

Considerations for Revised Global Typhoid Vaccination Policy and Strategies

10th International Conference on Typhoid and Other Invasive Salmonellosis

Kampala, 4-6 April, 2017

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WHO HQ, Immunization Vaccines and Biologicals

WHO processes supporting vaccine policy and delivery strategies

* Relevant WHO documents

Immunization policy

SAGE recommendations

* *WHO Position Paper*

Guidelines for manufacturing, licensing and regulation

* *ECBS guidelines on quality, safety, efficacy*

Establishment of WHO Reference Materials

Vaccine prequalification

(assesses acceptability for purchase by UN agencies)

* *Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification*

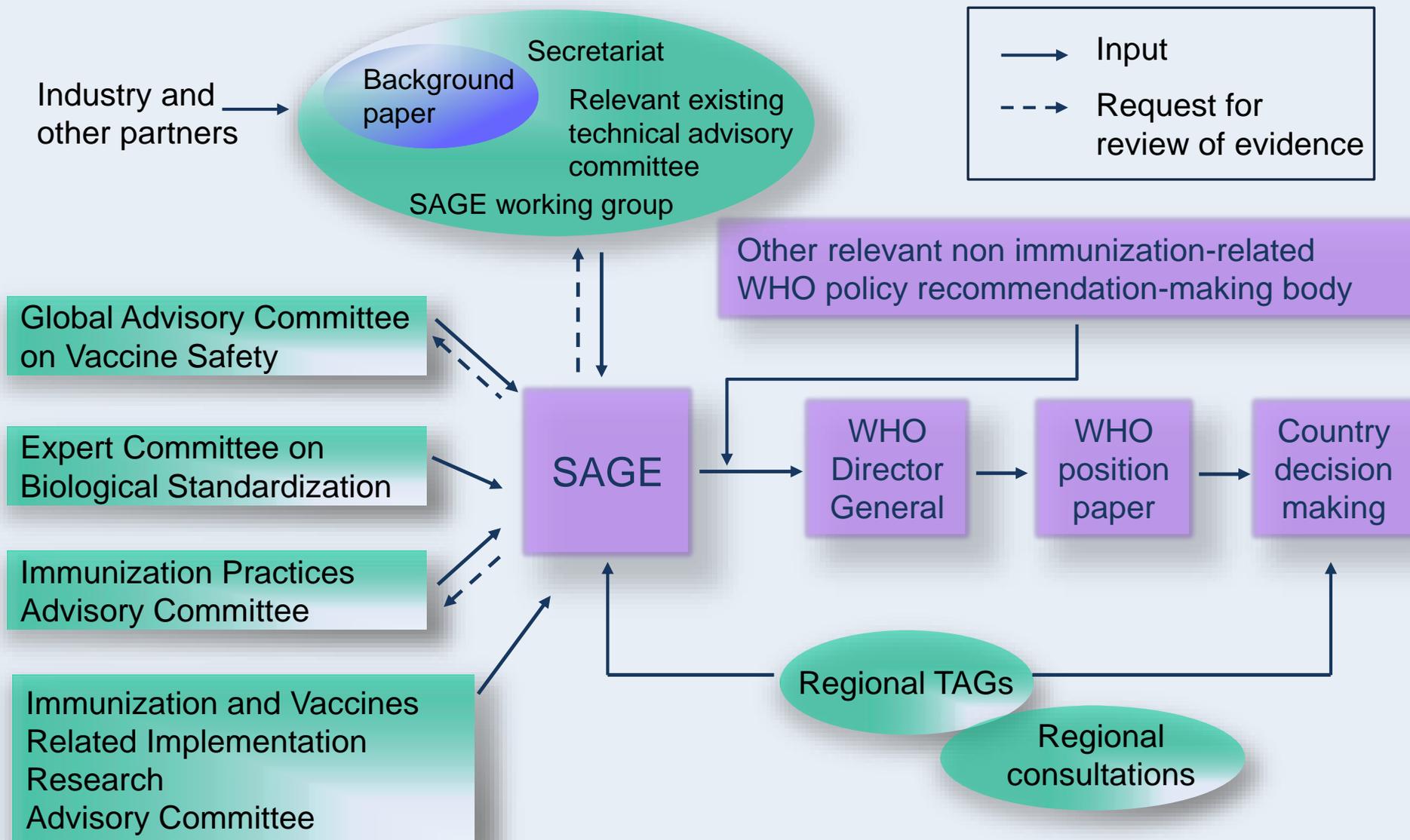


Donor funding
Supply by UN agencies

(PQ also used for direct procurement by some countries)



Pathways for WHO Recommendations on Vaccine Use



SAGE: Strategic Advisory Group of Experts on immunization

Pathway for revision of typhoid vaccine policy

- SAGE Working Group on Typhoid Vaccines conducts evidence review, including the quality of evidence to support policy recommendations (ongoing)
http://www.who.int/immunization/policy/sage/sage_wg_typhoid_mar2016/en/
- SAGE considers evidence review to issue recommendations (Oct 2017)



World Health
Organization

Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

8 FEBRUARY 2008, 83rd YEAR / 8 FÉVRIER 2008, 83^e ANNÉE

No. 6, 2008, 83, 49–60

<http://www.who.int/wer>

Revision of WHO position paper (2018)

Contents

- 49 Typhoid vaccines:
WHO position paper
- 60 WHO web sites on infectious
diseases

Typhoid vaccines: WHO position paper

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and

Vaccins antityphoïdiques: note d'information de l'OMS

Conformément à son mandat, qui est de fournir des conseils aux Etats Membres sur les questions relatives aux politiques de santé, l'OMS publie une série de notes d'information

Key considerations for evidence

Magnitude of the public health problem

- Disease burden estimates, epidemiological trends, risk factor analysis
- Diagnostic and surveillance challenges
- Cost of illness and Cost effectiveness
- Antimicrobial resistance

Prevention and control measures

- Use of current vaccines and barriers to uptake (in particular issues with potential implications for TCVs)
- Integration with WASH and other strategies

Vaccine characteristics and performance

(incl. new and relevant data on ViPS and Ty21a)

- Composition, safety, immunological parameters
- Dose-scheduling
- Vaccine effectiveness and impact on clinical disease (immunobridging to NIH Vi-rEPA; human challenge studies, mathematical modelling data)

Programmatic issues for vaccine use

- Target population in routine use
- Delivery strategies
- Logistics (packaging, cold chain volume, VVM, vaccine management)

Broad landscape of data to help shape global vaccine policy revision in 2017 and beyond

- Build on previously available data (DOMI, VIVA studies etc.)
- **New** regional/global epidemiological data anticipated from several key studies
 - SEAP
 - TSAP and SETA
 - STRATAA
 - Global trends in typhoid project
- Mathematical modelling studies
- Cost effectiveness and other economic analyses
- Critical for **data to be shared in timely manner to ensure “best available” evidence informs policy development.**

Translating burden data and surveillance capacities for broader action

- How do we optimize data generated in a limited set of countries for decision-making in other countries/settings
 - criteria to allow extrapolation of data to other countries?
 - socio-demographic and risk profiles
 - local data to bridge to data from the burden studies
 - development of guidance tools
- Transfer surveillance capacities to (or support) national surveillance systems where possible.
 - inputs to improve and implement enteric fever surveillance standards

Scope of evidence on typhoid conjugate vaccines

SAGE evidence review to consider quality of evidence

- US NIH Vi-rEPA; immunogenicity and efficacy data
- 2 licensed Vi-TT vaccines (Bharat, Biomed)
 - immunogenicity → immunobridging to NIH Vi-rEPA
 - safety data
 - efficacy data reported for Biomed Vi-TT in a Phase 4 cluster randomized study in 6-12 mth olds (India, *Mitra et al, 2016*)
- Data from human challenge study (University of Oxford) - as reported in the conference
- Evidence and policy decisions for other conjugate vaccines will be useful in informing the TCV policy
- Bharat Biotech Vi-TT undergoing WHO prequalification review

Some key considerations for policy & vaccination strategies

TCV schedule

- Burden in <2year olds
- Infant schedule becoming quite crowded
- 9 months contact already has measles, rubella, MenA, YF, JE, future RTS,S and IPV....
- Concern about multiple injections
- Co-administration

Delivery strategies

- Risk-based vs universal (age-based) strategy
 - challenges of identifying “high risk”
 - reaching “high risk” groups
 - heterogeneity
- Routine +/- catch-up
 - local epidemiology
 - modelling - catch-up provides better short-term impact
- Strategies for outbreaks and humanitarian emergencies
 - vaccine supply
 - integration with WASH, appropriate treatment, food handling

Related WHO policies and programmes

Global Priority Pathogen List (PPL)



Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics

The World Health Organization was requested by Member States to develop a global priority pathogens list (global PPL) of antibiotic-resistant bacteria to help in prioritizing the research and development (R&D) of new and effective antibiotic treatments. To date, the selection of pathogens for

<http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/>

*“The panel stressed the importance of new antibiotics for the paediatric population and for oral formulations for community diseases with a high morbidity burden such as drug-resistant *Neisseria gonorrhoeae*, *Salmonella Typhi* and ESBL-producing *Enterobacteriaceae*.”*

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- Need to leverage the Global Antimicrobial Resistance Surveillance System (GLASS) to improve surveillance of *Salmonella* AMR at country level.

Considerations for Gavi's Decision Pathway on TCV

VACCINE INVESTMENT STRATEGY (VIS) 2008

- The Gavi Board prioritised TCV for Gavi's portfolio, along with Rubella, JE and HPV; no financial commitment made

VIS 2013

- TCVs not revisited as already prioritised in 2008, noting that a support window would be open if a suitable TCV was prequalified

Towards VIS 2018

- Gavi support will be contingent on SAGE recommendations and PQ of at least one TCV (standing Gavi requirement)
- Scenarios for potential pathways under consideration and will be informed by timing of recommendations and PQ

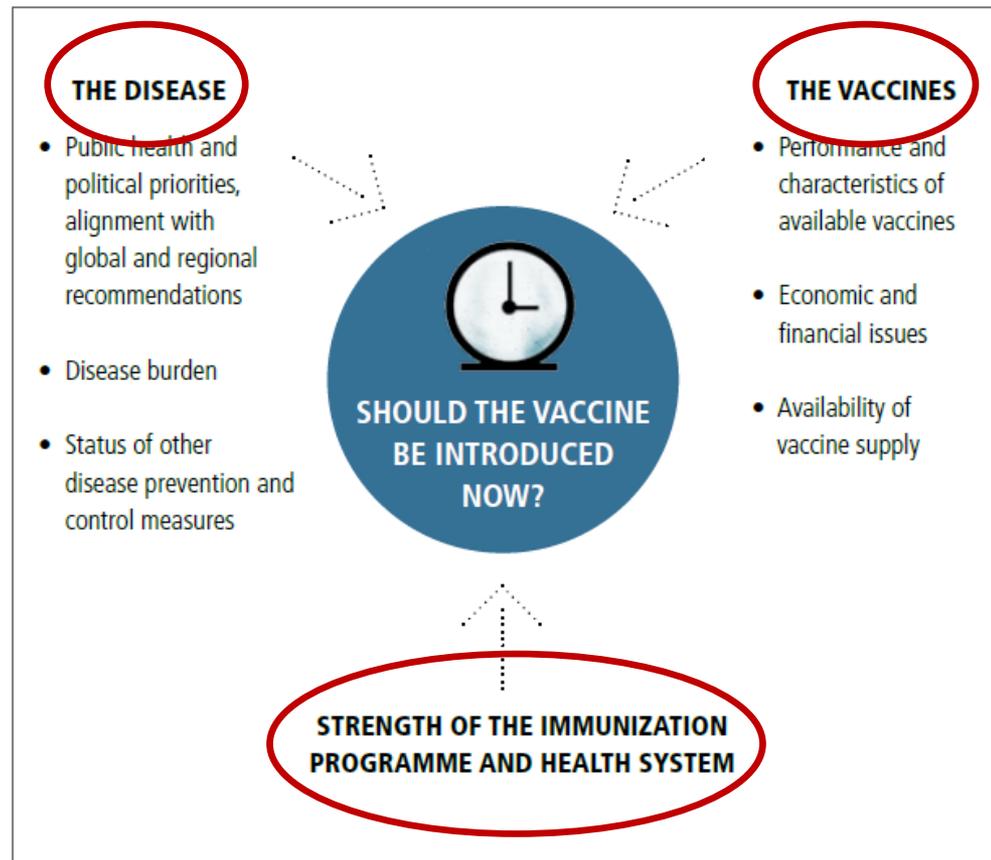
Principles and considerations for adding a vaccine to a national immunization programme

FROM DECISION TO IMPLEMENTATION AND MONITORING



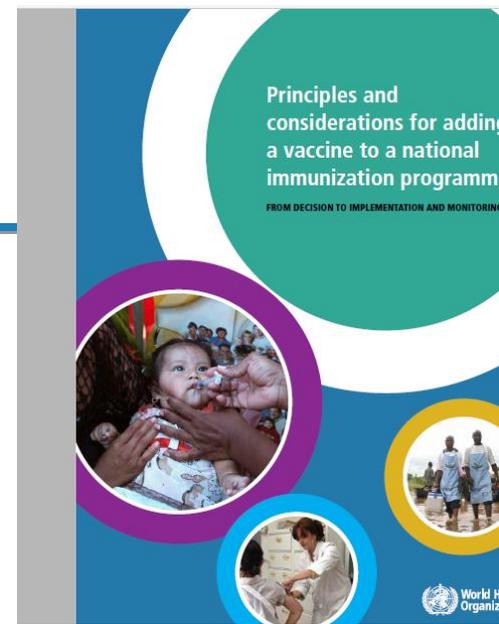
*“All **countries** [health policy makers] need to set priorities to determine which health problems to address and what specific interventions to implement, given the many health issues and resource constraints that each country faces, especially developing countries.”*

FIG. 1. Key issues to consider when deciding on the introduction of a vaccine



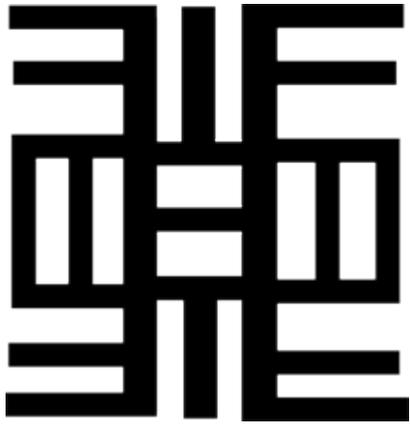
“The more visible and important the disease is to the community, the greater the acceptance of and demand for the vaccine will be.”

Data to support vaccine introduction has been the **major driver** of demand and acceptability by countries (and likely so for other public health interventions).



Translating data to decisions and investments in typhoid control strategies

- Does the disease cause **significant disease burden**?
- Does preventing the disease contribute significantly to the goals and **align with the priorities established in the national health and development plans**?
- Is the disease **perceived to be important** to the public and the medical community?
- Is control of this disease **in line with global or regional priorities**?
- Does preventing the disease **contribute to improving equity** among socio-economic classes and population groups?



(S)He who does not know can
know from learning

(Nea onnim no sua a, ohu)

Adinkra symbol of knowledge, life-long education
and continued quest for knowledge - Ghana

The elephant never gets
tired of carrying its tusks.

- *African proverb*



Acknowledgements

■ WHO Dept of Immunization Vaccines and Biologicals

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- Joachim Hombach
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■ SAGE Working Group on Typhoid Vaccines

http://www.who.int/immunization/policy/sage/sage_wg_typhoid_mar2016/en

- ## ■ WHO ad hoc meeting on considerations for TCV policy, 3rd April, Kampala
- SAGE WG members, BMGF, TyVAC, Gavi, invited experts

BILL & MELINDA
GATES foundation