World Health Organization

Introduction to oral cholera vaccines: characteristics, stockpile and production

15th March 2017

CHOLERA CONTROL

- Effective cholera prevention and control interventions are well-established and rely to a great extent on the implementation of integrated and comprehensive approaches that involve activities outside of the health sector.
- Cholera is often predictable, preventable and can ultimately be eliminated where access to clean water and sanitation facilities, and satisfactory hygiene conditions are ensured and sustained for the whole population.
- 40 million people are presently living in cholera-endemic areas in sub-Saharan Africa alone. With increased urbanization and climate change, this figure is expected to increase over the next decade.
- Although the mainstay for cholera control remains access to safe water, hygiene promotion and sanitation, there is mounting evidence that high coverage with oral cholera vaccines (OCV) results in significant reduction of cholera transmission in various settings.
- The Sixty-Fourth World Health Assembly Resolution WHA 64.15 (2011) "Cholera: mechanism for control and prevention" has reiterated the use of OCV as a measure for control of cholera.

ORAL CHOLERA VACCINES

- There are 3 OCVs that are currently pre-qualified by WHO – Dukoral®, Shanchol™ and Euvichol®.
- Dukoral® is a two dose vaccine that requires a buffer solution for administration. It protects against *V. cholerae* O1 and confers some protection against ETEC. It is used in all individuals over the age of 2. A minimum period of 1 week is required between doses. A third dose is required in children aged from 2-5 years. Dukoral® confers protection of >50% for at least two years, induces an immune response relatively quickly (7-10 days after the 2nd dose) and has a good safety profile. Production of Dukoral® is limited and it is primarily marketed to travellers.
- Shanchol™ and Euvichol® are essentially the same vaccine, derived from the same transfer of technology. Neither vaccine requires a buffer for administration. They protect against *V. cholerae* O1 and O139. They are administered to all individuals over the age of 1 year with a minimum period of 2 weeks between doses. Both vaccines provide sustained protection of >60% for at least 3 years after 2 doses. A single dose has been proven to give good short term protection for at least 6 months. Levels of protection are less among children under 5. Shanchol™ and Euvichol® have good safely profiles. Both vaccines constitute the OCV stockpile (see below).

- All OCVs currently require cold chain (2-8°C), but the vaccine has been given with no cold chain on the day of administration. Current packed volume for Shanchol™ and Euvichol® is 16.8 cm^3 and 15.0 cm^3 per dose respectively and must be taken into consideration when planning campaigns.
- Since 2010, the WHO recommendation is to use these vaccines in conjunction with other prevention and control strategies in areas where the disease is endemic and in areas at risk for outbreaks. Vaccination should not disrupt the provision of other high-priority health interventions to control or prevent cholera. Updated recommendations will be published in 2017.

OCV STOCKPILE AND USE

- In 2013, WHO formally established an OCV stockpile with an initial amount of 2 million doses of OCV for outbreak control and emergencies.
- Later the same year, Gavi, the Vaccine Alliance approved a contribution to the global cholera stockpile for use in epidemic and endemic settings, with an investment covering the period 2014-2018.
- As of 2016, almost 8 million doses of OCV have been shipped from the stockpile since mid-2013 for 40 mass campaigns implemented in 14 countries in various settings (outbreaks, highly endemic areas, humanitarian crisis).
- Currently, OCV for emergency use (outbreak response or humanitarian crises) is accessed via the International Coordinating Group (ICG).
- Vaccine for planned use in endemic settings is allocated via the Global Taskforce on Cholera Control (GTFCC) OCV working group.
- For the period up to the end of 2018, vaccine and up to 0.65 USD operational costs are provided for eligible countries by Gavi. Further investment by Gavi will be evaluated at the end of 2018.
- WHO and partners of the GTFCC have organised a series of workshops and meetings on OCV at global and country levels, produced numerous guidance documents for OCV use and conducted monitoring & evaluation and research activities during campaigns.
- Many countries and partners are now introducing OCV as part of their cholera control programs in endemic and epidemic settings and the demand for OCV has increased exponentially.

OCV PRODUCTION

- Requests for OCVs outpaced production capacity in 2015. Production doubled in 2016 and is expected to increase again to more than 10 million doses in 2017.
- A significant increase in OCV production capacity is expected in 2017 and beyond.