Creating a sustainable vaccine landscape for Typhoid Fever

Vinita Vishwanarayan | Clinton Health Access Initiative (CHAI)
10th International Conference on Typhoid and other Salmonellosis
Kampala, Uganda | April 2017
Agenda

- The elusive TCV vaccine
- Drivers of low manufacturer interest
- Supporting a healthy vaccine market for Typhoid Fever
In spite of huge need and pledged donor support in 2008, as of today still no Typhoid Conjugate Vaccine has been pre-qualified.

**High disease burden in Gavi and LMICs**

- **High burden** of typhoid fever:
  - Incidence rate of *21.7* M and *217,000* fatalities annually
- **Children** aged *2-14* bear greatest burden
- **High prevalence** of resistance to first-line multi-drug treatments

**Strong rationale for Gavi VIS decision in 2008 to support Typhoid Conjugate Vaccine**

- **Low cost** for TCV *~$12* per case averted
- Suitable for **children < 2 yrs.**
- **Gavi budget** for TCV vaccine in 2008 VIS *~$0.5B* between 2009-2020
- **WHO PQ’d** TCV initially expected in 2010-2011
- **Introduction delayed** as no available PQ’d TCV suppliers during 2008 Gavi VIS

**Long lag in TCV suppliers getting to market with earliest WHO PQ approval expected by Q4 2017**

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<td><strong>Anticipate 1-2 suppliers to get WHO PQ’d by next Gavi VIS in 2018</strong></td>
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**Source:**
2. Gavi Vaccine Investment Strategy 2008, Typhoid Analysis
3. Estimated WHO PQ timelines based on current development status of TCV candidate
Typhoid market is characterized by poor market dynamics, leading to internal de-prioritization of TCV development by suppliers and longer time to market.

**Typhoid Market Dynamics**

- High cost of entry
- Unpredictable demand
- Fragmented markets

= Risky Market

**Limited supplier interest due to low potential margins and demand uncertainty**
These market dynamics affect various stages of the product life-cycle and can negatively influence management’s decision to invest in TCV market. Suppliers face several development and market barriers across the product life-cycle:

**Vaccine Development** *(High cost of entry)*
- R&D Costs
- Clinical trial risks
- No suitable vaccine benchmarks

**Market Introduction** *(Unpredictable demand)*
- Unclear vaccine delivery strategy
- Vaccine price-sensitivity
- Extended WHO PQ timelines

**Scaling-up** *(Fragmented Markets)*
- Procurement uncertainty
- Funding uncertainty
- Lack of political will
- Regulatory risks
- Delayed country introductions

Limiting management's ability to make necessary business and investment decisions:

Management considerations include:
- **Allocation of limited resources** based on expected returns
- Budgeting for investments required in **manufacturing capacities/capabilities**
- **Prioritizing markets** and creating market **entry strategy**
- Aligning with **broader company strategy**
Framework for prioritization of vaccine pipeline

Expected return = \( A \) Potential return \( \times B \) Probability of realizing return

Probability of realizing return depends on:
- Development risks
- Political & funding support
- Manufacturing & delivery needs
- Competitive dynamics

Potential return depends on:
- Potential revenue: Need for vaccine, population size
- Potential margin: Geography, competition

Low potential return, high feasibility
- “Quick wins”

High potential return, high feasibility
- “Top priority”

Lower market opportunity, low feasibility
- “Long shots”

High market opportunity, low feasibility
- “High-risk/High-return”

Potential return depends on:
- Potential revenue: Need for vaccine, population size
- Potential margin: Geography, competition
The global community can help suppliers overcome these barriers and accelerate their time to market through a number of activities.

**Global Community can support suppliers in expediting development of new vaccines**

### Role for Global Community

**Demand Forecast**
- Share early estimates of potential vaccine demand with suppliers
- Provide periodic updates on findings from surveillance studies and implications

**Country Liaison**
- Share country feedback on potential need and introduction timelines
- Share country-specific issues around programmatic suitability

**Policy and funding**
- Share ideal vaccine TPP and potential delivery strategies with suppliers
- Clarify price targets and funding availability

**Partner support**
- Highlight partnership opportunities across the product development life-cycle
- Support DCVMNs with WHO PQ applications

**Expedite development of new and neglected disease vaccines**
Thank you for your attention

Merci de votre attention

Obrigado pela sua atenção

여러분의 관심에 감사드립니다

感谢您的关注

ध्यान देने के लिए आपका धन्यवाद

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CHAI’s vaccines program works with manufacturers to ensure affordable, adequate supply and with MoHs to improve immunization services.

CHAI complements efforts by other global stakeholders across the vaccines value chain:

- **Research and development**
  - Basic vaccine R&D
  - New immunization technologies, delivery models, evidence-based policy changes

- **Manufacturing, quality, WHO PQ**
  - Technical assistance
  - Support for WHO PQ

- **Funding and procurement**
  - Global demand forecasting
  - Funding for vaccines, infrastructure, CCE
  - Tendering, procurement

- **In-country delivery**
  - In-country delivery, logistics, data gathering

**CHAI role**

- Manufacturer support
  - LMIC commercial strategy, business planning
  - Volume guarantee and other deal making

- MoH support
  - New vaccine introduction
  - Long-term planning, budgeting
  - Cold chain logistics

**Other global stakeholders**

- Bill & Melinda Gates Foundation
- PATH
- Gavi, The Vaccine Alliance
- UNICEF
- Ministry of Health

**Manufacturers**

- Bill & Melinda Gates Foundation
- PATH
- Gavi, The Vaccine Alliance
- UNICEF