
Adverse Event

Global Advisory Committee on Vaccine Safety, 12 December 2005

[WER 2006, vol. 81, 2, pp 15-19](#)
page 16

GACVS was asked to consider whether the use of tetravalent rhesus reassortant rotavirus vaccine (commercially known as RotaShield) might be associated with a significantly lower risk of vaccine-induced intussusception if immunization is completed before 2 months of age.

The Committee concluded as follows:

1. The studies provide clarification and confirmation of a high risk of RotaShield-associated intussusception in infants immunized after day 60.
2. The available evidence is not sufficient to conclude that the use of RotaShield at an age less than 60 days is associated with a lower relative risk of intussusception.
3. Even strict recommendations for adherence to an early immunization schedule would be extremely difficult to implement in the field in many countries.

Cold Chain Equipment

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

GACVS

Global Advisory Committee on Vaccine Safety, 12 December 2005

[WER 2006, vol. 81, 2, pp 15-19](#)
page 16

GACVS was asked to consider whether the use of tetravalent rhesus reassortant rotavirus vaccine (commercially known as RotaShield) might be associated with a significantly lower risk of vaccine-induced intussusception if immunization is completed before 2 months of age.

The Committee concluded as follows:

1. The studies provide clarification and confirmation of a high risk of RotaShield-associated intussusception in infants immunized after day 60.
2. The available evidence is not sufficient to conclude that the use of RotaShield at an age less than 60 days is associated with a lower relative risk of intussusception.
3. Even strict recommendations for adherence to an early immunization schedule would be extremely difficult to implement in the field in many countries.

General

Rotavirus vaccines, an update (WHO position paper)

(N)o rotavirus vaccine is currently available internationally. As soon as new rotavirus vaccines have been licensed and become available on the international market, a fully revised position paper will be published in this journal (Weekly Epidemiological Record.)

[WER 2003, vol. 78, 1, pp 2-3](#)
page 2

Rotavirus vaccines, an update (WHO position paper)

WHO strongly recommends the rapid development of new and safe vaccine candidates against rotavirus disease and parallel evaluation of new candidates in developed and developing countries.

[WER 2003, vol. 78, 1, pp 2-3](#)
page 3

WHO also encourages measures to establish the burden of rotavirus disease in developing countries in order to provide the necessary information for advocacy and risk-benefit analyses, the outcome of which may vary with the epidemiological and socioeconomic setting

Global Advisory Committee on Vaccine Safety, 12 December 2005

GACVS was asked to consider whether the use of tetravalent rhesus reassortant rotavirus vaccine (commercially known as RotaShield) might be associated with a significantly lower risk of vaccine-induced intussusception if immunization is completed before 2 months of age.

[WER 2006, vol. 81, 2, pp 15-19](#)
page 16

The Committee concluded as follows:

1. The studies provide clarification and confirmation of a high risk of RotaShield-associated intussusception in infants immunized after day 60.
2. The available evidence is not sufficient to conclude that the use of RotaShield at an age less than 60 days is associated with a lower relative risk of intussusception.
3. Even strict recommendations for adherence to an early immunization schedule would be extremely difficult to implement in the field in many countries.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

[WER 2006, vol. 81, 1, pp 2-11](#)
page 8

SAGE noted that in Phase III trials to date, including those undertaken in south and central America, rotavirus vaccines had been shown to reduce the severity of rotavirus diarrhoea, rather than prevention of infection. SAGE recommended that in countries where rotavirus vaccines are introduced, clear communication strategies be implemented to prevent misconceptions regarding the efficacy of rotavirus vaccines to prevent all childhood diarrhoea. SAGE noted that promotion of the use of oral rehydration therapy should be maintained.

SAGE is not yet in a position to make global recommendations about the use of rotavirus vaccines. Additional efficacy studies do not need to be very extensive but should be representative of the respective regions. SAGE supports previous WHO recommendations for obtaining information on co-administration of rotavirus vaccines with routine EPI vaccines, and especially with OPV. The emergence of new serotypes should continue to be monitored after vaccine introduction.

SAGE considered that a regional and phased approach could be appropriate in those regions where successful Phase III trials have been undertaken, and provided that other elements such as the appropriate infrastructure and financing mechanisms were available. The lessons of vaccine introduction and post-marketing surveillance from one region could then be useful to others. At the same time, much needed efficacy data should be collected in Africa and Asia.

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

Weekly Epidemiological Record, No. 51-52, 2009

page 537

WHO recommends that rotavirus vaccine for infants should be included in all national immunization programmes. In countries where diarrhoeal deaths account for 10% of mortality among children aged <5 years, the introduction of the vaccine is strongly recommended.

Weekly Epidemiological Record, No. 51-52, 2009

page 537

WHO recommends that the first dose of either RotaTeq or Rotarix be administered at age 6-15 weeks. The maximum age for administering the last dose of either vaccine should be 32 weeks

Weekly Epidemiological Record, No. 51-52, 2009

page 537

It is recommended that 2 doses of Rotarix be administered with the first and second doses of DTP rather than with the second and third doses. This ensures maximum immunization coverage and reduces the potential for late administration beyond the approved age window. This schedule will be reviewed as new data become available.

Weekly Epidemiological Record, No. 51-52, 2009

page 537

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases; this strategy should include, among other interventions, improvements in hygiene and sanitation, zinc supplementation, community-based administration of oral rehydration solution and overall improvements in case management

New Vaccines

Rotavirus vaccines, an update (WHO position paper)

[WER 2003, vol. 78, 1, pp 2-3](#)
page 2

(No) rotavirus vaccine is currently available internationally. As soon as new rotavirus vaccines have been licensed and become available on the international market, a fully revised position paper will be published in this journal (Weekly Epidemiological Record.)

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

[WER 2006, vol. 81, 1, pp 2-11](#)
page 8

SAGE noted that in Phase III trials to date, including those undertaken in south and central America, rotavirus vaccines had been shown to reduce the severity of rotavirus diarrhoea, rather than prevention of infection. SAGE recommended that in countries where rotavirus vaccines are introduced, clear communication strategies be implemented to prevent misconceptions regarding the efficacy of rotavirus vaccines to prevent all childhood diarrhoea. SAGE noted that promotion of the use of oral rehydration therapy should be maintained.

SAGE is not yet in a position to make global recommendations about the use of rotavirus vaccines. Additional efficacy studies do not need to be very extensive but should be representative of the respective regions. SAGE supports previous WHO recommendations for obtaining information on co-administration of rotavirus vaccines with routine EPI vaccines, and especially with OPV. The emergence of new serotypes should continue to be monitored after vaccine introduction.

SAGE considered that a regional and phased approach could be appropriate in those regions where successful Phase III trials have been undertaken, and provided that other elements such as the appropriate infrastructure and financing mechanisms were available. The lessons of vaccine introduction and post-marketing surveillance from one region could then be useful to others. At the same time, much needed efficacy data should be collected in Africa and Asia.

Policy

Rotavirus vaccines, an update (WHO position paper)

[WER 2003, vol. 78, 1, pp 2-3](#)
page 2

(N)o rotavirus vaccine is currently available internationally. As soon as new rotavirus vaccines have been licensed and become available on the international market, a fully revised position paper will be published in this journal (Weekly Epidemiological Record.)

Rotavirus vaccines, an update (WHO position paper)

[WER 2003, vol. 78, 1, pp 2-3](#)
page 3

WHO strongly recommends the rapid development of new and safe vaccine candidates against rotavirus disease and parallel evaluation of new candidates in developed and developing countries.

WHO also encourages measures to establish the burden of rotavirus disease in developing countries in order to provide the necessary information for advocacy and risk-benefit analyses, the outcome of which may vary with the epidemiological and socioeconomic setting

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

Research

Rotavirus vaccines, an update (WHO position paper)

[WER 2003, vol. 78, 1, pp 2-3](#)
page 3

WHO strongly recommends the rapid development of new and safe vaccine candidates against rotavirus disease and parallel evaluation of new candidates in developed and developing countries.

WHO also encourages measures to establish the burden of rotavirus disease in developing countries in order to provide the necessary information for advocacy and risk-benefit analyses, the outcome of which may vary with the epidemiological and socioeconomic setting