



Instituto
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Spanish Science &
Innovation Ministry

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Health Technology Assessment Agency

Introduction of Rotavirus Vaccination in the Spanish Immunization Programme. A Cost-Utility Analysis

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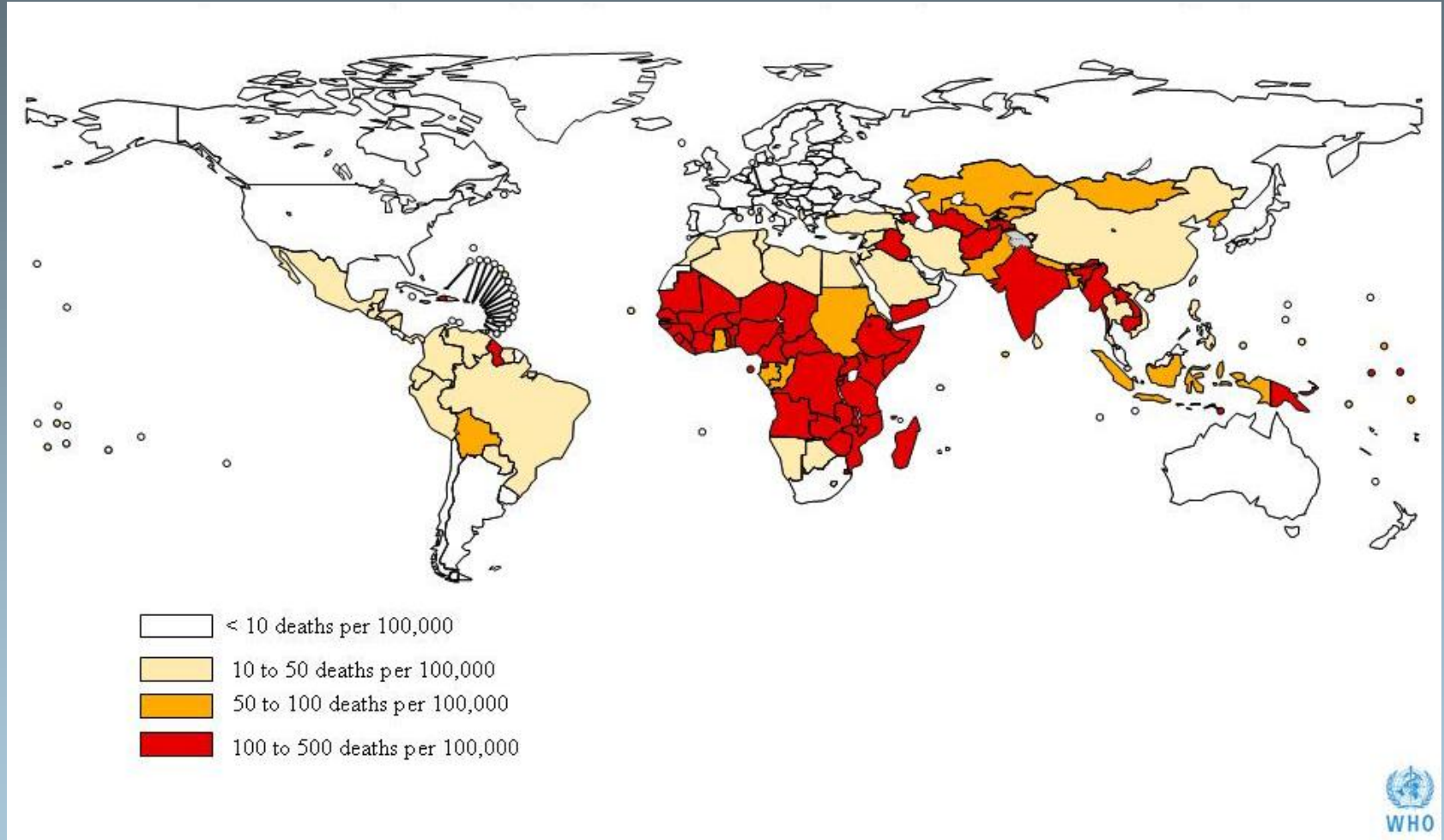
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Rotavirus

- **Leading cause of Acute Gastro-Enteritis (AGE) in young children worldwide**
- **1/2 million deaths/year of children < 5 years**
- **Half of AGE hospitalizations children < 5 years (Western countries)**
- **7M € / year (Spanish health-care costs)**

Rotavirus Associated Mortality Rates among children less than 5 years of age. WHO 2008.

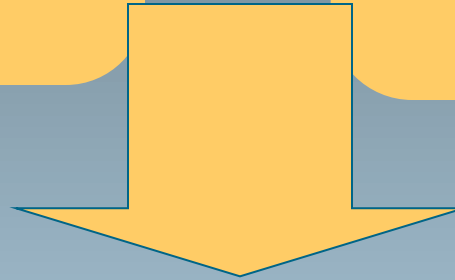


Rotarix[®]

- Alive,
- Monovalent
- Human derived
- 3 doses (2, 4 & 6 months)

Rotateq[®]

- Alive
- Pentavalent
- Human and bovin derived
- 2 doses (2 & 4 months)

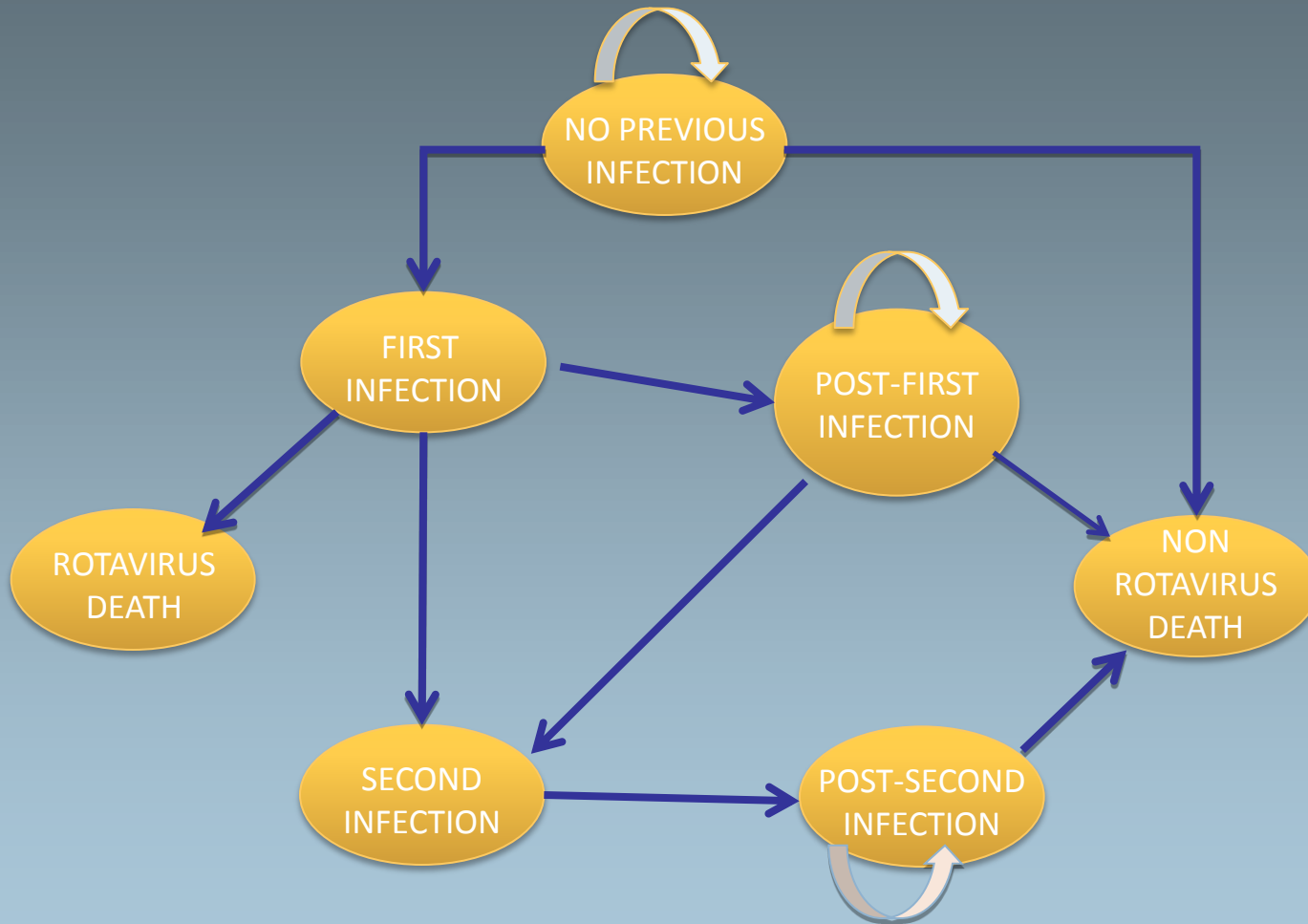


- ✓ Available but not included in the Spanish immunization programs
- ✓ Orally administered

To assess **cost-utility** of the introduction of rotavirus vaccination with Rotateq[®] or Rotarix[®] in the Spanish paediatric immunization program

- **Comparators:**
 - No vaccination vs.
 - Rotarix[®] and Rotateq[®]
- **Health outcome: QALY**
- **Perspectives:**
 - Public Health Care System
 - Societal
- **Population: Spanish children < 5 years old**
- **Markov model:**
 - Time horizon: 5 years
 - Cycle length: 1 month

Markov model



INCLUDED COSTS

PERSPECTIVE

Societal

Public Healthcare Service

Direct Medical

Vaccines, Primary care visit, Hospitalization including treatment and diagnostic tests, Emergency visit

Direct Non-Medical

Parents transportation, accomodation and extra-nappies

No

Indirect

Parent lost productivity,
Children home care

No

- **Efficacy data:**
 - Double-blind randomized placebo-controlled trials
 - Rotarix[®]: Vesikari T, et al. Lancet 2007; 370: 1757-63
 - Rotateq[®]: Vesikari T, et al. NEJM 2006; 354: 23-43
 - **Vaccine coverage:**
Current average for the Spanish Immunization Programme
- **One-way sensitivity analysis:**
 - Efficacy: 95%
 - Confidence Intervals**
 - Vaccine coverage
 - Price

Rotavirus vaccination with Rotarix® or Rotateq® vs. no vaccination in Spain

	Public health-care service perspective			Societal perspective		
	No vacc.	Rotarix®	Rotateq®	No vacc.	Rotarix®	Rotateq®
Unitary cost (€)	29.9	120	135.1	64.5	125.8	144.7
Unitary effect (QALY)	4.78250	4.78288	4.78285	4.78250	4.78288	4.78285
ICUR (€ / QALY)		237,105	300,571		161,315	229,143

Sensitivity analyses by vaccine efficacy. Societal perspective

ROTARIX®	ICUR (€ / QALY)
92%	134,205
86%	165,873
80%	207,867

ROTATEQ®	ICUR (€ / QALY)
80%	191,696
73.5%	232,390
67%	287,635

Sensitivity analyses by price: Societal perspective

Rotarix price (€)	ICUR (€/QALY)
65	25,231
70	37,482
96	101,187
120	159,993
140	218,798

Rotateq price (€)	ICUR (€/QALY)
55	18,924
60	32,283
107	157,861
134	228,826
160	299,471

- **Limitations:**
 - Indirect comparisons (drug vs placebo)
 - Maintained efficacy during the 5 years
 - No Group Immunity
 - Utility measures => from parents
 - Underestimated AGE incidence => mild GE are not often diagnosed

- The introduction of **rotavirus vaccination** in the Spanish immunization program **would not be efficient** neither from public health-care service perspective nor societal one.
- Vaccination with **Rotarix®** would be in a better cost-utility ratio than with Rotateq®.
- **Vaccines price reduction** would have a greater impact on cost-utility than vaccination coverage or efficacy increases.
- Vaccination against rotavirus would be efficient if prices fell below 70€ for Rotarix® and 60€ for Rotateq®.



44% reduction



56% reduction