Global Framework for Rotavirus Vaccine Implementation Research

Ad-hoc Consultation – Scoping Meeting

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SAGE meeting – April 2012

• Systematic review of VE and safety from RCTs and effectiveness from observational studies

• Review of morbidity and mortality by age and WHO region

• Risk benefit analysis of RV vaccines

WHO position paper on rotavirus vaccines – January 2013

“Previously, WHO recommended that rotavirus immunization be initiated by 15 weeks of age ...” [This] “could exclude a substantial number of children from vaccination, especially in low income countries, where delays in vaccination are common.”

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 ....”

RV1 - 2 doses with DTP1 and DTP2.
RV5 - 3 doses with DTP1, DTP2, and DTP3,
interval between doses: 4 weeks at least
RV vaccines can be administered with other vaccines
Vaccination of children > 24 months is not recommended
Objectives -- to examine:

• ... the preliminary outcomes of the systematic reviews of the evidence on the effects of all rotavirus vaccines licensed or in phase III clinical trials on rotavirus related disease outcomes.

• ... whether the emerging evidence supports a proposal to SAGE for a new formal review of current policy recommendations or guidelines.

• ... if additional data and reviews are needed to inform future policy recommendations

Evidence elements considered

1. RV vaccines: introduction, coverage, characteristics and operational challenges
   • Introduction and operational challenges
   • Characteristics
   • Coverage and timeliness of vaccination

2. BoD and epidemiology
   • WHO RV Global Surveillance Network and surveillance guidelines
   • Age distribution of RV infection
   • Burden of diarrhoeal diseases in children

3. Vaccine efficacy
   • Efficacy against all cause mortality and disease outcomes by number of doses, age at first dose, interval, co-administration
   • Duration of protection

4. Vaccine effectiveness
   • Effectiveness in routine programmes
   • Effect on RV hospitalization and reduction in AGE hospitalization and mortality

5. Safety
   • Safety profile of RV vaccines

6. Risk - benefit analysis
   • Estimated benefits of mortality reduction vs risk of fatal IS

7. Operational issues: thermostability
   • Analysis of the thermostability of RV vaccines

8. Economic considerations
   • Systematic review of economic analyses (CEA and budget impact analyses)
   • CE in 73 Gavi countries
   • CEA of nationally licensed RV vaccines
Questions

1. What are the preliminary conclusions from all the evidence reviewed?

2. What additional data and reviews could help inform future discussions on the policy recommendations for RV vaccines?

3. Do the data reviewed suggest the need to adjust current WHO recommendations?