Informal Consultation of experts on Typhoid Fever, South East Asia Region

28-29 September, 2016 New Delhi, India
**Brief Overview**

Typhoid fever continues to be an important public health problem, affecting many low-income and middle-income countries with over 21 million typhoid cases and 200,000 deaths estimated globally each year. The majority of the morbidity and mortality associated with typhoid fever is reported in Asia and Africa, including 90% of the fatal outcomes of globally estimated case fatality rates.

The existing challenges to combat typhoid fever include non-availability of rapid diagnostic tests, inadequate use of standard treatment practices, emerging antimicrobial resistance, lack of safe water, inadequate sanitary facilities and poor hygienic standards. All of these underscore the importance of expanding efforts to prevent typhoid infection.

Currently, a number of important research studies or projects are ongoing in a variety of settings to examine a broad range of issues such as further understanding of the disease burden including risk factors, disease severity and long-term sequelae; the importance of long-term carriers in disease transmission; antimicrobial resistance; economic burden; and approaches to strengthening surveillance systems including the feasibility of integrating typhoid and other invasive salmonellosis in the WHO-coordinated Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) surveillance network.

In recent years, considerable knowledge has been generated on typhoid vaccine use through experience in a number of demonstration projects as well as modelling studies; and on projections for vaccine demand to guide investment decisions by potential donors. With available typhoid vaccines and promising new candidate vaccines in development, it is imperative to assess the measures to effectively reduce the burden of typhoid through vaccination and/or other control strategies. Many countries have controlled typhoid without vaccination, but investments in safe drinking water and better sanitation are long-term solutions for typhoid, while vaccination has the potential for rapid control of disease as well as for reduction in the unnecessary usage of antibiotics. Progress towards the Millennium Development Goals (MDGs) and projected urbanization put a huge burden on resources for maintaining safe water and improving hygiene standards in each of the Member States in SEAR. The available data in the Region also highlight a need for well-coordinated efforts for effective WASH interventions.

Vaccination has emerged as an effective strategy to control endemic disease or to interrupt transmission during outbreaks. However, despite the demonstrated safety and efficacy of the available parenteral Vi polysaccharide and oral, live attenuated Ty21a typhoid vaccines for enteric fever prevention and control, the public health programmatic use and private sector use of typhoid vaccines has been limited in high burden countries.

In 2008, WHO issued updated global policy recommendations for the use of the Vi polysaccharide and Ty21a vaccines in areas where typhoid remains a significant public health problem and where antibiotic resistance is prevalent. Since then significant progress has been achieved in the development of typhoid conjugate vaccines (TCVs). WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) will be requested to consider the updated evidence for typhoid vaccines in general and TCVs in particular in 2017 for recommendations on use.
It is the need of the hour to review the evidence on the immunogenicity of typhoid conjugate vaccines, their potential effectiveness and to consider future vaccine introduction within a framework for typhoid control in the Region.

The current enteric fever burden in selected SEAR countries was reviewed based on published and unpublished estimates. Most of the studies reporting typhoid and/or paratyphoid fever burden estimates in the SEAR are over a decade old and there is significant heterogeneity among them. Though the data in most cases are not denominator-based there is evidence of a large burden of laboratory-confirmed typhoid in India, based on both culture and serological tests. The local epidemiological data are crucial for developing strategies and policies.

The emergence of antimicrobial resistance in Salmonella species in South-East Asia Region (SEAR) indicates significant resistance to fluoroquinolones and rising resistance to the first line of available drugs and this makes tackling the disease even more challenging. With the availability of antibiotics, typhoid is neglected by policy makers and there is a need now to focus attention on this important cause of illness in the SEAR and consider what strategies might be most appropriate in different settings.

The focus on vaccine preventable diseases in the South East Asia Region (SEAR) of WHO has led to remarkable achievements such as maintaining a polio-free status and attaining maternal and neonatal tetanus elimination. There is a strong need for strengthening surveillance, strengthening health systems, exploring latest diagnostic methods and developing vaccine strategies along with guidelines for antimicrobial treatment in a SEAR regional plan for typhoid prevention and control in endemic, outbreak and emergency settings.

**Objectives**

The meeting was convened with regional and international typhoid experts with the following specific objectives:

- To review global and regional enteric fever disease burden, ongoing studies to further improve understanding of the disease and economic burden, surveillance challenges including diagnostics, and the feasibility and effectiveness of control strategies.

- To review the status of typhoid conjugate vaccine development and current knowledge on vaccine performance, as well as expected timelines for global typhoid vaccine policy revision and activities to support future vaccine introduction.

- To share global activities to accelerate prevention and control of typhoid and other invasive salmonellosis, and discuss considerations for development of a regional plan aimed at (a) ensuring visibility of typhoid and paratyphoid fever as a priority public health problem; and (b) an agreed program for typhoid control in general and typhoid vaccine introduction specifically.
Key discussions
Several key studies - recent, ongoing and planned - are anticipated to provide results globally and in the SEAR by 2018/2019. These recent and ongoing studies aim to generate data collectively on a variety of issues, mainly burden, transmission and antimicrobial resistance patterns, modelling of typhoid dynamics, vaccine impact and economic analyses.

Data are needed to support the development of global policy including the SAGE recommendations and the WHO position paper on typhoid vaccines which will further support vaccine introduction decisions at the regional and country levels and facilitate funding decisions by donors for support on typhoid vaccine use.

Past experience has shown that the lack of robust epidemiological data to map out high-risk populations to be targeted for vaccination contributed to low typhoid vaccine uptake. Further, experience with introduction of new vaccines in general indicates that availability of data to support vaccine introduction, as outlined above, will be a major driver of vaccine demand and acceptability by countries.

These economic analyses and supporting tools are good for advocacy with Member States as they can facilitate evidence-based decision at the national level. In the regional context it was opined that improvements in water and sanitation services will result in very small pockets of typhoid disease, therefore economic analyses should include the benefits of investments in water and sanitation.

In countries with limited resources, economic considerations are increasingly relevant as additional arguments in decision-making and planning to introduce vaccines. The WHO is making efforts to strengthen the capacity to assess public health, economic and other implications of health interventions and technologies in developing countries by providing countries with the necessary guidance and tools to support strong and efficient processes for decision-making on immunization.

Following are the key considerations for designing typhoid control strategies in SEAR:

1. Needs in endemic, outbreaks and emergency settings
2. Potential vaccine delivery strategies and supply issues
3. Vaccine acceptability and programmatic consideration
4. Limitations in using burden data for revising typhoid vaccine policy
5. Challenges
1. Needs in endemic, outbreaks and emergency settings

It is important to evaluate the relevant data and understand the disease burden in a variety of settings with varying levels of transmission in order to achieve effective reduction in the disease burden.

In endemic settings, defining the geography of disease, access to healthcare and water and sanitation are important to ensure promotion of equity by addressing population needs.

The population at risk of outbreaks needs to be identified with an appropriate surveillance system. Issues related to safe water, rapid diagnostics, sample transport to sites with diagnostic capacity and drug availability need to be addressed in a well-formulated outbreak management plan.

SAGE has developed guidelines for the use of vaccines in emergencies and Member States should make the best use of this guidance. Further, Member States are encouraged to provide feedback to SEARO on the use of the guidelines to assist with improvements where needed.

Geography

The available data indicate that typhoid and paratyphoid fever are prevalent in SEAR across national boundaries. There can be benefits in highlighting the epidemiological data to emphasize typhoid (and paratyphoid fever) as a regional public health problem and not only a problem for individual countries. This would also give greater weight to the need for a regional approach to enteric fever control.

Population density/slums

Poor personal hygiene has far reaching consequences beyond health and needs to be addressed as a societal problem and not only in the public health context. The potential solutions to tackle poor hygiene are often resource intensive and there is a need to advocate for change in societal standards and norms. Active participation of the community is essential and there is a need for continuous emphasis on issues such as improvements in education that can have a long-term impact on socio-economic indicators.

Water & Sanitation

In the Southern Asian region, trends in the number of people using improved, shared or unimproved sanitation facilities indicate a marked reduction in the number of people practising open defecation. However, although a significant reduction was noted in overall open defecation during the last two decades, regional and national averages mask the existing inequalities in sanitation coverage. Clean water and improved sanitation are effective in prevention and control of typhoid when coverage is uniformly high, but data from the region indicates that partial improvement in sanitation does not necessarily translate to health benefits.

Currently the progress of WASH interventions in SEAR is not uniform. Inequity in coverage of interventions puts the health of those in areas of low coverage at higher risk. Definitions of access to safe water and improved sanitation do not necessarily correlate with better health outcomes. Increasing urbanisation and scarcity of water pose a huge challenge against
addressing the need for safe water and sanitation services. Personal hygiene especially of food handlers needs augmented focus. Strong integration will need to be built between Ministries of Health and ministries and other governmental bodies responsible for sanitation and water distribution.

**Health care access**

The access to health care facilities is essential to support early diagnosis and initiate evidence based treatment in case of enteric fever. The lack of diagnostics complicates case management and contributes to resistance to commonly used antibiotics which is a growing challenge. Access to affordable, specific and rapid diagnostics needs urgent attention. Another challenging area is the diagnosis and treatment of carriers/asymptomatic individuals and guidelines should be developed on this.

Emergence of antimicrobial resistance in *Salmonella* species clearly indicates the urgency for developing solutions at the earliest to rationalize antimicrobial usage. It is also evident that widespread use of antimicrobials alters the gut microbial flora and may increase susceptibility to infection, thus further worsening the situation.

Strengthening laboratory supported surveillance will prevent over-reliance on clinical diagnosis and support evidence-based treatment options thereby helping to address antimicrobial resistance.

**2. Potential vaccine delivery strategies and supply issues**

Typhoid vaccination is the fastest and most effective way to prevent typhoid fever and lower the disease burden. Typhoid vaccines have been demonstrated to be effective in programmatic use and also have a potential significant role in outbreak response or managing the risk of infection in humanitarian emergencies.

The availability of typhoid vaccine is not uniform at both sub–national and national levels in the Region. The private sector remains the key provider of typhoid vaccine as affordability and financial sustainability remain a problem for public sector delivery in most countries.

Development and evaluation of strategies to reach high-risk populations are critical. There is a need to enhance data comparability to provide the best evidence to support introduction of typhoid vaccines in the Region, therefore efforts should be made to harmonize study methods and tools for data collection.

**3. Vaccine acceptability and programmatic consideration**

There is no evidence of significant vaccine hesitancy in the Region. Data provided by SEAR countries indicate acceptability of typhoid vaccine, but currently vaccine is available only with the private sector. Policy makers need cost effectiveness data and adequate funding sources to ensure sustainable vaccine supply post-introduction.

Typhoid incidence is very low in countries such as Sri Lanka due to strengthened health systems and WASH strategies, so an integrated approach for effective typhoid management is important. It is essential to work on communication strategies to promote desired changes in the community as a long-term solution for typhoid control.
In the short-term, effective surveillance ensuring meaningful indicators are monitored is important to measure disease burden, detect outbreaks, track antimicrobial resistance patterns and evaluate progress towards control.

4. Limitations in using burden data for revising typhoid vaccine policy

Availability of disease burden data in SEAR is varied and limited in some countries. A standard uniform case definition has not been used in generating evidence, thus making data non-comparable.

Visits to general physicians are rarely reported and thus there are no mechanisms to review case management. In most countries burden data are primarily from the health management information systems or notification of communicable diseases with or without laboratory confirmation of typhoid fever or paratyphoid fever. Patients are often treated based on clinical diagnosis prior to laboratory confirmation. A low cost diagnostic test of adequate specificity for laboratory confirmation is not available.

The collected data are often not analysed adequately to understand the epidemiology of the disease and mortality data are not usually reported. Also the reporting is not usually targeted to identify cases among high-risk groups.

There is limited use of available vaccines in the Region confined only to the private sector. The Medical/Paediatric Associations have varied or no recommendations for typhoid vaccine use. No guidance exists for typhoid vaccine use in Bangladesh and Bhutan whereas national Medical/Paediatric Associations in India, Indonesia and Myanmar have recommended use of typhoid vaccines in their populations. The Nepal NITAG proposed vaccination for food handlers and persons in high-risk areas whereas in Sri Lanka vaccination is confined to high-risk populations.

Evidence of typhoid vaccine co-administration with other vaccines in EPI schedule is required. There is currently no conclusive evidence on the duration of protection offered by the licensed TCVs and the need for booster doses. The potential role of vaccine in lowering typhoid transmission by lowering the faecal shedding of S. Typhi is unknown.

Data from ongoing studies and projects will be required for decision-making and advocacy for typhoid vaccine introduction in routine public health programmes such as school-health programmes or in the EPI schedule.

5. Challenges

• Obtaining geographically representative data on typhoid fever including
  – cases, deaths and case fatality ratio
  – identification of clustering of cases and pattern of antibiotics use
  – limited information on complications and antimicrobial resistance.
• Addressing competing priorities including other vaccine preventable diseases
• Not enough evidence on cost of morbidity due to typhoid fever to guide decision-making.
Way forward
There is a need to strengthen intersectoral coordination to enhance cost effectiveness of preventive measures, vaccine introduction and WASH interventions. Developing guidelines regarding antimicrobial treatment for enteric fever in each member state of SEAR, WHO, is likely to prevent further emergence of antimicrobial resistance. To support the innovative, rapid and specific diagnostics a meticulous analysis of data from different studies and other sources is crucial. There is a need to embark on harmonization efforts for comparability of data and for appropriate use of the data (epidemiological and economic) on typhoid fever in Southern Asia.

Data and surveillance
• Defining the data sources to improve the availability and quality of data and establish systems for data collection, analysis, interpretation and dissemination.
  • Indicators to monitor the progress of typhoid disease burden including data from rural areas, age-specific morbidity & mortality, asymptomatic/chronic carriers at the regional, national and sub- national levels.
  • Sentinel surveillance for high-risk areas/populations in selected countries; screening high-risk groups (e.g. food handlers) to determine the magnitude of the problem..
  • Review rates of complication due to typhoid and paratyphoid fever to capture both immediate and longer-term outcomes as part of the evidence on disease burden
  • Monitoring antimicrobial resistance and tracking the incidence of paratyphoid fever with a declining in S. Typhi incidence

Vaccine studies and strategies
• Active engagement with endemic countries in SEAR to ensure and support a robust plan for typhoid vaccine introduction including establishing the relevant baseline/pre-vaccination data to assist in vaccine impact evaluation. (SAGE recommendations on typhoid vaccines and an updated WHO position paper are anticipated in 2017-2018. In addition, there is anticipation for at least 1 prequalified vaccine by end of 2018 to inform a vaccine investment strategy by Gavi for eligible countries. Additional data on safety and co-administration of Typbar TCV with measles-containing vaccines are expected to be available by 2018-2019 to inform decision-making on TCV introduction.)
  • Assessment of the potential value of existing ViPS and Ty21a vaccines in the short- to medium-term or in specific situations (such as humanitarian emergencies) needs based on country demand and to ensure adequacy of vaccine supply and pilot projects to demonstrate effectiveness of vaccine use along with other interventions.
  • Sharing evidence to support potential recommendations for vaccination of food handlers and frequent travellers visiting high-risk areas.
  • Inclusion of measures such as WASH interventions for control and prevention of enteric fever and developing cost evaluation tools including measurement of productivity loss and gains, including through herd effects.
  • Projection of vaccine supply needs, both for routine vaccination and for campaigns in collaboration with vaccine manufacturers.
  • Exploring domestic funding opportunities to ensure sustainable funding for introduction of vaccines following externally funded pilot studies and develop guidelines on when typhoid vaccination can potentially be stopped.
• Requesting NITAGs to review country disease burden status and adequacy of control measures including national consultations targeting appropriate stakeholders.

**WASH interventions and other control measures**

• Improving sanitation and provision of clean safe water as the long term sustainable measures along with vaccine introduction for prevention and control of typhoid fever.

• Re-enforcement of medical and para-medical services teaching curricula with current knowledge on disease transmission and the importance of the environment and behavioural changes to prevention and control of typhoid.

• Implement approaches that target effective behaviour change for the appropriate use of available safe water and sanitary facilities, and development of communication strategies for improving hygiene standards.

• More cohesive engagement across governmental and non-governmental institutions responsible for water supply and sanitation and with professional bodies or other relevant areas to improve standards of personal hygiene.

• Ensuring commitment from the highest levels of government and strong political engagement to ensure the sustainability of measures embarked upon by Member States for the prevention and control of typhoid.

**Typhoid case management**

• Thorough assessment of causes of fever of unknown origin to more accurately determine the burden of typhoid and of other febrile illnesses.

• Developing and using affordable diagnostics to strengthen laboratory confirmation of typhoid fever cases to improve clinical diagnosis and appropriate use of antibiotics preventing further emergence of antimicrobial resistance.
Annexures
## Annex 1: Agenda

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<tr>
<th>28 Sept</th>
<th>Presenter/Lead discussant</th>
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<tr>
<td>9.00 – 9.10</td>
<td>Introduction &amp; Objectives of the meeting</td>
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<td>9.10 – 9.35</td>
<td>- Update on current knowledge about typhoid and paratyphoid disease burden – global and regional (15 mins)</td>
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<td>- Landscape of relevant studies/activities (recent, ongoing and planned) to generate further data to guide policy and vaccine introduction (10 min)</td>
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<td>Part 1: DISEASE BURDEN &amp; EPIDEMIOLOGICAL DATA</td>
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<td>9.35 – 10.45</td>
<td>- Reports on enteric fever studies in SEAR countries</td>
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<td>o Severe Enteric Fever in Asia Program (SEAP) (D Garrett) – 15 mins</td>
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<td>o SEAP Bangladesh (J Uddin) – 15 mins</td>
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<td>o SEAP India (D Sur) – 15 mins</td>
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<td>o SEAP Nepal (J Andrews) – 15 mins</td>
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<td>Discussion – 10 mins</td>
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<td>10.45 – 11.15</td>
<td>Tea / Coffee Break</td>
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<td>11.15 – 12.30</td>
<td>- Reports on enteric fever studies in SEAR countries (contd)</td>
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<td>o CMC study - India (J John) – 15 mins</td>
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<td>o CDC study - Mumbai, India (K Date) – 15 mins</td>
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<td>o Strategic Typhoid Alliance across Africa and Asia (STRATAA)</td>
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<td>o Nepal (B Basnyat) – 15 mins</td>
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<td>o Bangladesh (F Qadri) – 15 mins</td>
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<td>Discussion – 15 mins</td>
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<td>Part 2: ECONOMIC BURDEN &amp; ECONOMIC EVALUATION</td>
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<td>12:30 - 13:15</td>
<td>- Global and regional studies/activities (recent, ongoing and planned) to generate further economic data (15 mins)</td>
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<td>- Preparation for WHO guidance and technical support for economic evaluation of typhoid and TOV use (15 mins)</td>
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<td>Discussion (15 mins)</td>
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<td>13:15 – 14:15</td>
<td>Lunch Break</td>
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<td>14:15 - 14:45</td>
<td>Limitations/challenges in SEAR to understand disease and economic burden and/or using burden data to design and implement effective vaccination strategies (as well as other control strategies)</td>
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<td>- What have been the key issues with the use of ViPS and Ty21a vaccines?</td>
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<td>- Are there gaps in knowledge at country level?</td>
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<tr>
<td>14:45 - 15:15</td>
<td>Update on typhoid vaccines</td>
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<td>Discussion (15 mins)</td>
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<td>15:15 - 15:45</td>
<td>Tea / Coffee Break</td>
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<td>15:45 - 16:15</td>
<td>SAGE pathway and expected timelines for update of vaccine policy and WHO position paper &amp; vaccine introduction</td>
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<td>Discussion (10 mins)</td>
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<td>16:15 - 16:45</td>
<td>SEAR needs: Key considerations in revising typhoid vaccine policy?</td>
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<td>- endemic settings (national, subnational), outbreaks and emergencies</td>
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<td>- other programmatic considerations</td>
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<td>Presentation followed by open (moderated) discussion</td>
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<td>116:45-17:00</td>
<td>Wrap up of Day 1</td>
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<td>29 Sept</td>
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<td>9:30 – 10:30</td>
<td>What would be the key considerations for SEAR regional plan for typhoid prevention and control (objectives and targets in context of integrated control strategies …..)</td>
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<td>10:30 - 11:00</td>
<td>Tea / Coffee Break</td>
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<td>11:00 - 12:00</td>
<td>Summary of key discussion points and gaps identified</td>
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Annex 2: List of participants

Technical Experts

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   Translational Health Science and Technology Institute (THSTI); and Head,

8. Dr Harish Iyer  
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