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Initial results on the effectiveness of routinely administered Rotasiil Vaccine among children aged 6 to 30 months in the Democratic Republic of Congo

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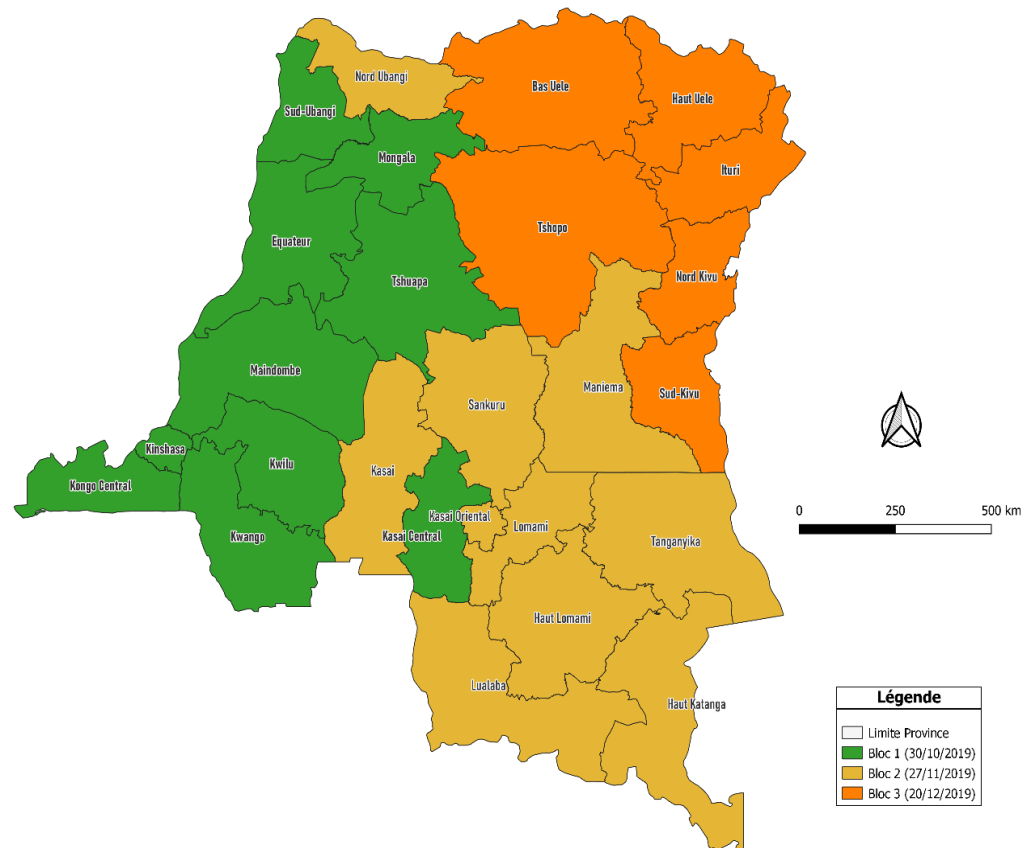
DRC Expanded Vaccination Program & Paris-Saclay University

15th International Rotavirus Symposium | 30 Sept – 2 Oct 2025 | Cape Town, South Africa
Session V: The Road to Protection - Vaccine Development, Efficacy, and Impact (part 1)

Before vaccine introduction, 60% of children hospitalized for acute gastroenteritis were rotavirus positive.

- Diarrheal diseases are important and preventable causes of disability and mortality in DRC.
- The DRC Ministry of Health started rotavirus gastroenteritis sentinel surveillance in August 2009 with support from WHO.
- Before vaccine introduction, 60% rotavirus positivity among admitted children under 5 with acute gastroenteritis (AGE).

Rotasiil vaccine introduced in October 2019 and national vaccination coverage for complete series ranged 49%–56%.



Deployed in phases across all 26 provinces.

Available countrywide, December 2019.

National coverage among children 12 to 23 months old:

	1 dose	2 doses	3 doses
2021	75 %	64 %	49 %
2022	78 %	67 %	56 %
2023	74%	61%	49%

Source: Independent survey of vaccination coverage, Kinshasa school of public health.

No real-world data on Rotasiil effectiveness in Africa

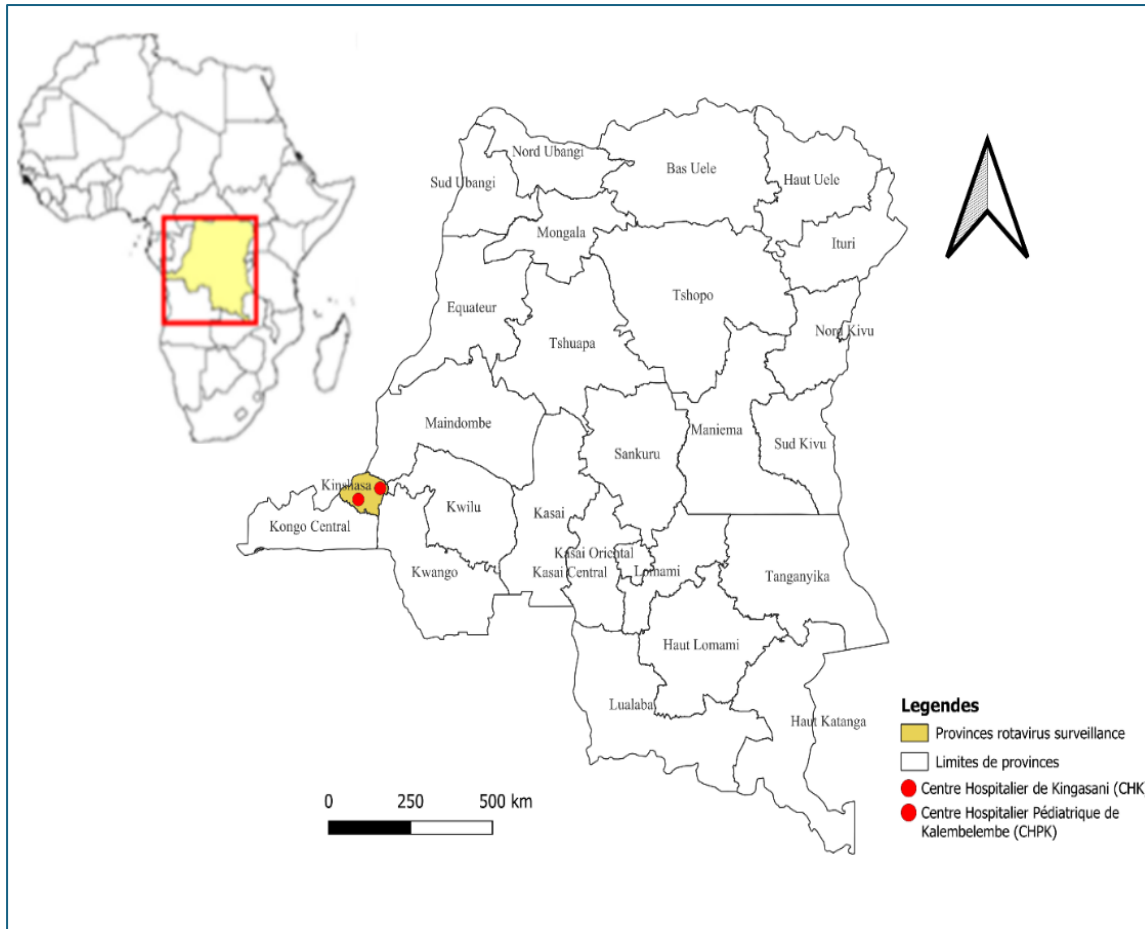
- Efficacy (*clinical trial setting in Niger, protection against severe rotavirus AGE up to 2-years of age*)
 - Per-protocol: 55% (95% CI: 38–67)
 - Intent-to-treat: 64% (95% CI: 51–74)
- Effectiveness (real-world settings in Africa)
 - Rotarix and RotaTeq: 43% - 65% effective in preventing rotavirus-associated hospitalizations.
 - Rotasiil: ?

Sources:

- Isanaka et al, 2021 (doi: 10.1371/journal.pmed.1003720)
- Burnett et al, 2025 (doi: 10.1093/infdis/jiae597)

Estimated Rotasiil vaccine effectiveness (VE) against rotavirus-associated hospitalizations using sentinel surveillance data collected from 2 sites in Kinshasa Province during 2020–2023.

Rotavirus gastroenteritis sentinel surveillance, DRC.



Sentinel sites: hospitals treating pediatric gastroenteritis.

Acute gastroenteritis: ≥ 3 episodes of watery diarrhea within 24 hours non-bloody diarrhea lasting ≤ 7 days among children younger than 5 years admitted for the treatment.

Laboratory confirmation: ELISA test

VE evaluated using a test-negative, case-control design

- Included 6–30 months old children who:
 - Received AGE care at sentinel sites from 1 January 2000 to 31 December 2023;
 - Had written documentation of rotavirus vaccination status.
- Case-control status based on ELISA test results.
 - Cases—positive
 - Controls—negative
- VE calculation: $(1 - \text{adjusted odds ratio}) \times 100$
 - *Adjustment variables:* age groups in months, season, Vesikari score, admission year, & sites.

Selected characteristics of children included in the complete series analysis.

Characteristics	Rotavirus Test Result	
	Case—Positive N = 118	Control—Negative N = 192
	N (%) ^a	
Vaccination status		
Unvaccinated (0 doses)	22 (19)	17 (9)
Completed series (3 doses)	96 (81)	175 (91)

^aPercentages have been rounded and may not total 100.

^bVesikari severity score was categorized as follows: mild, 0–10 moderate, 11–14; severe 15–20.

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Age (months)		
6–11	75 (64)	120 (63)
12–17	34 (29)	53 (28)
18–30	9 (8)	19 (10)
Vesikari severity score^b		
Mild	9 (8)	13 (7)
Moderate	77 (65)	120 (63)
Severe	32 (27)	59 (31)

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Vesikari severity score^b		
Mild	9 (8)	13 (7)
Moderate	77 (65)	120 (63)
Severe	32 (27)	59 (31)
Outcome		
Recovered	114 (97)	188 (98)
Deceased	2 (1)	3 (3)
Transferred or not specified	2 (1)	1 (0)

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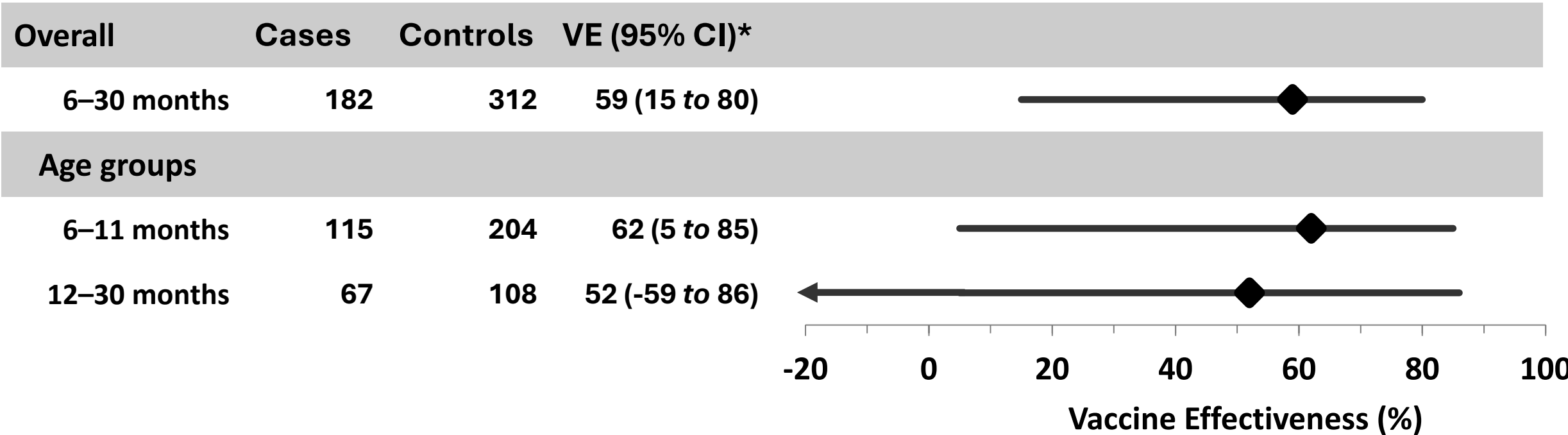
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Rotasiil (completed series) in DRC performed similarly to Rotarix and RotaTeq based on real-world evidence from other African countries.

60%

(95% CI: 20–80)

No differences in VE across age groups when compared receiving ≥ 1 vs 0 doses.



*Overall: adjusted for *age groups in months*, season, Vesikari score, admission year, and surveillance site
 *Age-group: adjusted for season, Vesikari score, admission year, and surveillance site

Summary

- During 2020–2023, preliminary results show that Rotasiil was effective in preventing rotavirus-associated hospitalizations among children 6–30 months old in the DRC.
- Overall, Rotasiil performed similarly to ITT results in clinical trial settings and to Rotarix and RotaTeq based on real-world evidence from other African countries.
- Strong protection in the first year of life, when most hospitalizations occur in DRC
 - No clear decrease in protection in the second year, but VE is imprecise.
- Additional data collection will allow us to evaluate Rotasiil VE in specific subgroups including age groups, most common genotypes and moderate to severe infections.

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