WHO typhoid policy and practice: current and future

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Acknowledgement

- Pem Namgyal, WHO SEARO
  (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
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

- 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
    - implementation research (use, uptake, impact of ViCV)