute gastroenteritis or fever with moderate to severe illness.

The epidemiological impact of rotavirus vaccination should be monitored. High-quality surveillance should be conducted in selected countries and defined populations, including high child mortality settings. However, lack of population-based surveillance should not be an impediment to the introduction of rotavirus vaccine.

References

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