New developments: Preventive Cholera Vaccine Programme & Diagnostics Initiative

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Outline

- Expansion of support for OCV & Development of preventive OCV programme within Gavi's portfolio
- 2. What is changing, and what is not?
- 3. Cholera diagnostic procurement support

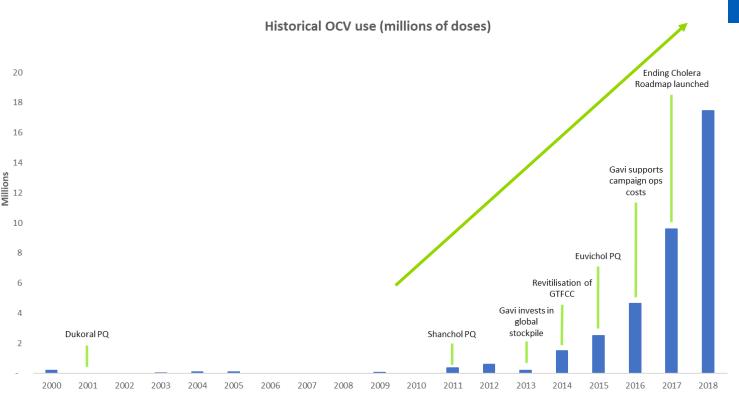


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Expansion of support for OCV & Development of preventive OCV programme within Gavi's portfolio



Gavi has demonstrated commitment to the growth of the OCV program



Gavi's support for OCV helped catalyse countries' uptake of OCV and growth of the vaccine supply

2021: 29m



Expansion of Gavi's investment in OCV over past decade



Investment decisions based on:

Demand Forecasting

- Vaccine products
- Vaccination & delivery strategy
- Schedule/dosing
- Target population
- Country introduction
- Coverage

Impact Modelling

- Burden of disease
- · Case fatality rate
- Efficacy
- Duration of protection

Price Forecasting

- Products
- Supplier projections
- Price projections

Other quant. analyses

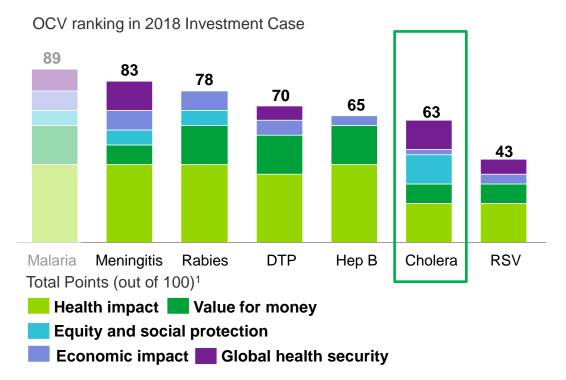
- Procurement cost
- Operational costs
- Value for money
- Economic impact: cost of illness
- Global burden of disease

Qualitative analyses

- Epidemic potential
- Impact on AMR
- Implementation feasibility
- Vaccination policy
- Other qualitative input



Cholera investment recommended during VIS 2018



Recommendation

- Investment in planned, preventive vaccination with OCV, shifting away from only financing outbreak response
- Learning agenda on cholera vaccine implementation in disease hotspots

1. Maximum 40pts for health impact (30pts for total deaths averted, 10pts for deaths averted per 100k), 20pts for value for money (cost per death averted), 15pts for equity and social protection impact, 10pts for economic impact and 15pts for global health security

Note: Malaria not up for investment decision. Used as comparator with Health impact and economic impact based on high-level estimates

Gavi The Vaccine Alliance

Timeline for preventive OCV programme design and launch

•Initiation of stakeholder consultation & exploratory dialogue 2021Q4 Draft application tools and guidelines developed 2022Q1 •External stakeholder consultation on funding guidelines and application materials •Final draft of application tools approved and translated into French 2022Q2 •Dissemination of funding guidelines and application materials for 2023 onward Transition period begins 2022Q3 Applications submitted to Gavi via new process 2023



Goals of the updated programme design

Implement a **holistic**, **interactive review** of multi-year plans to improve quality of campaigns and outcomes

Through multi-year plans, improve planning and predictability of campaigns, and more reliably forecast demand for the manufacturers over a longer time horizon

Leverage campaigns to strengthen routine immunization and integrate WASH and other health activities by engaging EPI and WASH teams

Achieve greater health impact resulting from increased **focus on prevention**

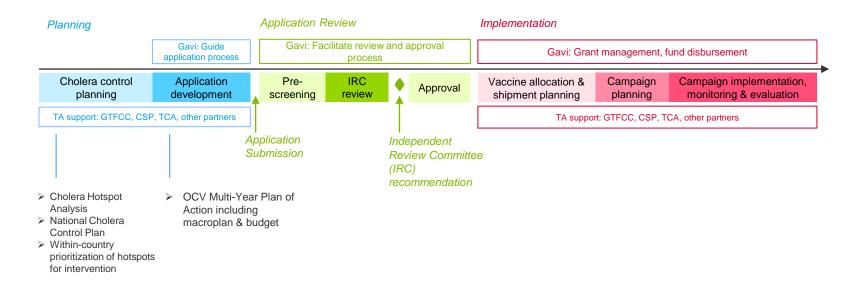


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What is changing, and what is not?



Revised preventive campaign application starting in 2023



Note: Emergency requests will still be submitted to the ICG



What the review committee will be looking for in preventive use OCV applications

Strong Rationale

- Targeted based on epidemiology
- Data-driven decisions
- Increased use of diagnostics to determine needs
- Timing and feasibility of implementation

Advance planning

- Multi-year vaccination plans
- Annual implementation plans and budgets
- Demonstrated readiness
- Strategies to reach high coverage in all targeted areas

Immunization Program Coordination

- Reducing burden on HCW
- Improving efficiency of planning & delivery
- Achieving greater impact!

Leveraging campaigns

- More holistic care approach, capitalizing on opportunities to reach individuals with WASH interventions and other needed health measures
- •Identifying and reaching missed communities with other vaccines

Part of a **broader cholera control strategy** – demonstrated commitment, investment and improvement in WASH, surveillance and other control measures; working with local organizations for community engagement



Overview of Gavi's support

Vaccine Support

Non-Vaccine Support

Routine
Vaccination
&
Introduction

Preventive Vaccination Campaigns (Vaccines & Operational Costs) Outbreak Response (Vaccines, Operational Costs, and TA for preparedness and response)

Diagnostic tests (for surveillance & targeting)

Health System Strengthening Cold Chain (CCEOP)

Partners Engagement Framework – TCA

Equity Accelerator Fund



Cholera diagnostic procurement support



Gavi-supported Yellow Fever (YF) diagnostic efforts: progress

Since Gavi Alliance started to address YF Dx capacity

- 21 countries have received regular Gavi YF Dx procurement funding approved through regular Gavi application processes
- Number of high-risk African countries able to confirm own YF cases has quadrupled
- Time to confirm YF cases has dropped by over 60%.
- Multiple potential YF outbreak response campaigns have been deferred





Expansion of Gavi Alliance diagnostics initiative

In December 2021, Gavi's Board approved funding to improve availability of fit-forpurpose diagnostic tools for:

- Cholera
- Typhoid

- Meningococcus
- Yellow Fever

- Measles
 - Rubella

Goal:

To use improved diagnostic testing to make vaccine programs in countries eligible for new vaccine support through Gavi more effective, efficient, and equitable



Improved cholera diagnostic testing could aid targeting of vaccination campaigns

- Cholera testing in many countries eligible for Gavi new vaccine support is quite limited, particularly outside of cholera outbreaks
- More regular and extensive testing, especially in suspected cholera hotspots, could help with:
 - Determining need for OCV preventive campaigns in a particular area
 - Building case for OCV preventive campaigns among competing priorities for national ministries of health
 - Facilitating more flexible and targeted OCV outbreak response vaccination
- Once cholera diagnostic testing is more widespread, vaccination decision making can rely more on diagnostically confirmed cholera cases
 - Particularly relevant for decisions on revaccinating preventively with OCV



Current cholera diagnostic market status

- Culture is mainstay but major gaps in availability, logistical & technical challenges to scale-up
- Rapid diagnostic tests (RDTs) are potentially the most practical and costeffective options for addressing surveillance questions relevant to vaccination programme planning
 - Currently no validated commercially available RDTs, but WHO PQ standards exist
 - Multiple RDTs; Arkray and Abbott O1/O1139 and Arkray O1 tests have potential
- PCR tests are a viable alternative to culture and RDTs but expensive & complicated
 - Scale-up challenges
 - Suited for quality control to validate RDTs, if adequate lab platforms available



Cholera diagnostic test procurement by countries: accessing Gavi support

- To be eligible for Gavi funding for procurement, diagnostic tests need:
 - WHO prequalification OR
 - Interim recommendation for use from WHO expert committee (e.g., GTFCC)
- Once validated tests are available, countries may request Gavi funding for cholera diagnostic test procurement
 - Application guidance informed by Gavi-funded RDT pilot projects to identify and test distribution strategies and trade-offs
 - Once guidance ready, process for countries to request Gavi funding for cholera test procurement will begin
 - Countries to use Gavi's diagnostics support application guidance (similar to preventive campaign application guidance)
 - Applications to be reviewed by Gavi Independent Review Committee (IRC)



Thank you

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