TYPHOID CONJUGATE VACCINE SUPPORT WINDOW

BOARD MEETING Michael F Thomas 29-30 November 2017, Vientiane, Lao PDR



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Agenda

- Why TCVs?
- 2 Historical decisions and update
- Results of updated analyses 3
- 4
- Key opportunities, learning agenda, PPC discussion
- 5
 - Recommendations





Why should Gavi consider typhoid conjugate vaccines?

Disease burden

- Largely eliminated from industrialised countries, burden remains in low and middleincome countries with the most at risk in the marginalised populations
- 11-22 million cases globally per year
- 128,000 to 223,000 deaths globally per year

< 5 years of age burden

- SAGE Working Group review showed ~27% of all typhoid disease in children < 5 yrs
 - Of this, 29% occurs in < 2 yrs

Antimicrobial resistance (AMR)

- Increasing cases of multiple drug resistance expensive treatments, limited access, difficult administration, fuels further transmission
- Focus will shift from treatment to prevention interventions
- Case-fatality rates in pre-antibiotic era can rise to as high as 20%





Historical decision with updates

- TCVs were prioritised in VIS 2008, awaiting PQ and SAGE to open a funding window
 - Delays in vaccine development
- PQ: 1 product anticipated by end of 2017; SAGE reviewed on 17 Oct
- Updated forecast reflects refined assumptions
 - Increased number of countries
 - 25 countries vs 39 countries over first 10 years
 - New market intelligence
 - More visibility and engagement on supply
 - Inclusion of sub-national scenarios
 - Target age range based on age distribution





October 2017 SAGE overview

- Noted the continued high burden of typhoid fever and the alarming increase in AMR in low- and middle-income countries. Re-emphasized the importance of programmatic use of typhoid vaccines in controlling endemic disease
- TCVs are safe and recommended as a single dose in typhoid endemic countries of children over 6 months plus a one time catch-up of up to 15 years
- Decision on preferred immunisation strategy should be based on disease burden, availability and quality of data, affordability and operational feasibility
- Recommended prioritisation to countries with highest burden of disease or high burden of AMR *S.* Typhi
- Data will be needed on co-administration of TCV (co-admin data available for M/MR) and countries should strengthen surveillance and monitor occurrence of AMR



Results of updated analyses

- Estimated impact and value for money is comparable to Gavi's current funded vaccines
- TCVs are expected to be heavily supply constrained in the initial years with improvements after 2020
 - Uncertainty on estimated amounts (2021-2025)

Million USD (by programmatic year)	2019-20	2021-25
Vaccine procurement	\$65	\$705
VIG	\$5	\$15
Op Costs	\$15	\$145
Total	\$85	\$865





4

Key Opportunities for the Alliance



Health impact

- Burden estimates remains unchanged, large proportion affects < 15 yrs
- Opportunity to catalyse
 prevention efforts
- Decrease AMR threat



Equity

- Developed countries have eliminated typhoid
- AMR creates treatment access / costs issues
- The most at risk of infection are marginalised populations
- Links with ongoing C&E work





Market shaping

1 anticipated PQ manufacturer by 2017
Another 5 in the pipeline
Supply constraints create a market shaping opportunity





Learning Agenda

- Investment should be sufficient to incentivise manufacturer investment and market shaping activities and filling identified gaps for efficient implementation
- Scientific questions
 - Improved understanding of impact on disease (e.g. AMR)
 - Interference with similarly timed vaccines (e.g. YF, Meningitis)
 - Challenge in diagnosis (e.g. poor sensitivity)
- Programmatic questions
 - Prioritisation of typhoid over other health agenda items (e.g. generate better data to inform country decision making especially in Africa)
 - Use of the vaccine on risk-based (sub-national) populations
 - Improving data on outbreaks
 - Managing available supply/demand dynamics
 - Active engagement with industry





Overview of PPC discussions

- The PPC recommended to the Board the opening of a funding window subject to receiving confirmation on WHO PQ:
 - Recognised that the manufacturer fulfilled Gavi's request and developed a safe and effective vaccine with an appropriate price and longer duration of protection
 - Agreed that an investment in TCV links with Gavi's missions and objectives on health impact, market shaping and coverage and equity
 - Discussed the potential the trade-offs in delaying the decision, but recommended opening of a funding window contingent on WHO PQ
- The PPC recognised the importance of a learning agenda:
 - Emphasised the need to address the identified gaps and ensure informed decision making considering sustainability issues as well as reporting back to both PPC and Board



Recommendation

The Gavi Alliance Programme and Policy Committee recommends to the Gavi Alliance Board that it:

- a) <u>Approve</u> the opening of a funding window for TCVs subject to the Secretariat receiving confirmation of WHO PQ of a vaccine such that in 2018, the Secretariat can invite country proposals for support from Gavi eligible countries.
- **b)** <u>Note</u> that the financial implications associated with the above approval for the period of 2019-2020 are expected to be approximately US \$85 million, which has been taken into account in the financial forecasts to be presented to the November 2017 Board for the 2016-2020 period.
- c) <u>Request</u> the Secretariat to develop a process to enable allocation of vaccines in Gavisupported countries if needed in case of a typhoid outbreak and if requested by WHO.
- d) <u>Request</u> that, no later than two years from the first country introduction and in addition to regular updates, the Secretariat formally report back to the PPC and Board on lessons learned from initial country introductions and outbreak usage.









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