Update on the Use of Oral Cholera Vaccines (OCV) and Integration with WaSH: Challenges and Opportunities

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U.S. Centers for Disease Control and Prevention (CDC)

Global Taskforce on Cholera Control (GTFCC)
WaSH Working Group Meeting
27 February 2018

Global Immunization Division
Center for Global Health

Outline

- Oral cholera vaccines (OCV) background
- OCV stockpile and Gavi support
- SAGE Recommendation and WHO position update
- OCV use since 2013
- OCV and WaSH integration
  - Related evaluations/studies
  - Challenges
  - **Opportunities**

Cholera Prevention and Control

- **Mainstay measures**
  - **Safe water, sanitation and hygiene (WaSH) interventions**
  - **Disease treatment (oral and intravenous rehydration, antibiotics)**

- **Important complementary tool – use in conjunction with mainstay interventions**
  - **Oral cholera vaccines (OCVs)**

Currently Available and Prequalified OCVs

Dukoral

Shanchol

Euvichol

Main Characteristics: Shanchol and Euvichol

- Bivalent (O1 and O139), killed whole cell vaccines
- 2 doses, 14 days apart among individuals ≥1 year old
- 1.5 ml volume, no buffer requirement (compared with Dukoral)
- Available through the global OCV stockpile

Shantha/Sanofi (India)

Licensed since 2009 (India)

Prequalified by WHO in 2011

Multiple studies – good safety, efficacy and field effectiveness, feasibility data

2018 – Prequalified by WHO for controlled temperature chain (CTC) use

Eubiologics (S. Korea)

Licensed and prequalified in 2015

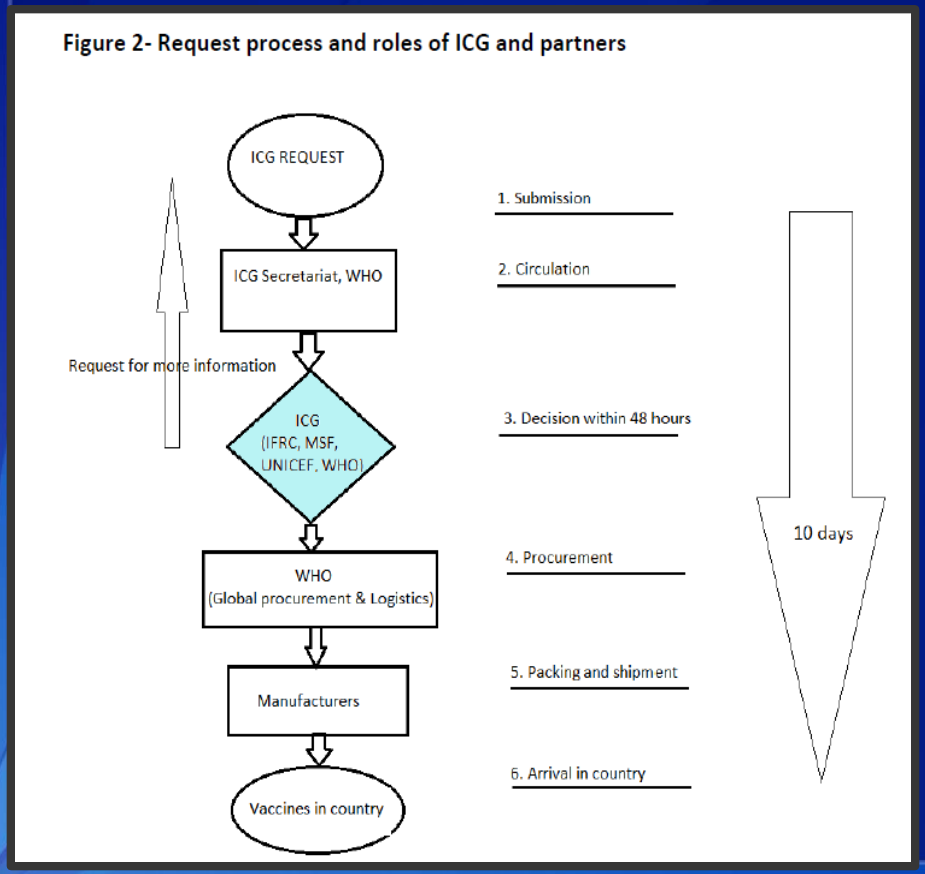
Safety and efficacy: non-inferiority compared with Shanchol

Global OCV Stockpile

- **Sep 2011: WHO consultation called for creation of an OCV stockpile for outbreaks and emergencies**
- **Jul 2013: Stockpile established for initial 2 million doses through funding from multiple donors**
  - Managed by the International Coordinating Group (WHO, UNICEF, MSF and IFRC) similar to other stockpiles
- **Nov 2013: Gavi board approved a contribution to the global cholera stockpile during 2014–2018; included funding for operational costs in 2016**
- **2014: Establishment of the Gavi OCV subteam and transition to the GTFCC OCV working group (endemic use)**

Global OCV Stockpile
Requests and Decision Making Mechanism

Emergency stockpile (ICG)



Non-emergency reserve

Country Request to GTFCC Secretariat (WHO)

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GTFCC OCV working group

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Decision by voting (excluding members with conflicts of interest)

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GTFCC Secretariat

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Manufacturers

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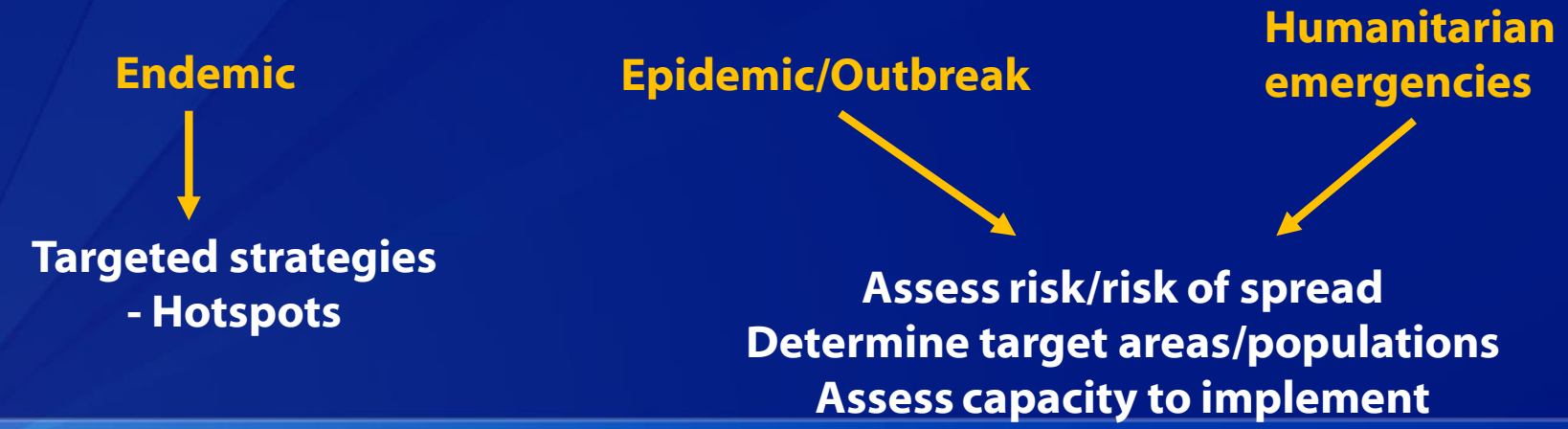
Vaccines in country

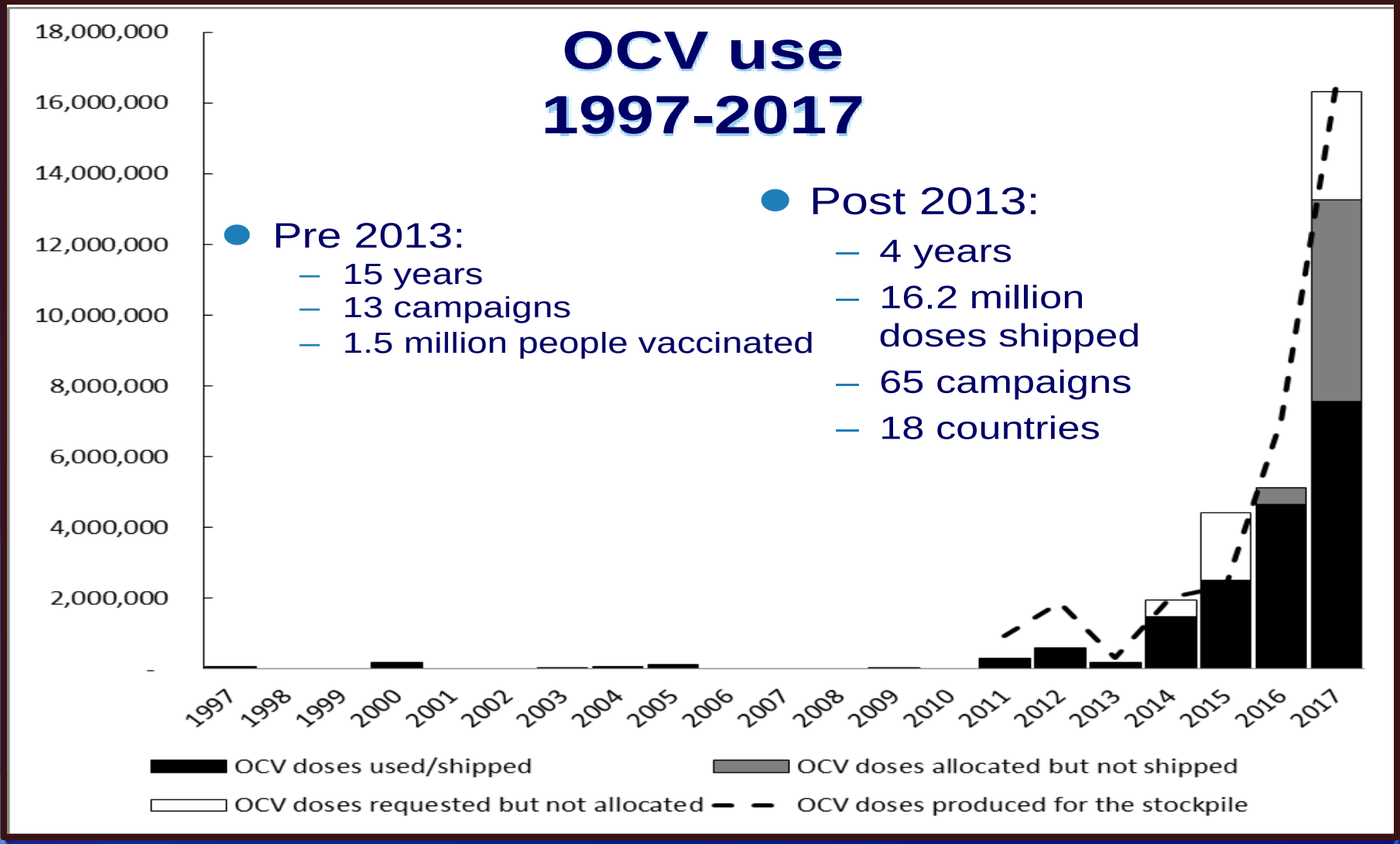
Global Recommendations

Strategic Advisory Group of Experts on Immunization (SAGE) and WHO Position Paper, 2017

- Implement as a complementary cholera prevention and control measure in the short-to-medium term while access to other primary prevention measures (safe water and sanitation) improve globally
- Given the current availability of killed whole-cell OCVs and data on their safety, efficacy, field effectiveness, feasibility, impact and acceptability in cholera--affected populations, use in different settings in conjunction with WaSH
- Ensure equitable access to the OCV stockpile among populations exposed to the risk of cholera in emergency and endemic settings

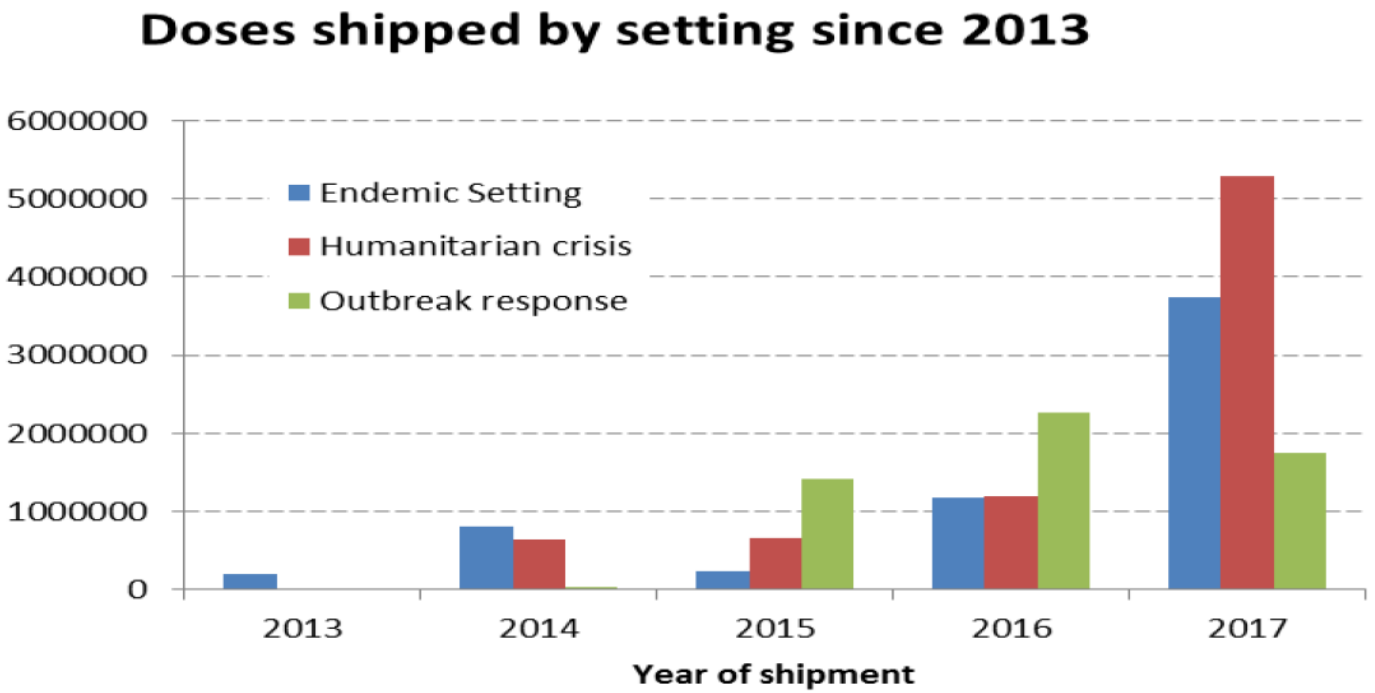


Global OCV Use (1)



Source: WHO (Report of the OCV Working Group meeting, Oct 2017

Global OCV Use (2)

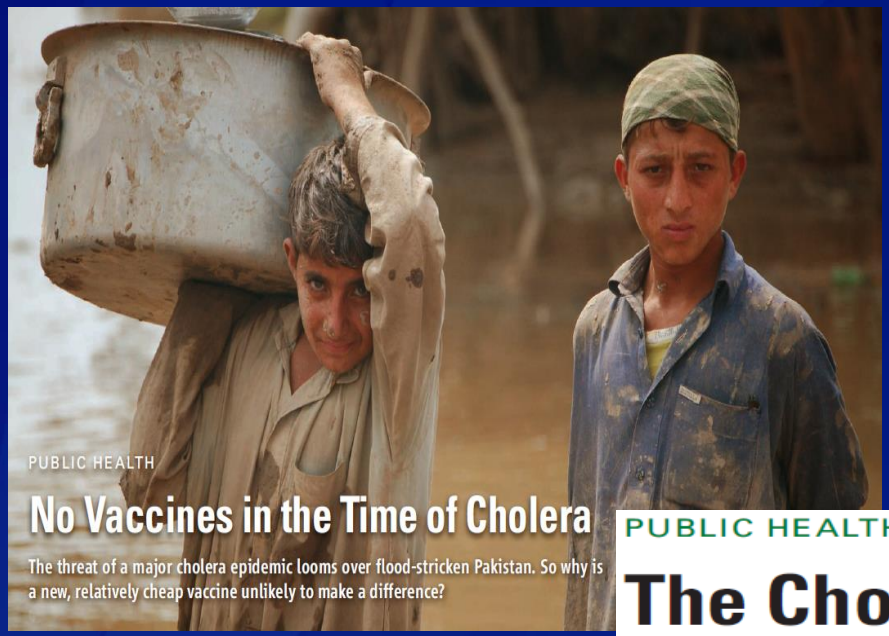


Row Labels	Sum of Doses requested	Sum of Doses shipped
2013	204,500	204,500
2014	1,962,485	1,486,215
2015	4,219,127	2,302,775
2016	5,021,672	4,645,345
2017	22,040,653	12,049,620
2018	2,301,971	1,406,708
Grand Total	**35,750,408**	**22,095,163**

Source: WHO (Dominique Legros)

OCV and WaSH Integration

The Past ….



PUBLIC HEALTH

Cholera vaccine plan splits experts

Opinion is divided over how to tackle the disease in Haiti.

PUBLIC HEALTH

The Cholera Crisis in Africa

S. Bhattacharya,[1] R. Black,[2] L. Bourgeois,[3] J. Clemens,[4] A. Cravioto,[5] J. L. Deen,[5*] Gordon Dougan,[6] R. Glass,[7] R. F. Grais,[8] M. Greco,[9] I. Gust,[10] J. Holmgren,[11] S. Kariuki,[12] P.-H. Lambert,[13] M. A. Liu,[14] I. Longini,[15] G. B. Nair,[16] R. Norrby,[17] G. J. V. Nossal,[10] P. Ogra,[18] P. Sansonetti,[19] L. von Seidlein,[5] F. Songane,[20] A.-M. Svennerholm,[11] D. Steele,[3] R. Walker[3]

Considerations for Oral Cholera Vaccine Use during Outbreak after Earthquake in Haiti, 2010–2011

Summary of Knowledge, Attitudes and Practices Studies

Country	Implementation Setting
Solomon Islands, 2012	Preemptive campaign in response to an outbreak in a nearby region
Haiti, 2012	Campaign in rural Haiti by an NGO (included intense messaging on WaSH)
Haiti, 2013	Government-led campaign in a rural and urban area (limited social mobilization and messaging)
Thailand, 2014	Preemptive campaign by an NGO (included WaSH messaging and subsequent reinforcement of WaSH messaging)

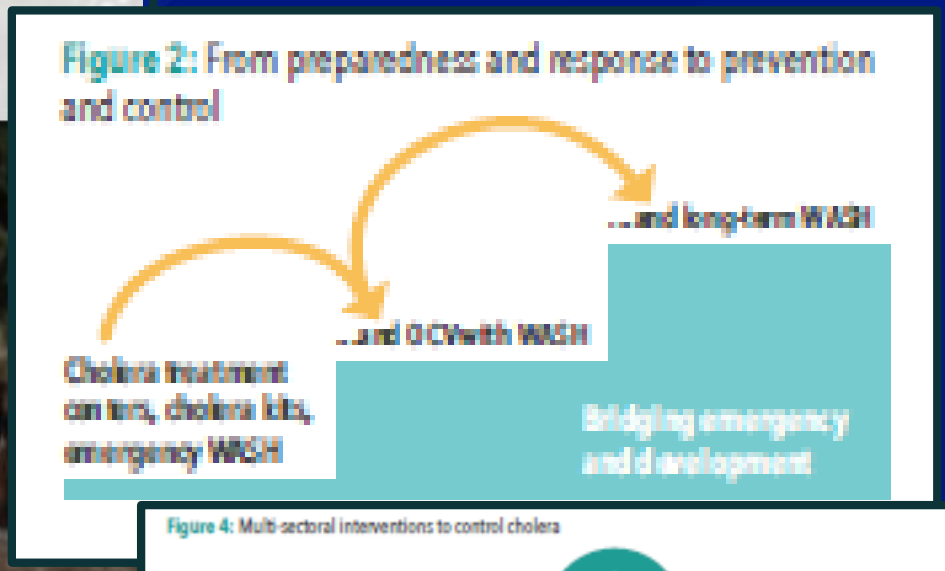
Conclusions

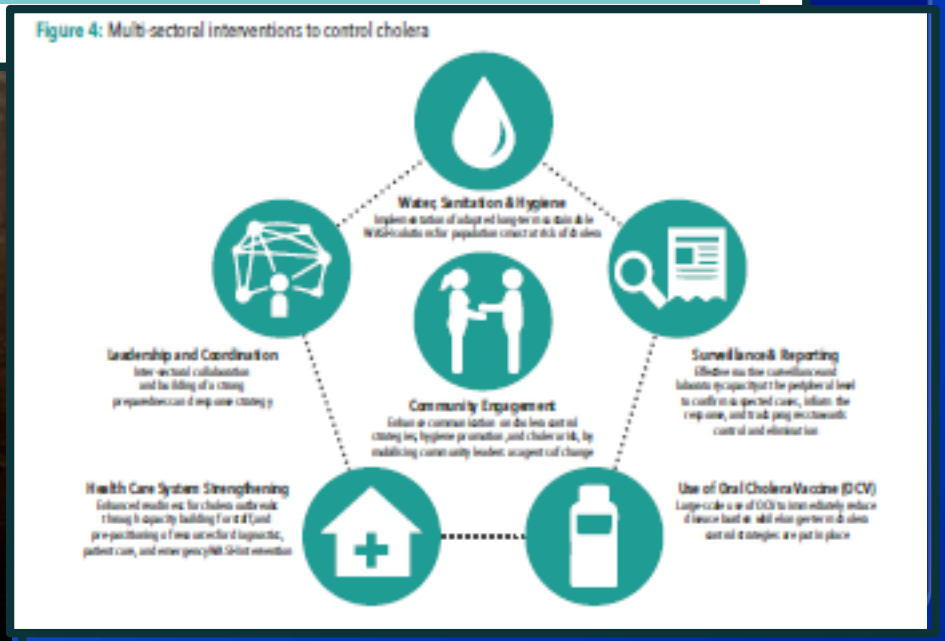
- With careful planning, timing, implementation and messaging, OCV campaigns have the potential to improve WaSH knowledge, attitudes and behaviors
- A potential 'entry point' for further engaging countries and regions in longer term prevention and control efforts

Key Challenges

- **Vaccines as "quick fix" – lack of need for longer-term, more sustainable approaches**
- **Where does this belong! Roles and responsibilities for disease prevention and control versus broader wat-san infrastructure management**
  - Health ministries – communicable diseases, immunization program
  - Non-health ministries – wat-san engineering, development
  - Finance ministries
- **Exactly what and how much WaSH is needed?**
  - No one size fits all
- **Funding**
  - Gavi support requests (endemic use) at country level through the immunization program – not a priority for the immunization program
- **Adequate planning and support for M & E**

Opportunities (1)

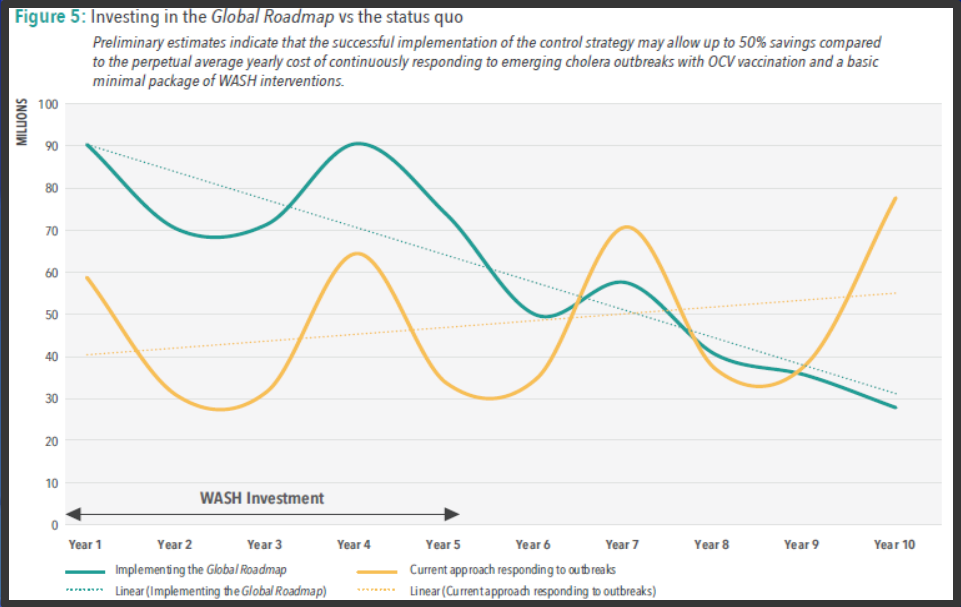




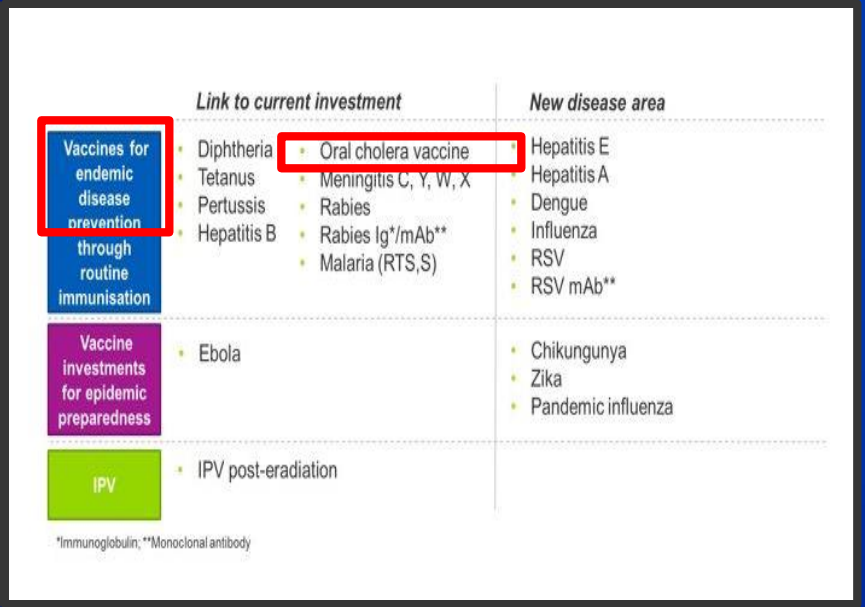
Opportunities (2)

GLOBAL TASK FORCE ON CHOLERA CONTROL

Cholera Investment Case



Gavi Vaccine Investment Strategy



Thank You!

For more information please contact Centers for Disease Control and Prevention

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Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

Dukoral (WC-rBS*)

- Manufactured by Crucell, Sweden
- Monovalent (O1) killed, whole cell oral vaccine - mixture of Classic and El Tor strains
- Includes B subunit of cholera toxin: short-term protection against enterotoxigenic *Escherichia coli* (ETEC)
- First licensed in 1991; currently in ~61 countries
- Prequalified by WHO in 2001
- Cost ~ US$6/dose
  ($12 - $18 for full schedule
  of 2 – 3 doses)

* Whole cell, recombinant B-subunit