

WHO typhoid policy and practice: current and future

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(previous WHO/HQ focal point for typhoid and other vaccines against enteric & diarrheal diseases)

Current typhoid vaccines & policy

- 2 licensed vaccines:
 - Vi-polysaccharide (ViPS) - injectable single dose vaccine
 - Ty21a - oral 3-4 doses live vaccine
- WHO Position Paper on Typhoid vaccines revised in Feb 2008
 - recommended that countries consider programmatic use to control endemic disease (targeting high risk groups / high burden populations) & for outbreak control in context of other control efforts
- Sanofi Pasteur ViPS vaccine was WHO pre-qualified in June 2011
- Large scale demonstration projects in several Asian countries have shown feasibility of introducing current vaccines and positive impact on typhoid disease epidemiology.....
-BUT vaccine uptake has been low for multiple reasons

Reasons why the currently available vaccines are not used (1/2)

■ Vaccine particulars

ViPS

- only to ≥ 2 year children; difficult to fit into existing national immunization programmes
- provides around 70% protection, BUT needs to be repeated every 3y due to waning
- programmatic challenges of a vaccine that requires repeated doses

Ty21a

- delivery is challenging for both routine setting and campaigns (3-4 doses administered on alternate days)
- cost of the vaccine
- the need to repeat after 5-7 years

Reasons why the currently available vaccines are not used (2/2)

- **Challenges to defining disease burden**
 - diagnosis difficult to confirm (blood culture, the current gold standard, is unavailable to most health centres)
 - clinicians can't wait for blood culture; mostly ask for serology (Widal) - not very useful
 - difficulty of ascertaining 'high risk groups'
- **Financing**
 - a disease of the impoverished affecting those least able to pay for services
 - lack of champions at national level in many countries (no funds allocated)
 - GAVI's investment strategy focused on ViCV
 - other donors follow GAVI's cue – no commitment to support ViPS or Ty21a

Preparing for future vaccines: WHO's role

- Several formulations of Vi conjugate vaccines in development (not all expected to apply for WHO pre-qualification)

- WHO work in progress:
 - establishing the scientific basis for the regulatory evaluation of ViCV candidates
 - development of WHO guidelines on the quality, safety and efficacy of typhoid conjugate vaccines
 - public consultation process starting March 2013
 - final stage of approval by ECBS expected by end 2013
 - WHO pre-qualification of Ty21a oral vaccine

Policy processes for the introduction of future typhoid ViCVs (1/2)

Likely steps following the first registration of a ViCV by a competent national regulatory authority:

- initial for-information session to the WHO Strategic Advisory Group of Experts (SAGE) - presentation of the clinical development data → 2015?
- if sufficient information is available from the developer(s), a SAGE subgroup may be established to examine the available data for the new product(s) and specific questions related to use; report to be submitted to full SAGE
- SAGE may request for further information or points of clarification
- SAGE recommendations for use

Policy processes (2/2)

- If recommended for use by SAGE, WHO will move to update the current position paper
 - technical information, programmatic strategy, policy guidelines on use
- **Critical for WHO to support processes to move from the policy/recommendations to action in countries**
 - SAGE recommendations & WHO position paper will be widely disseminated. Relies on immunization fora at all levels: global, regional (Regional TAG and EPI mtgs), country
 - Role of NITAGs and other "champions" essential to develop local policies/guidance based on national needs

Potential role of other WHO advisory groups in the SAGE policy-setting process

- Expert Committee on **Biological Standardization** (ECBS)
- **Implementation Research** Advisory Committee (IVIR-AC)
- formerly Quantitative Immunization and Vaccines Related Research (QUIVER)
- Global Advisory Committee on **Vaccine Safety** (GACVS)
- **Immunization Practices** Advisory Committee (IPAC)

Other activities to support the introduction of typhoid ViCVs

- Vaccine prequalification
 - assesses acceptability for purchase by UN agencies (= funding by GAVI and other donors)
 - initiated ONLY if manufacturer applies for specific vaccine
- Partnerships and collaborations with CaT, GAVI, UNICEF, other key partners
 - investment strategy and framework for GAVI support
 - support to countries
 - applications for GAVI funding support
 - vaccine procurement and introduction
 - strengthening surveillance/evidence on burden and impact
 - › (2011 & 2012: Nepal, Bhutan, Sri Lanka, Fiji, Solomon Island, Viet Nam, Myanmar)
 - implementation research (use, uptake, impact of ViCV)