FOURTEENTH INTERNATIONAL

ROTAVIRUS SYMPOSIUM

MARCH 14–16 **2023** BALI INDONESIA

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GLOBAL OVERVIEW OF ROTAVIRUS AND ROTAVIRUS VACCINES

14th International Rotavirus Symposium
Bali, Indonesia
14-16 March, 2023

CONTEXT

2018 – Minsk, Belarus

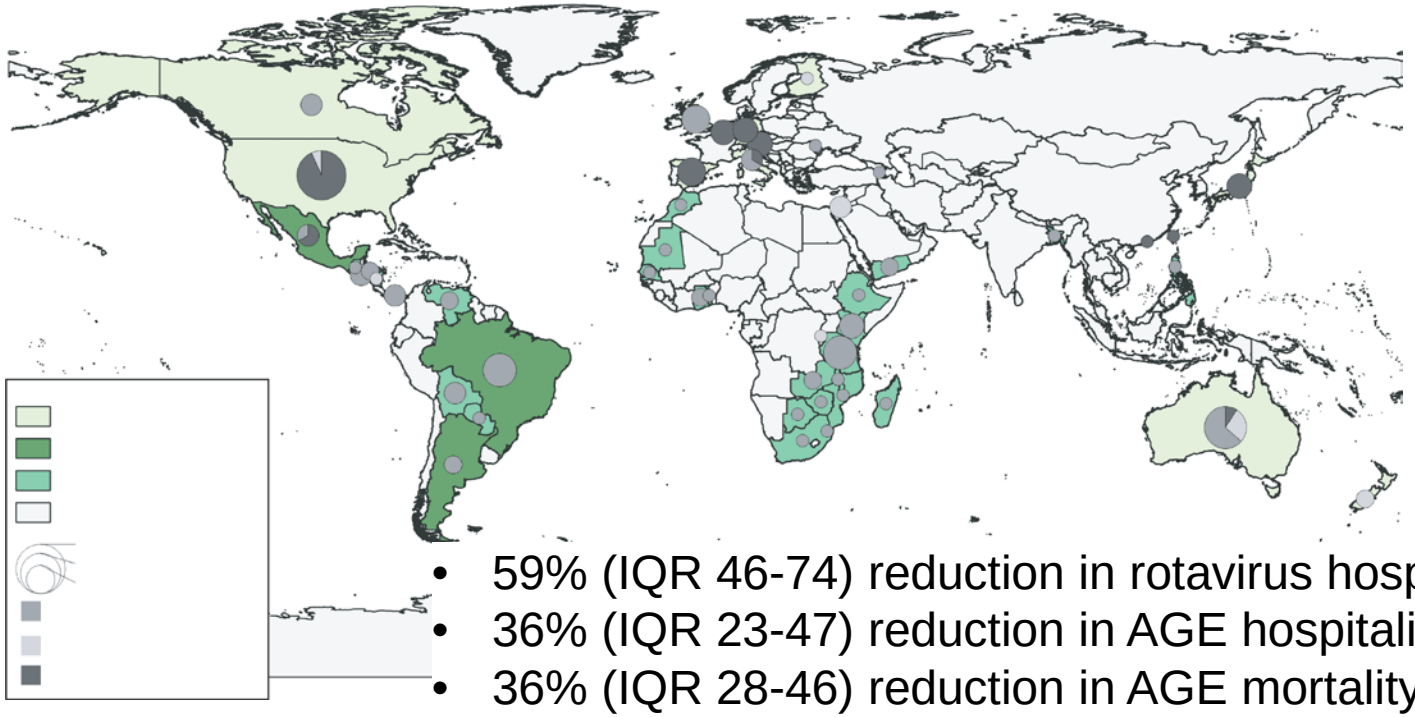
2020 – New Delhi, India

Union Minister launches Rotavirus Vaccine in India, March 2016

2023 – Bali, Indonesia

- 375+ registered delegates
- 38 countries
- Launched Rotavirus vaccine in December 2022
- Development of the neonatal RV3-BB vaccine at PT Biofarma

IMPACT OF ROTAVIRUS VACCINE INTRODUCTIONS: 2006 - 2019



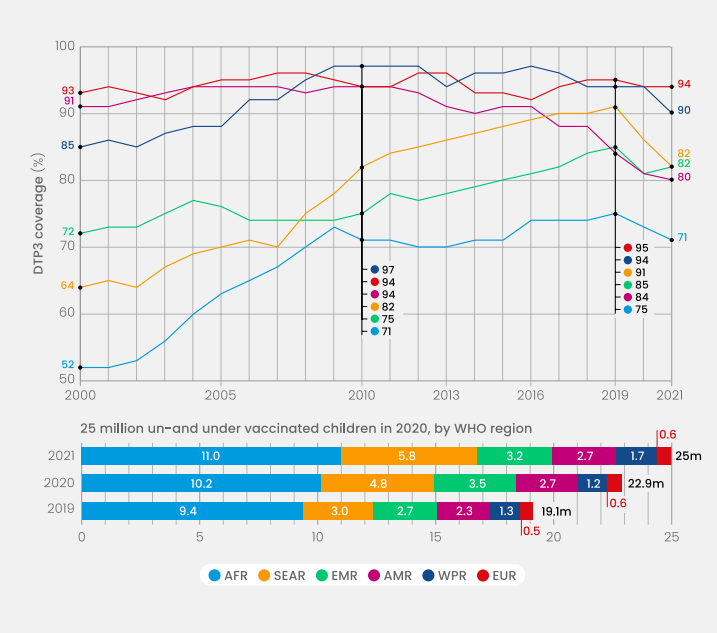
- 59% (IQR 46-74) reduction in rotavirus hospitalizations
- 36% (IQR 23-47) reduction in AGE hospitalizations
- 36% (IQR 28-46) reduction in AGE mortality

Median percentage of rotavirus positive diarrhea hospitalizations pre-rotavirus introduction – 40%
Four years after – 20%

Burnett E et. Journal of Infectious Diseases 2020

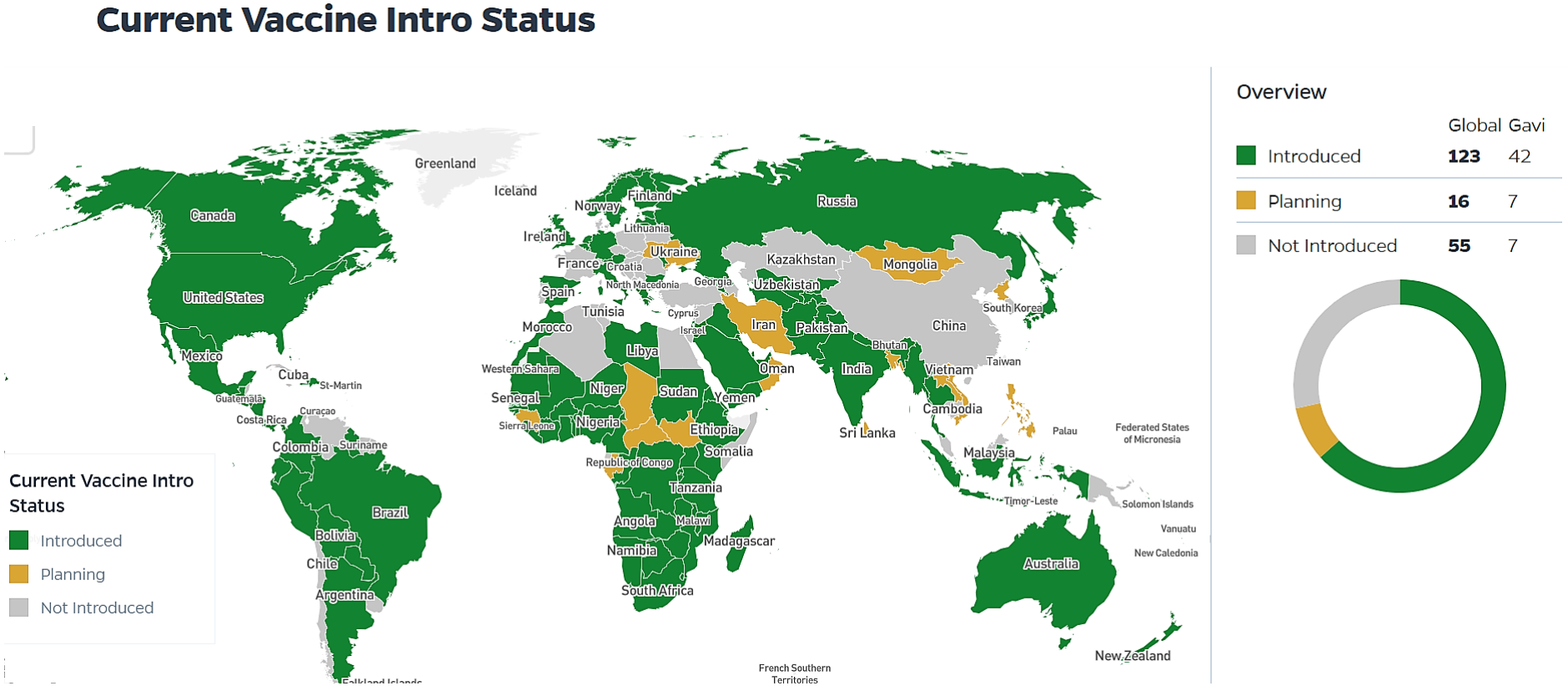
VACCINE COVERAGE HAS BEEN IMPACTED BY COVID - SIGNIFICANT EFFORTS ARE NEEDED TO CATCH-UP

- Only 25 vaccine introductions other than COVID-19 vaccine were reported in 2021.
- Global coverage dropped from 86% in 2019 to 81% in 2021
- An estimated **25 million children** under the age of 1 year did not receive basic vaccines, which is the highest number since 2009.
- The number of girls not vaccinated against human papillomavirus (HPV) increased by 3.5 million, compared to 2019.
- In 2021, the number of **completely unvaccinated children increased by 5 million since 2019**.



SOURCES: *2021 WUENIC Report: https://www.who.int/data/immunization*

CURRENT STATUS OF ROTAVIRUS VACCINE INTRODUCTIONS



Overview

	Global	Gavi
Introduced	**123**	42
Planning	**16**	7
Not Introduced	**55**	7

DRC – December 2019
Nigeria – August 2022
Indonesia – December 2022

IVAC Viewhub.

AMONG CHILDREN UNDER 5 YEARS OF AGE: ROTAVIRUS IS THE TOP CAUSE OF DIARRHEAL DEATHS

Rotavirus is major cause of diarrhea in all regions – particularly heavy burden in the African, SE Asian, and Eastern Mediterranean Regions

Estimated all-cause and pathogen-attributable diarrhoeal deaths in 2017-2018 with 95% confidence intervals both globally and by WHO region in children less than 5 years of age. ETEC=enterotoxigenic E. coli.

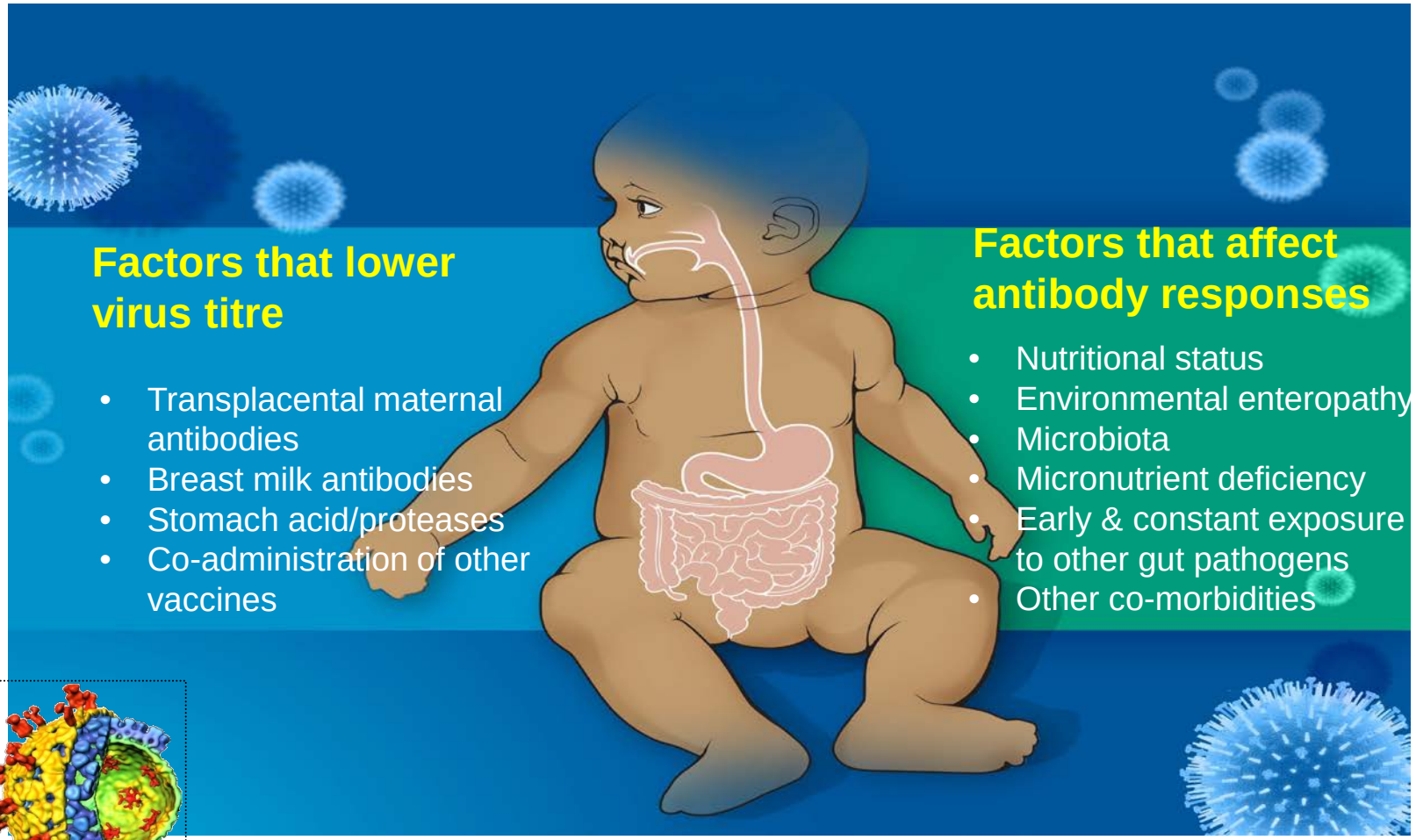
	Global	African Region	Region of the Americas	Eastern Mediterranean Region*	European Region	South-East Asian Region	Western Pacific Region
All-cause	582295 (493241, 683788)	396459 (321310, 482064)	10483 (7385, 14682)	79661 (56853, 108689)	1623 (1069, 2597)	84565 (70943, 101038)	8175 (6057, 10868)
Rotavirus	208009 (169561, 259216)	148931 (115068, 191171)	1857 (1221, 2898)	28343 (20445, 39430)	342 (207, 560)	25829 (20780, 31466)	2283 (1590, 3307)
Shigella	62853 (48656, 78805)	43947 (30852, 57086)	1570 (995, 2376)	7837 (5221, 11774)	193 (116, 319)	9164 (6608, 11997)	106 (54, 211)
Adenovirus 40/41	36922 (28469, 46672)	15117 (9339, 20597)	765 (439, 1166)	8182 (5333, 12275)	54 (17, 97)	12701 (9130, 16202)	175 (100, 250)
Norovirus	35914 (27258, 46516)	19562 (13936, 26002)	1843 (1201, 2883)	5881 (3267, 9851)	156 (96, 243)	6960 (3958, 11553)	1094 (816, 1475)
Sapovirus	22704 (16452, 29354)	17060 (12249, 22275)	396 (245, 605)	2539 (1176, 4507)	108 (65, 185)	2302 (578, 4550)	143 (103, 208)
ETEC	22530 (17762, 28869)	18879 (14817, 24304)	338 (205, 559)	1988 (1224, 2971)	63 (37, 109)	1158 (726, 1700)	28 (17, 52)
Cryptosporidium	19905 (14364, 26984)	17121 (11950, 23540)	116 (62, 194)	1553 (949, 2527)	51 (22, 95)	984 (664, 1278)	22 (8, 55)
Astrovirus	17213 (12095, 22573)	13208 (8547, 18064)	289 (164, 460)	1832 (1077, 2773)	63 (32, 110)	1670 (862, 2477)	110 (80, 151)
C. jejuni/C. coli	9741 (4023, 15478)	4130 (2144, 6778)	321 (150, 503)	2263 (372, 4468)	9 (5, 16)	3032 (291, 5388)	92 (53, 153)
Salmonella	6021 (3391, 8442)	3688 (1188, 5794)	55 (29, 97)	965 (614, 1404)	1 (0, 3)	1160 (788, 1450)	104 (44, 175)

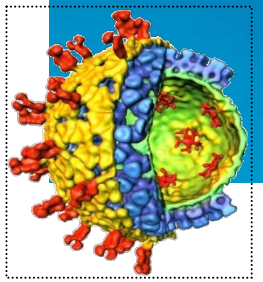
Cohen & Platts-Mills et al. BMJ Global Health 2021.

WHAT ARE THE CHALLENGES WE NEED TO ADDRESS FOR GLOBAL ROTAVIRUS INTRODUCTION AND CONTROL?

- Efficacy in high burden / low-income countries is modest when compared to in high-income countries
  - ~50% vs. >90% efficacy against severe disease
  - Next generation rotavirus vaccines disappointing results
- Costs of the vaccine
  - Countries are transitioning from Gavi support
- Insecure global supply
  - Multiple vaccine products – country switches challenging and resource intensive

CHALLENGES FOR ORAL ROTAVIRUS VACCINES





VACCINE SUPPLY CHALLENGES

Ongoing challenges with vaccine supply, impacted >20 countries, forcing countries to switch from vaccine of first choice

- RotaTeq left the GAVI market in 2018
  - 4 African countries had to switch vaccines
- Supply disruptions in 2021/22, due to production and delivery issues
- Supply issues have resulted in
  - delayed introduction & stock outs (ie. unimmunized infants)
  - 7 countries had to switch vaccines

The greatest challenge currently facing the Rotavirus market is ensuring continuity of supply of preferred presentations for ongoing NIP.

WHO PREQUALIFIED ORAL ROTAVIRUS VACCINES

Rotarix (GSK)	RotaVac (Bharat)	RotaSIIL (Serum Institute)	RotaTeq (Merck)
Monovalent attenuated human rotavirus strain	Monovalent attenuated human strain	Pentavalent, human-bovine reassortant vaccine	Pentavalent, human-bovine reassortant vaccine
G1P[8]	G9P[11]	G1-4, G9 human proteins with P[5] bovine in bovine rotavirus backbone	G1 - 4, P[8] human proteins in WC3 backbone
2 dose regime	3 dose regime	3 dose regime	3 dose regime
liquid presentation 1.0ml, single dose Plastic/BFS	Frozen & Liquid presentation 5&10 dose vial frozen 1&5 dose vial liquid	Lyophilized & liquid 1&2 dose presentation	Liquid presentation: 2ml, single dose Do not supply GAVI withdrew 2018
			2008

The products - various presentations, immunization schedules, formulations, number of doses per vial, vaccine vial monitors (VVM) and cold chain volume needed.

14TH INTERNATIONAL ROTAVIRUS SYMPOSIUM

- Exciting scientific program with a diverse group of presenters globally
- Full oral and poster sessions with interesting data on basic science, molecular epidemiology and advances in immunology of rotavirus
- Rotavirus vaccine effectiveness data and programmatic implementation challenges
- New / novel rotavirus vaccine candidates
- Policy-making and what are important considerations for countries


THE WORK IS
COMPLICATED.
WHY WE DO IT IS NOT.