

BBV131

**Bharat Biotech's
Next Generation
Oral Cholera Vaccine (OCV)**

In collaboration with



OUR SINCEREST THANKS TO

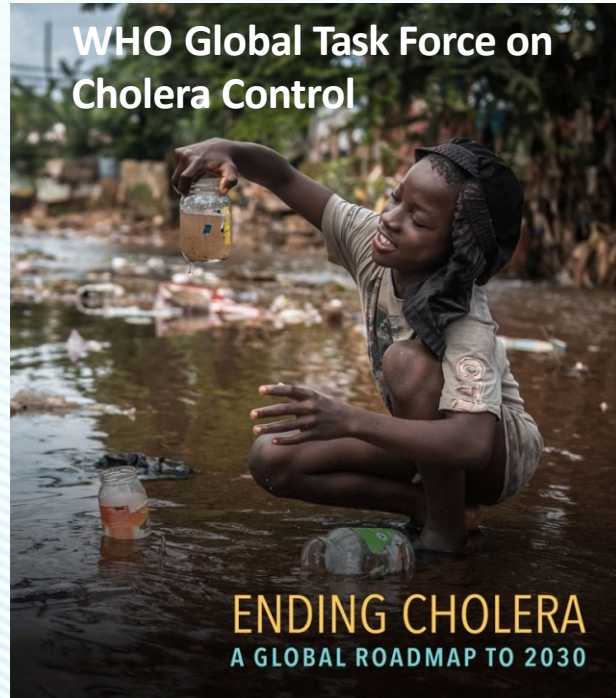


PROF. JAN HOLMGREN



DR. MICHAEL LEBENS

ORAL CHOLERA VACCINE (OCV) IS A CORNERSTONE IN WHO'S ROADMAP FOR ENDING CHOLERA BY 2030



**Launched in October 2017 by
WHO and 50 partners**

The Strategy

Massive use of OCV + WASH

improvements in “cholera hotspots” to

- Reduce global cholera deaths by 90 %
- Eliminate cholera transmission

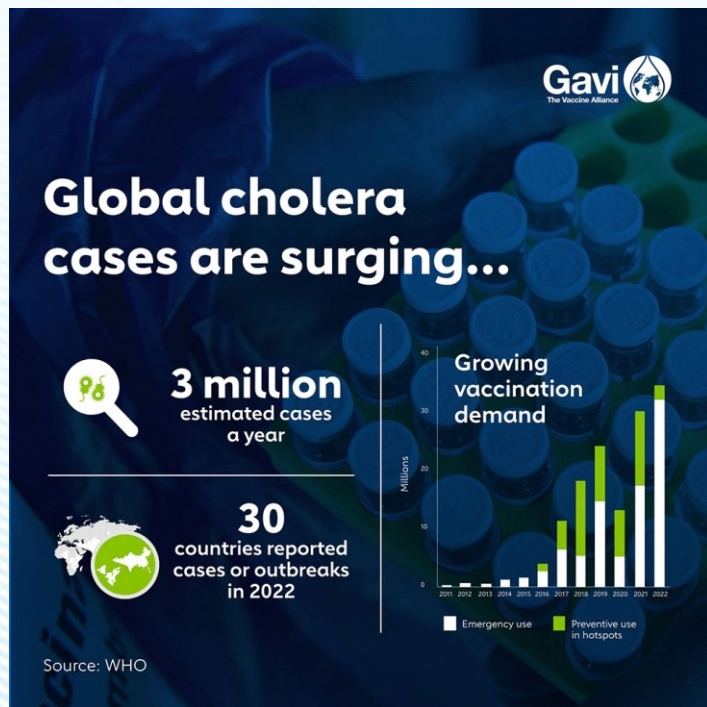
WHO has called OCV “A game-changer in the fight against cholera”

- OCV has immediate strong impact; WASH investment effects are slower and cost more

Why the URGENT Need to Develop a New Cholera Vaccine?

- Current WHO PQ vaccines are effective but were unable to meet demand.
- Enough capacities were not set up.
- Complexities of existing OCVs were realized early on.

NAVIGATING THE CHOLERA VACCINE SHORTAGE



Cholera vaccine shortage to last until 2025 as cases surge, Gavi says

By Jennifer Rigby

May 22, 2023 4:24 PM GMT+5:30 · Updated 4 months ago



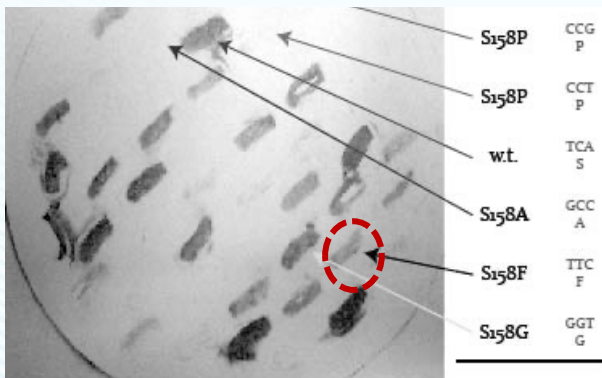
REUTERS

BBV131: Single-component OCV **(U Gothenburg/Hilleman/Bharat Biotech):**

- A novel strain engineered to express the required antigens has been developed at the University of Gothenburg, Sweden.
- Uniqueness of BBV131 is its simplified manufacturing process leading to high production capacity.

Development of the Hikojima Hillchol OCV

Generating a stable Hikojima strain



- Rather than inactivating the *wbeT* gene the aim was to reduce its activity
- We therefore performed **random mutagenesis at a pivotal site (S158) and screened for a Hikojima phenotype** (colony blots, agglutination and ELISA)

The Hillchol OCV MS1568 strain is a stable Hikojima El Tor strain (derived from Phil6973) that co-expresses ca 50% each of Inaba and Ogawa LPS antigens

- Preclinical development at Gothenburg Univ
- Further development & Phase 1+2 with Hilleman Labs., India
- Production of final vaccine and Phase 3 by Bharat, India

BBV131 - DEVELOPMENT JOURNEY(1)

2009 –2010



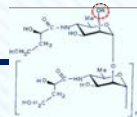
2013



2019



Product Development



Preclinical Studies

- Technology Transfer from Hilleman Laboratories to BBIL.
- Comprehensive development work @ BBIL.
- New facility for production of BBV131 commissioned & qualified at BBIL.
- Large Scale Production
- Test, Release & Regulatory approvals obtained

- Performed in both rodent (BALB/c mice and Wistar rats) and non-rodent (Rabbits) models.
- BBV131 is immunogenic and safe via the human-intended route (Oral) with full Human Single Dose (HSD).

Clinical Studies

Phase 1/2

(Safety, Tolerability & Immunogenicity)
(Hilleman Labs)

- Registration: NCT02823899
- Location: Bangladesh
- Study Population: 560
- Test vaccine is as safe as the currently licensed OCVs.
- Elicits comparable levels of antibody titers like other licensed OCVs against prevalent serotypes of cholera.

Phase 3

(Immunogenicity & Safety)
(BBIL)

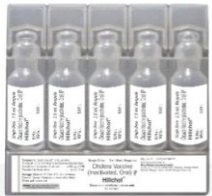
- Registration: CTRI/2022/01/039734
- Location: India
- Study Population: 3600
- Immune responses to V. cholerae O1 Inaba and O1 Ogawa following administration of two doses of BBV131, were non-inferior to the WHO PQd control vaccine.
- Excellent Safety profile.





BBV 131 - VACCINE PRESENTATION & ADMINISTRATION


**Presented in respules (plastic tubes).
Single Dose respules: 1.5 mL**




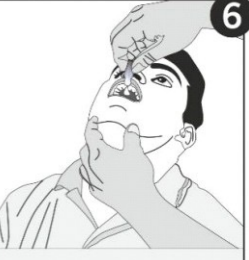
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Vaccine Respules Strip
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Remove one (1) Unit dose respules from the strip.
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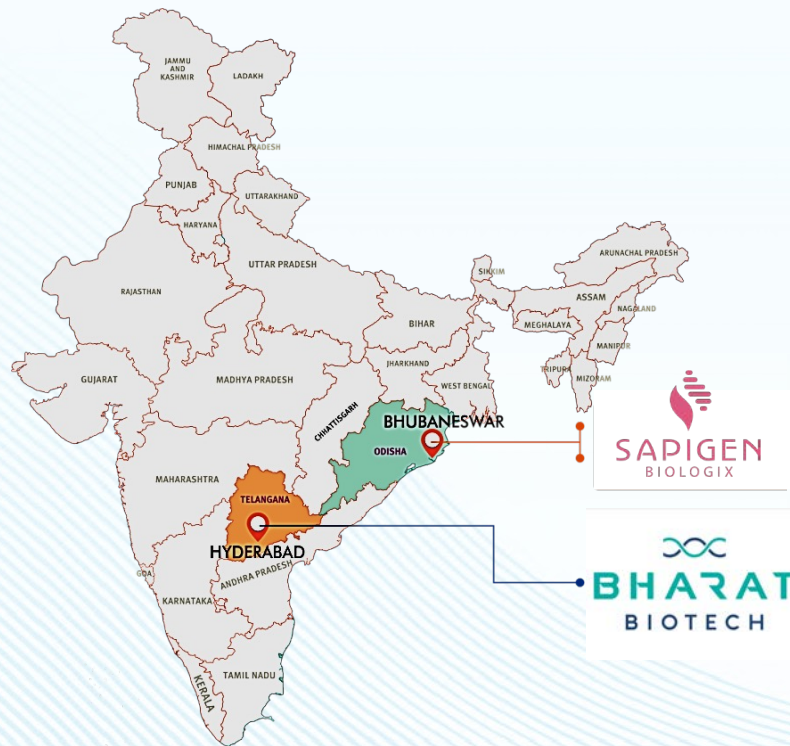
Gently shake the respule
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To open the respule, upright without squeezing twist off the cap
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Pull out the respule cap for oral Administration
- 

Administer single dose into the mouth

BBV131 MANUFACTURING SITES (Capacities built to serve the world)



BBIL and SAPIGEN FACILITIES
~ 150 million doses per annum
Largest Manufacturing Capacity globally for cholera vaccine



Thus, Bharat Biotech would continue its endeavors to contribute for global control of infectious diseases.

THANK YOU