Impact of Rotavirus Vaccine in Kenya and around the World

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Agenda

1. Background – RVGE burden
2. Efficacy and broad protection
3. Co-administration with other paediatric vaccines
4. Inclusion of rotavirus vaccination in immunisation programmes worldwide
5. Safety
6. Impact and effectiveness studies
Background – RVGE burden
Rotavirus: a significant global burden

Pneumonia and diarrhoea are the leading causes of death due to infectious diseases in children <5 years of age

Factors contributing to the burden of rotavirus gastroenterology

- RV cause of 40% of all diarrhoeal hospitalisations in developed and developing countries
- Leading cause of severe acute dehydrating diarrhoea <5 years
- Infects almost every child worldwide by age 5 years
- Diarrhoea, vomiting, fever
- Timely intervention with IV fluids not always available in developing countries
- Burden on healthcare resources
- Resistant to hand-washing
- Highly contagious, (may be symptomatic), and transmitted by the faecal-oral route
- Epidemics peak in winter in temperate zones; no clear seasonality in the tropics

Rota (Latin, wheel-shaped) virus

IV, intravenous; RV, rotavirus

Distribution of rotavirus strains varies across different regions, 2007–2012

Between 2007 and 2012, the genotypes of a total of 46,967 RV strains were reported from 81 countries. Figure developed by GSK using data from Dóró, et al. Infect Genet Evol 2014; 28: 446–61. WHO Regions: AFR, Africa; AMR, Americas; SEAR, South-East Asia; EUR, Europe; EMR, Eastern Mediterranean; WPR, Western Pacific.

Rotavirus exposure is common in infants <6 months of age

Mean age pre-Dose 1
Mean age post-last dose
Seropositivity pre-Dose 1
Seropositivity post-last dose

Age and seropositivity rates in infants who did not receive RV vaccine (placebo groups)

In studies conducted in developing countries in Asia, up to 26% of infants were seropositive pre-Dose 1 (~9–12 weeks of age)

In studies conducted in Africa, 4.3–13.0% of infants were seropositive pre-Dose 1 (~6 weeks of age)

In studies conducted in Latin America, up to 9% of infants were seropositive pre-Dose 1 (~8 weeks of age)

In studies conducted in Europe, 0–9% of infants were seropositive pre-Dose 1 (9–11 weeks of age)

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RV, rotavirus
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Goal of vaccination
Vaccination is a recommended prevention method

Prevention and treatment of RV diarrhoea

- Clean drinking water
- Breast milk and ORS for management of diarrhoea
- Hygiene
- Nutrition

RV vaccination is globally recommended

ACIP1, PAHO2, WHO6, ESPID/ESPGHAN3,4, APPA5

ACIP, US Advisory Committee on Immunization Practices; APPA, Asia Pacific Pediatric Association; ESPGHAN, European Society for Paediatric Gastroenterology Hepatology and Nutrition; ESPID, European Society of Paediatric Infectious Disease; ORS, oral rehydration solution; PAHO, Pan American Health Organization; RV, rotavirus; WHO, World Health Organization

Goal of rotavirus vaccination

- RV vaccination aims to mimic protection conferred by natural RV infections
  - Two natural RV infections provide 100% protection against a subsequent moderate/severe infection and 75% protection against mild diarrhoea
  - This finding implies that an attenuated vaccine that caused asymptomatic infection could induce immunity
  - It is therefore assumed that two ‘vaccine infections’ could provide ~50% protection against natural infection and ~100% protection against moderate-to-severe disease

Rotarix – efficacy and broad protection
Efficacy of Rotarix in different settings

Variable levels of vaccine efficacy against severe RVGE* in diverse settings

- Europe¹: 95.8%‡
- China²†: 72.0%‡
- Japan³†: 91.6%‡
- Hong Kong, Taiwan, and Singapore⁴†: RD: 2.7 95% CI: 1.2–4.9
- Latin America (OPV co-admin.): 81.6%‡
- Latin America⁵: 83.1%‡
- Malawi and South Africa⁶: 61.2%‡
- China²†: 96.1%‡

Note: In Madhi et al 2010 we report a pooled efficacy of children receiving either 2 or 3 doses of Rotarix is presented, with no statistically significant difference in vaccine efficacy between the two regimens. Rotarix is intended for a 2 dose schedule.

CI, confidence interval; OPV, oral poliovirus vaccine; RD, rate difference; RVGE, rotavirus gastroenteritis. Figure developed by GSK using data from references 1-7.

*Severe RVGE defined as ≥11 on the Vesikari scale (requiring hospitalisation and/or rehydration therapy at a medical facility). † Data from two weeks post-dose 2 up to two years of age.
*During the period from 2 weeks after Dose 2 until 1 year of age, or the end of the first RV season after vaccination.

**Meta-analysis of five studies (ATP cohort for efficacy)**:

- **Rota-004**
  - NCT00425737
  - Finland

- **Rota-006**
  - NCT00385320
  - Brazil, Mexico, Venezuela

- **Rota-007**
  - NCT00429481
  - Singapore

- **Rota-023**
  - NCT00140673
  - Latin America (11 countries)

- **Rota-036**
  - NCT00140686
  - Europe (6 countries)

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Lower efficacy does not translate into lower impact: focus on Malawi

Episodes of severe RVGE prevented by Rotarix vaccination, Years 1 and 2 combined

<table>
<thead>
<tr>
<th></th>
<th>Two doses</th>
<th>Three doses</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotarix n=525</td>
<td>5.9</td>
<td>7.1</td>
<td>6.5</td>
</tr>
<tr>
<td>Placebo n=483</td>
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</table>

Putting the results into context
- Impoverished population
- High incidence of severe RVGE
  - RV detected in one-third of young children
  - Identified as the cause of acute GE in these cases
- High exposure to rotavirus early in infancy
- Wide diversity of circulating RV strains
- Concomitant administration of OPV
- Exposure of infants to HIV

Therefore despite a vaccine efficacy of 38.1%*, the high burden of disease in this country means that routine RV vaccination can have a substantial impact on public health and is recommended by the WHO.

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*95% CI: 9.8-57.3
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Rotarix – co-administration with other paediatric vaccines
Co-administration of Rotarix with other paediatric vaccines in healthy infants

High Rotarix immune responses maintained

No impairment of immune responses to any co-administered vaccine antigens

 ✓ Indicates other paediatric vaccines that can be co-administered with Rotarix.

DTaP, diphtheria-tetanus-acellular pertussis; DTwP, diphtheria-tetanus-whole cell pertussis

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Rotarix – inclusion of rotavirus vaccination in immunisation programmes worldwide
Global Rotavirus Vaccine Introduction Status (April 2018)
95 countries have introduced rotavirus vaccines

ROTA Council Country introduction List
http://rotacouncil.org/vaccine-introduction/global-introduction-status/ Accessed 17/04/2018
Rotarix – safety
Timely administration of rotavirus vaccines is important

Global incidence of IS in the first year of life

Vaccination course ideally completed by as early as possible* (as per the prescribing information)

Dose 1 may be given from the age of 6 weeks (Rotarix and RotaTeq)

Mean incidence of IS among children <1 year of age: 74 per 100,000 infant years

Current RV vaccines are administered at a time when natural IS incidence starts to rise

Administration of age of RV vaccines within 5 months may avoid an overlap between physiological and vaccine-related intussusception

*Rotarix full vaccination course may be completed by 10 weeks of age and must be completed by 24 weeks; RotaTeq full vaccination course may be completed by 14 weeks of age and must be completed by 32 weeks. IS, intussusception; RV, rotavirus. Figure reproduced from Jiang, et al. PLoS One 2013; 8(7): e68482 (doi: 10.1371/journal.pone.0068482)

### Rotarix pivotal clinical trial (Rota-023*)
No increased risk of definite intussusception versus placebo

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Vaccine Group</th>
<th>Placebo Group</th>
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<tbody>
<tr>
<td>0 → 31 days¹</td>
<td>Safety cohort N=31,673</td>
<td>Safety cohort N=31,552</td>
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<tr>
<td></td>
<td>RR=0.85 (95% CI: 0.30–2.42)</td>
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</tr>
<tr>
<td>0 → 100 days¹</td>
<td>Safety cohort N=31,673</td>
<td>Safety cohort N=31,552</td>
</tr>
<tr>
<td></td>
<td>RR=0.56 (95% CI: 0.25–1.24)</td>
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</tbody>
</table>

**Number of IS cases**
- **Vaccine group**
  - 0 → 31 days¹: 6 cases
  - 0 → 100 days¹: 9 cases
  - Subset followed until 12 months of age²: 4 cases
  - **RR=0.28 (95% CI: 0.10–0.81)**
- **Placebo group**
  - 0 → 31 days¹: 7 cases
  - 0 → 100 days¹: 16 cases
  - **RR=0.56 (95% CI: 0.25–1.24)**

* NCT00139347 and NCT00263666.CI, confidence interval; IS, intussusception; RR, relative risk

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Risk estimates for intussusception in the 7-day period after first vaccine dose

The overall estimate of risk of IS during the 7 days after Dose 1 vaccination with Rotarix was 5.4 (95% CI 3.9–7.4), and 5.5 (95% CI 3.3–9.3) after Dose 1 for Human Bovine Reassortant Vaccine.
Risk estimates for intussusception in the 7-day period after second vaccine dose

The overall estimate of risk of IS during the 7 days after Dose 2 vaccination with Rotarix was 1.8 (95% CI 1.3–2.5), and 1.7 (95% CI 1.1–2.6) after Dose 2 for Human Bovine Reassortant Vaccine

Error bars represent 95% CI
*Fixed model estimate (weighted average). CI, confidence interval; IS, intussusception; RR, relative risk
Why is risk–benefit analysis important?

The potential benefits of a vaccine must be weighed against the potential risk of undesirable outcomes (adverse events) occurring after administration\(^1\)

In 2008, the Global Advisory Committee on Vaccine Safety emphasised the importance of continued post-marketing surveillance on IS following RV vaccination\(^2\)

A small increased risk of IS was identified with both Rotarix and RotaTeq but the extensive benefits to health of RV vaccination outweigh the low-level risk of IS\(^3\)–\(^5\)

Number of diarrhoea hospitalisations prevented

- Japan\(^3\)
- England\(^4\)
- USA\(^5\)
- Australia\(^5\)
- Brazil\(^5\)
- Mexico\(^5\)

<table>
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<tr>
<th>Country</th>
<th>Number of Cases Prevented</th>
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<td>Japan</td>
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<td>England</td>
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<tr>
<td>USA</td>
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<tr>
<td>Australia</td>
<td>6</td>
</tr>
<tr>
<td>Brazil</td>
<td>55</td>
</tr>
<tr>
<td>Mexico</td>
<td>41</td>
</tr>
</tbody>
</table>

Number of IS cases possibly caused by vaccination

- Japan\(^3\)
- England\(^4\)
- USA\(^5\)
- Australia\(^5\)
- Brazil\(^5\)
- Mexico\(^5\)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Cases Possibly Caused</th>
</tr>
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<tbody>
<tr>
<td>Japan</td>
<td>50</td>
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<tr>
<td>England</td>
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<tr>
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<td>Brazil</td>
<td>55</td>
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<tr>
<td>Mexico</td>
<td>41</td>
</tr>
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</table>

IS, intussusception; RV, rotavirus

The risk of intussusception after administration of human rotavirus vaccine was not increased in lower-income sub-Saharan African countries.

Figure 1. Ages at Immunization and at Onset of Intussusception, February 2012 through December 2016.

Gray bars indicate the numbers of intussusception cases according to age at symptom onset, and the blue and orange lines indicate the numbers of doses of rotavirus vaccine administered according to age at immunization.

DOI: 10.1056/NEJMoa1713909
Rotarix – impact and effectiveness studies
Increasing vaccination coverage correlates with a decline in RV incidence in different settings

**Malawi: Low-income country**

Data illustrate how increased vaccination coverage correlates with a decrease in incidence of RVGE.2,3

**Incidence of RVGE* at a single hospital in Malawi and RV vaccination coverage (2012–2014)**

- **Incidence of RVGE:**
  - <5 years
  - <12 months
  - RV vaccination coverage among children <5 years of age

**Figures:**
- Pre-vaccination in this region of Malawi: 44 50
- Jan–Jun 2012: 42 40
- Jan–Jun 2013: 29 31
- Jan–Jun 2014: 0 5%

*Proportion of samples positive for RV

**England: High-income country**

Rapid vaccination uptake and high coverage correlated with sudden decline in reported RV cases.4,5

**Weekly RV laboratory reports** and full-course vaccination coverage in England (2004–2016)

- Coverage:
  - Feb 2016–Jul 2016
  - One dose: **94.1%**
  - Two doses: **89.7%** aged six months

**Figures:**
- Number of laboratory reports
- Week

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Impact of rotavirus vaccination

Reduction in mortality rates

Rates of reported all-cause AGE deaths

Mexico

Rotarix VC: ~90%*1


56% (95% CI 49–63) relative reduction of death rates during RV seasons1

46% (95% CI 42–50) reduction annually in children aged <5 years (from mean 18 deaths per 100,000 pre-vaccination to 9 deaths per 100,000 post-vaccination)1

Panama

Rotarix VC: 77.0%2

8.2% (95% CI -13–25) relative reduction of death rates† in children aged <1 year (47 expected deaths 2002–2005 compared with 43 observed deaths 2006–2009)2

3.0% (95% CI -12–15) relative reduction of death rates † in children aged <5 years (102 expected deaths 2002–2005 compared with 97 observed deaths 2006–2009)2

Rotarix VC: 71.0%3

45% (95% CI 40–51) reduction in 2008 in infants aged <1 year vs 2000–2005 (from mean mortality rate of 73 per 100,000 pre-vaccination to 40 per 100,000 post-vaccination)3

54% (95% CI 48–60) reduction in 2008 in children aged 1–4 years vs 2000–2005 (from mean mortality rate of 20 per 100,000 pre-vaccination to 9 per 100,000 post-vaccination)3

El Salvador

Rotarix VC: 61.4%2

47.6% (95% CI 39–55) relative reduction of death rates in infants aged <1 year (111 expected deaths 2002–2005 compared with 57 observed deaths 2006–2009)2

49.5% (95% CI 42–56) relative reduction of death rates in children aged <5 years (154 expected deaths 2002–2005 compared with 77 observed deaths 2006–2009)2

Brazil

Rotarix VC: 81.9%2

45.0% (95% CI 43–47) relative reduction of death rates in children aged <1 year (2,031 expected deaths 2002–2005 compared with 1,128 observed deaths 2006–2009)2

42.1% (95% CI 40–44) relative reduction of death rates in children aged <5 years (2,505 expected deaths 2002–2005 compared with 1,465 observed deaths 2006–2009)2

*Approximate figure for children aged <2 years. †Not significant.

AGE, acute gastroenteritis; CI, confidence interval; RV, rotavirus; VC, vaccine coverage

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Impact of rotavirus vaccination on AGE hospitalisations

Australia, Brazil, Mexico, South Africa, UK, USA

**USA**
- All-cause AGE hospitalisations decreased by 55% (95% CI 54–55) in children aged <5 years in 2012 compared with 2000–2006.

**Brazil**
- All-cause AGE hospitalisations reduced by 29% in children aged <5 years.

**Mexico**
- All-cause diarrhoeal hospitalisations decreased by 48% (95% CI 46–50) in infants aged <11 months and 38% (95% CI 36–39) in children aged <5 years.

**South Africa**
- All-cause diarrhoeal hospitalisations in children aged <5 years decreased by 33% in 2010 compared with 2009 (May–December).

**UK (England & Wales)**
- All-cause AGE hospitalisations reduced by 26% (95% CI 16–35) in infants aged <1 year.

**Australia**
- All-cause AGE hospitalisations decreased by 23% in infants aged <1 year and by 38% in children aged <5 years in 2009–2010 compared with 2001–2006.

*Rotarix used exclusively; †Both Rotarix and RotaTeQ used. AGE, acute gastroenteritis

Impact of rotavirus vaccination on RVGE hospitalisations

Australia, Belgium, Brazil, Germany, Malawi, South Africa, UK, USA

**UK (England & Wales)**<sup>9</sup>*
RVGE hospitalisations reduced by 77% (95% CI 68–84) in infants aged <1 year

**Germany**<sup>8</sup>†
RVGE hospitalisations in infants aged <1 year decreased by 60% in HVA and 19% in LVA

**Belgium**<sup>7</sup>†
RVGE hospitalisations decreased by 83% in infants aged <1 year and 80% in children aged <5 years 4 years post-vaccination

**USA**<sup>1</sup>,<sup>2</sup>†
RVGE hospitalisations decreased by 94% (95% CI 94–95) in children aged <5 years in 2012 compared with 2000–2006

**Malawi**<sup>5</sup>*
RVGE hospitalisations in children aged <5 years decreased by 15% in 2012 compared with 2014

**Australia**<sup>6</sup>†
RVGE hospitalisations in children aged <5 years decreased by 71% in 2009–2010 compared with 2001–06

**Brazil**<sup>3</sup>*
RVGE hospitalisations decreased by 82% in infants aged <11 months and by 59% in children aged <5 years

**South Africa**<sup>4</sup>*
RVGE hospitalisations in children aged <5 years decreased by 58% in 2010 compared with 2009 (May–December)

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*Rotarix used exclusively; †Both Rotarix and RotaTeq used. AGE, acute gastroenteritis; HVA/LVA, high/low vaccination coverage area


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The impact of herd effect after vaccine introduction among infants ≤2 months of age*

Sustained herd protection among infants 0–2 months of age

*NCT01563146. RV, rotavirus.
Figure developed by GSK using data from Standaert, et al. Infect Dis Ther 2016; 5(1): 31–44.
Direct and indirect benefits of rotavirus vaccination

Reduction in severe diarrhoea among vaccinated and unvaccinated children after the introduction of RV vaccination in various countries\(^1\)

- **Vaccinated age groups (direct benefits)**
- **Unvaccinated age groups (indirect benefits)**

**Country**
- USA
- USA
- USA
- USA
- USA
- USA
- Australia
- Australia
- Austria
- Brazil
- El Salvador

Decline in RV hospitalisations (%)
- USA: 83%, 75%, 74%
- Brazil: 80%
- Australia: 82%, 71%, 57%, 41%
- USA: 80%, 60%
- USA: 92%, 91%
- Austria: 73%, 78%
- Brazil: 63%
- El Salvador: 83%, 61%

*Each entry represents a different study.\(^2\)

Figure reproduced from Glass, et al. Rotavirus vaccines: Successes and challenges. *J Infect* 2014; 68: S9–18, Copyright 2014, with permission from Elsevier.

RV, rotavirus

Country-specific impact and effectiveness data
Vaccination has had a substantial impact on reducing rotavirus hospitalisations.

Observed impact of RV vaccination on the number of RVGE hospitalisations, 2 and 4 years post-vaccination.

Infants aged <1 year

Infants aged 1–2 years

Decrease of 72% in Year 2 and 83% in Year 4

Decrease of 49% in Year 2 and 77% in Year 4

RV, rotavirus; RVGE, rotavirus gastroenteritis


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Rapid, high vaccination coverage resulted in a substantial decrease in RV cases

Full course (2 doses) vaccination coverage was 93%* by 25 weeks age

77% (95% CI 68–84) reduction in laboratory-confirmed infections in infants <1 year of age

66% (95% CI 50–77) reduction in cases in infants 1 year of age

*Two doses by 25 weeks of age.
RV, rotavirus
Effectiveness of Rotarix vaccination in a region of high infant HIV infection

HIV exposure without infection has been shown to be a potential childhood risk factor for diarrhoeal disease requiring hospitalisation\(^1,2\).

Studies in South Africa provide insight into the effectiveness of RV vaccination in a setting where infant HIV exposure and infection is high\(^1\).

Two doses of Rotarix demonstrated similar effectiveness in HIV-exposed and HIV-unexposed infants (based on adjusted vaccine effectiveness data)\(^3\).

Rotarix helped to protect against RVGE regardless of HIV exposure\(^1,3\).

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*See notes

HIV, human immunodeficiency virus; RV, rotavirus; RVGE, rotavirus gastroenteritis. Figure developed by GSK using data from Groome, *et al.* Lancet Infect Dis 2014; 14(11): 1096–104. Rotarix is a trade mark owned by or licensed to the GSK group of companies.

## Impact of rotavirus vaccination across Africa

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Botswana¹</th>
<th>Botswana²</th>
<th>Zambia³</th>
<th>Zambia⁴</th>
<th>South Africa⁵</th>
<th>Togo⁶</th>
<th>Ghana⁷</th>
<th>Rwanda⁸</th>
<th>Malawi⁹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine coverageᵃ</td>
<td>RV +ve 82%</td>
<td>RV +ve 92%</td>
<td>90%</td>
<td>70%</td>
<td>2013: 39%ᵇ</td>
<td>2013: 100%</td>
<td>RV +ve 94%</td>
<td>2013: 75%ᵇ</td>
<td>2013: 75%ᵇ</td>
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<tr>
<td></td>
<td>(at least 1 dose)</td>
<td>(at least 1 dose)</td>
<td>infants aged 4–11 months</td>
<td>children aged 0–59 months (for 1 dose)</td>
<td>2010: 67%ᵇ</td>
<td>2011: 96%ᵇ</td>
<td>2010: 67%ᵇ</td>
<td>2010: 67%ᵇ</td>
<td>2013: 75%ᵇ</td>
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<td></td>
<td>Dose 1: 100%</td>
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<tr>
<td>Reduction in hospitalisations</td>
<td>23%d</td>
<td>23%d</td>
<td>2013: 29%ª</td>
<td>2013: 29%ª</td>
<td>2010: 33.8%ª</td>
<td>32%ª</td>
<td>aRR 49%c</td>
<td>2014: 43%ª</td>
<td>2015: 54%ª</td>
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<tr>
<td></td>
<td>(95% CI 16–29)</td>
<td>(95% CI 16–29)</td>
<td>infants aged &lt;5 years</td>
<td>infants aged &lt;5 years</td>
<td>2011–2014: 48–57%ª</td>
<td>children aged &lt;5 years</td>
<td>(95% CI 32–63)</td>
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<tr>
<td>Reduction in deaths</td>
<td>22%d</td>
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<td>2013: 27%ª</td>
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<td>65%ª</td>
<td>71%ª</td>
<td>2014: 92%ª</td>
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<td>infants aged &lt;1 year (in-hospital diarrhoea deaths)</td>
<td>(95% CI 80–93)</td>
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<td>against RV hospitalizations</td>
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<td>(95% CI 23–73)</td>
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<td>requiring hospitalisation; infants aged ≥6 months</td>
<td>(95% CI 80–93)</td>
<td>(95% CI 34–87)</td>
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<td>infants aged ≥6 months</td>
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</table>

See notes for further data and information.

AGE, acute gastroenteritis; aRR, adjusted rate reduction; GE, gastroenteritis; NIP, national immunisation programme; RV, rotavirus; VE, vaccine effectiveness

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Rotarix Succinct Safety Statement

- Rotarix should be administered orally and should NOT be injected under any circumstances.

- Rotarix should not be administered to subjects with known hypersensitivity to any component of the vaccine, to subjects with known hypersensitivity after previous administration of rotavirus vaccines, to subjects with a history of intussusception, to subjects with uncorrected congenital malformation (such as Meckel’s diverticulum) of the gastrointestinal tract that would predispose to intussusception, or to subjects with severe combined immunodeficiency (SCID) disorder.

- In clinical trials the most commonly reported adverse reactions were irritability and diarrhoea. During routine use of Rotarix the following adverse reactions have been rarely reported: intussusception, haematochezia, and gastroenteritis with vaccine viral shedding in infants with SCID disorder. Intussusception is a very rare adverse reaction of Rotarix. The signs of intussusception may include severe stomach pain, persistent vomiting, blood in stools, a swollen belly and/or high fever. As early diagnosis and therapy is crucial in the management of intussusception, parents/guardians must be systematically informed of the very rare risk of intussusception and advised to seek medical care immediately should symptoms suggestive of intussusception occur within a month of vaccination or anytime after that.

- Administration of Rotarix should be postponed in subjects suffering from acute severe febrile illness, or suffering from diarrhoea or vomiting. The presence of a minor infection, however, is not a contraindication for immunisation.

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Rotarix Prescribing information
Rotarix contraindications

• Hypersensitivity:
  – either to the active substance or to any of the excipients
  – or after previous administration of RV vaccines

• History of IS

• Subjects with uncorrected congenital malformation of the gastrointestinal tract that would predispose to IS

• Administration of Rotarix should be postponed in:
  – subjects suffering from acute severe febrile illness*
  – subjects suffering from diarrhoea or vomiting

• Infants with SCID

*Presence of a minor infection is not a contraindication for immunisation.

– IS, intussusception; RV, rotavirus;
– SCID, severe combined immunodeficiency disease

1. Rotavirus Vaccine Prescribing Information,
GSK is committed to the effective collection and management of human safety information relating to our products and we encourage healthcare professionals to report adverse events to us on +254 20 693 3200 or ke.safety@gsk.com

Full Prescribing Information available on request
Thank you!
Annual global disease burden of rotavirus gastroenteritis (pre-vaccination era)

RVGE is the most common cause of severe gastroenteritis in infants and young children <5 years of age worldwide

- Deaths: 453,000
- Hospitalisations: 2 million
- Clinic visits: 25 million
- Episodes: 111 million

By the age of 5 years, an estimated 1 in 293 children will die due to RVGE.

Annual RVGE-related events

- An estimated 1 in 65 children required hospitalisation for RVGE by 5 years of age.
- Nearly every child is affected by RVGE by 5 years of age.
- An estimated 1 in 5 children required an outpatient visit for RVGE by 5 years of age.

- RVGE accounts for 37% of diarrhoea-related deaths and 5% of all deaths in children <5 years of age.
