MINUTES OF THE MEETING OF THE NATIONAL TECHNICAL ADVISORY GROUP ON IMMUNIZATION

1:45 pm-2:30 pm, Friday, 9 December 2016

Nirman Bhawan, New Delhi

Agenda

Chair : Shri C. K. Mishra, Secretary MoHFW ***Co-chairs: Dr K. VijayRaghavan, Secretary DBT & Dr Soumya Swaminathan, Secretary DHR***		
1345-1355	➢ Welcome & action taken report on previous meeting of NTAGI, August 25, 2015 • Progress on new vaccine introduction- PCV • Progress on Code of Practice • Status update: Housing NTAGI Secretariat at NIHFW with GoI support	JS (RCH)
1355-1415	STSC Discussion and Recommendations • HPV disease burden in India • Typhoid disease burden in India • Diphtheria disease burden in India • Hepatitis A disease burden in India	Co-Chairs
1415-1425	Discussion	
1425-1430	Recommendations	Chair and Co-Chairs

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LIST OF ATTENDEES

Chair	
Shri C.K. Mishra	Secretary, Ministry of Health and Family Welfare
Co-chairs	
Dr K VijayRaghavan	Secretary, Department of Biotechnology
Dr Soumya Swaminathan	Secretary, Department of Health Research
Core Members, Ex- Officio	
Dr Jagdish Prasad	Director General of Health Services, Govt. of India
Dr Arun K. Panda	Additional Secretary & Mission Director, National Health Mission
Dr S. Venkatesh	Director, National Centre for Disease Control
Dr Rajlaxmi Vishwanathan	Representing Director, National Institute of Virology
Director	Translational Health Science and Technology Institute
Core Members, Independent Experts	
Dr J.P. Muliyil	Christian Medical College and Hospital, Vellore
Dr Gagandeep Kang	Executive Director, Translational Health Science & Technology Institute, Faridabad, Haryana
Dr Parvez Koul	Sher-i-Kashmir Institute of Medical Sciences, Srinagar
Dr Dileep Kumar Das	Burdwan Medical College, West Bengal
Dr YK Gupta	Professor and Head, Department of Pharmacology, AIIMS, New Delhi
Dr MD Gupte	Chair-Epidemiology, Indian Council of Medical Research (ICMR)
Dr G Sridharan	Advisor and Emeritus Scientist, Sri Narayani Hospital and Research Centre, Vellore
Dr Jacob Puliyel	Consultant Paediatrician and Head of Department (Paediatrics), St. Stephens Hospital, New Delhi
Liaison Members/ MoHFW representatives	
Ms Vandana Gurnani	Joint Secretary, Reproductive and Child Health , MoHFW
Dr Pradeep Haldar	Deputy Commissioner, Immunization, MoHFW
Dr Vijay Sonami	Representing Joint Drugs Controller, Central Drugs Standard Control Organization
Representatives of Professional Organization	
Dr Vipin M. Vashishtha	Co-Chair, IAP Advisory Committee on Vaccines & Immunization Practices, Indian Academy of Paediatrics (Representing President, IAP)
Dr K.K. Aggarwal	President Elect and Honorary Secretary General, Indian Medical Association
Representatives from International Partners	
Dr Henk Bekedam	Country Representative, World Health Organisation
Dr Yaron Wolman	Representing Country Representative, The United Nations Children's Fund
Special invitees	
Dr Rashmi Arora	Scientist G & Head, Division of ECD, Indian Council of Medical Research
Dr Pankaj Bhatnagar	Acting Team Leader, WHO-NPSP
Dr Satish Gupta	Health Specialist, UNICEF

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Dr Mainak Chatterjee	NIHFW
Prof Sanjay Gupta	Professor & Head, Epidemiology, NIHFW
NTAGI Secretariat representatives	
Dr Jyoti Joshi	Deputy Director and lead - AEFI surveillance and vaccine safety, ITSU
Dr Vineeth Varanasi	Associate Advisor – Evidence to Policy, ITSU
Dr Monika Setia	Program Manager- Evidence to Policy, ITSU
Ms Suchi Kapoor	Program Associate- Evidence to Policy, ITSU
Dr Amit Harshana	Technical Officer, MoHFW
Members apologised	
Dr J.K. Batra	Director, National Institute of Immunology
Dr M.K. Bhan	Society for Applied Sciences, New Delhi
Dr VK Paul	Professor, Division of Neonatalogy, Department of Paediatrics, AIIMS, New Delhi
Dr Dileep Mavalankar	Indian Institute of Public Health Gandhinagar
Dr Arun Kumar Agarwal	Postgraduate Institute of Medical Education & Research, Chandigarh
Dr D.K. Taneja	Maulana Azad Medical College, New Delhi
Dr NK Arora	Executive Director, the INCLEN Trust International, New Delhi
Dr Indrani Gupta	Professor and Head, Health Policy Research Unit, Institute for Economic Growth, New Delhi
Lt General Raghunath	Independent consultant
Dr M.K. Agarwal	Deputy Commissioner, Universal Immunization Programme, MoHFW
Prof. K. Srinath Reddy	President, Public Health Foundation of India

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The National Technical Advisory Group on Immunization (NTAGI) met as per calendar on Friday 9th December 2016, at Nirman Bhawan, New Delhi under the chairpersonship of Secretary, Ministry of Health and Family Welfare (MoHFW). The meeting was also co-chaired by secretaries from Department of Health Research (DHR) and Department of Biotechnology (DBT).

The Co-Chair welcomed the members and participants to the meeting. Following a round of self-introduction, the meeting was called to order. As per the agenda, following items were discussed:

Agenda Item 1. Action taken report on previous meeting of NTAGI, August 25, 2015

The Joint Secretary, Reproductive and Child Health (JS,RCH) presented an update on key agenda items from the minutes of the previous NTAGI meeting, held on August 25, 2015.

1. The members were informed that the NTAGI's recommendation of pneumococcal conjugate vaccine (PCV) in its meeting of 25th August, 2015 has been accepted by the MoHFW and recommended by MSG for its introduction.
   a) PCV expert group constituted to guide the rollout has identified five states (Bihar, Madhya Pradesh, Himachal Pradesh, and Parts of Uttar Pradesh and Rajasthan) for initial introduction of the vaccine beginning in the last quarter of 2016-17. The operational guideline and training materials have been prepared and the vaccine will arrive in February 2017.
   b) As per recommendation of NTAGI, three doses of the vaccine will be given (2 primary and 1 booster) 6 weeks, 14 weeks and 9 months.
2. The members were apprised that the detailed and successful process of development of Code of Practice (CoP) for NTAGI has been concluded and the final draft of the CoP has been finalized and approved for implementation.
   a) Members were informed that subsequent to the review of the Code of Practice based on the comments received from NTAGI members after the NTAGI meeting of 25th August 2015, the draft CoP was displayed on the MoHFW website during the month of August, 2016 inviting public comments.
   b) The public comments were reviewed and the draft CoP was revised based on the comments between October to December 2016. Subsequent to this review, the CoP was approved by the Chair and Co-Chairs of the NTAGI for implementation and to be displayed on the MoHFW

website for information. The contribution of the members of the NTAGI towards developing the CoP was gratefully acknowledged. The NTAGI secretariat was thanked for their effort.

3. The NTAGI Secretariat was established in 2013, at the Immunization Technical Support Unit (ITSU) under MoHFW to provide techno-managerial support to NTAGI and STSC and its working groups. The members were informed that in a meeting of the Chair and Co-Chairs in April, 2016, it was decided that the NTAGI Secretariat would now be completely supported by the Government of India and a proposal to establish the NTAGI Secretariat at the National Institute of Health and Family Welfare (NIHFW) has since been approved. The NIHFW is currently in the process of recruitment of human resources and working out other modalities for the establishment of the NTAGI Secretariat.

Agenda Item 2. STSC Discussion and Recommendations

a) The Co-Chair, Secretary, Department of Biotechnology (DBT) presented to the NTAGI, a detailed overview of the work undertaken by the Standing Technical Sub-Committee (STSC) over the past year. In the past year the STSC of the NTAGI met four times and deliberated on HPV, typhoid, diphtheria, Hepatitis A and cholera disease burden in India. One working group was active at the beginning of year (Hepatitis A), and three subject specific working groups comprising of members from the STSC and independent subject matter experts had been established for undertaking detailed technical review on agenda items. Three working groups (on Hepatitis A, typhoid and cholera) have submitted their reports to the STSC and the working group on HPV is continuing deliberations.

b) Over the course of four meetings, the STSC had deliberated on following issues:

1) HPV disease burden in India

- In the STSC meeting of 28th April 2016, the STSC reviewed available evidence of HPV disease in India and opined that there is significant evidence on HPV burden, but more information is required on the disease burden, programmatic issues and effectiveness of vaccine and recommended strengthening of cancer screening programs. The STSC recommended the formation of a Working Group under the leadership of Dr NK Arora to undertake an in-depth analysis of HPV disease burden in India and control strategies.

- The Working Group met on 5th October 2016 and decided to review evidence of HPV disease burden undertake a critical appraisal of vaccine efficacy and effectiveness of HPV vaccines, and conduct a study to evaluate the economic consequences of HPV disease and available HPV disease control strategies.
- The STSC deliberated on the discussions of the HPV Working Group in its meeting on 5th October 2016 and suggested that a comprehensive cost-effectiveness framework should be developed by the Working Group and recommended for the strengthening of AEFI surveillance system with support provided to states that are planning introduction of HPV vaccine. The NTAGI was informed that the HPV Working Group has been asked to expedite its review and report to the STSC in a time bound manner.
- The members were informed that Punjab has undertaken a facility based limited introduction of HPV vaccine in the state with a high coverage, and the implementation has so far been uneventful.

Recommendation: The NTAGI endorsed the STSC recommendation to undertake a thorough evaluation of HPV control strategies including a cost effectiveness analysis and underscored the need for an expeditious decision in this regard.

2) Typhoid disease burden in India

- The STSC meeting of 30th June 2016 reviewed the epidemiology and burden of typhoid disease and examined if the available evidence in the country was sufficient to consider immunization as a control strategy. The group also considered the available typhoid vaccines and global recommendations for their use. An evidence gap on typhoid disease burden was identified as a key barrier to formulating a recommendation and the need for strengthening surveillance data was highlighted. The STSC recommended the formation of Working Group under the leadership of Dr Gagandeep Kang and Dr NK Arora to identify key questions that need to be addressed when reviewing the disease burden and potential use of the vaccine in the country.
- In the 5th October 2016 STSC meeting, Typhoid Working Group reported its findings and suggested establishment of typhoid surveillance mechanisms to examine: the epidemiology and burden of typhoid disease in community and hospital based settings across states and

geographic zones of the country, to study age specific incidence of typhoid disease and, examine determinants of susceptibility to identify pockets of high typhoid burden.

- It was discussed that various surveillance systems for typhoid disease are in existence, including reporting through the Integrated Disease Surveillance Program (IDSP) and laboratory based reporting by the National Centre for Disease Control (NCDC), besides reporting through the Central Bureau of Health Intelligence (CBHI). The NTAGI was informed that Translational Health Science and Technology Institute of DBT, in collaboration with ICMR, is in the process of establishing a tiered surveillance system for typhoid (both hospital based and community based), that is likely to be established by next year. The Co-Chairs informed that this is an important initiative and such science or technology driven initiatives that are needed will be supported under the leadership of DBT and ICMR.
- The members emphasized the need to enhance typhoid surveillance systems and encourage collaboration between agencies to increase the standardization of surveillance methodology including laboratory methods and improve the quality and comparability of data generated from different sources. The usefulness of a task force on pharmaco-economics to undertake cost benefit analyses of various vaccine and inform future policy decision making was discussed.
- The NTAGI was also informed that the WHO is planning to undertake a feasibility study on typhoid conjugate vaccine in Navi Mumbai.

Recommendation: The NTAGI endorsed the STSC recommendation for enhancing typhoid surveillance mechanisms to inform a future NTAGI discussion and recommendation on typhoid vaccine use in India.

3) Diphtheria disease burden in India

- In its meeting on 5th October 2016, the STSC discussed if available surveillance mechanism accurately establish the burden of diphtheria in India, evidence of an epidemiological shift in age specific incidence of the disease, and evaluated the current strategies to control the burden of diphtheria in India.
- The STSC concluded that there is a shift in burden of diphtheria cases in adolescents and adults and acknowledged the low booster dose coverage and the lack of platforms to provide booster

doses and highlighted the need to strengthen these platforms. It was noted that Maternal and neonatal tetanus elimination in India was achieved through high routine immunization without any campaigns. Therefore it would be feasible to protect a significant population of pregnant women against diphtheria by replacing TT with Td. Supplementation of school age vaccination and routine coverage with Td would further increase coverage against diphtheria. It was also discussed that the WHO recommends the use of Td vaccine for all age groups >7 years and recommends for use of vaccine combinations containing diphtheria and tetanus toxoid, rather than TT alone, when immunization against tetanus is indicated.

- The STSC recommended strengthening of diphtheria surveillance systems and replacement of TT vaccine with Td vaccine as an intervention to address the issue of susceptibility to diphtheria and contribute to effective protection from diphtheria in all age groups.
- Members discussed the evidence for incidence of disease after 7 years of age and were informed that during the Kerala outbreak, most of the cases were above 7 years of age. Similar data were collected by the IAP through its online passive surveillance portal, IDSurv, where a large number of cases were being reported in the older than 5 year age group.
- Concern was expressed over the unavailability of anti- diphtheric serum (ADS) at district level hospitals and the lack of awareness of its use in treatment of diphtheria. The NTAGI requested the Government of India to improve the availability and training for use of ADS.

Recommendation: The NTAGI endorses and accepts the recommendation of the STSC for replacement of TT vaccine with Td vaccine in India's immunization programme for all age groups, including pregnant women.

4) Hepatitis A disease burden in India

1. In the 22nd December 2014 meeting, the STSC discussed the evidence to highlight epidemiological shift with increased susceptibility to Hepatitis A in the older population in India and potential strategies that India should adopt to control the Hepatitis A burden and whether a vaccine for Hepatitis A should be introduced in the national universal immunization program. The STSC recommended establishment of a Working Group led by Dr MD Gupte for collating evidence on the burden of Hepatitis A in India, including estimates on mortality and morbidity, caused by the pathogen.

- The working group met on 7th April 2015 to conduct a critical appraisal of evidence on burden of disease, changing epidemiology and epidemiological shift of disease, analysis of outbreaks of disease and vaccine use and cost effectiveness. The group recommended the need for robust data and more well planned studies to inform future decision making.
- In its 5th October 2016 meeting, the STSC reviewed the report presented by the Hepatitis A working group. The STSC determined that because of socio economic transitions, there is a recognizable shift in demographics of Hepatitis A infection, however the available evidence did not indicate a need for introduction of Hepatitis A in the routine immunization program. Therefore, the STSC recommended for use of Hepatitis A vaccine in the context of epidemic control and for individuals who can afford the vaccine.
- It was discussed that epidemiology and surveillance should not be looked as an activity to be undertaken in isolation but should be part of an ongoing processes that is geared to detect a variety of diseases. In this context it was informed that the Department of Health Research is planning on a priority basis, setting up of community-based surveillance sites which can be used for both community based prevalence studies and surveillance of VPDs as well as inform on emerging diseases of concern. The Chair stressed the need for follow up action and commitment to ensure the establishment of surveillance systems.
- The importance of monitoring Hepatitis A outbreaks was emphasized and setting up of surveillance systems through ICMR study sites was discussed. In addition, setting up of sero-prevalence studies was highlighted as an important means to measure population susceptibility and improve assessment of disease burden, which are believed to be highly underestimated at present time.

Recommendation: The NTAGI endorsed the findings of the STSC and recommended the use Hepatitis A vaccine in the context of epidemic control and for individual use, and did not recommend for its inclusion in the national immunization program at this time.

- NTAGI Co-Chair, Dr. Swaminathan enquired if the school immunization policy varies from state to state. Although the immunization schedule is same but implementation is dependent on the state and there is a need to build up a school health program, with entry point through

the RBSK scheme. The operational aspects of school health immunization program were discussed and efforts to strengthen it further will be explored by Immunization Division with other departments of MoHFW and states.

- NTAGI Co-Chair, Dr. VijayRaghavan shared that epidemiology and surveillance should not be looked as an activity to be taken but ongoing processes and should be scaled up for variety of diseases. DHR is planning to start community-based surveillance sites which can be used for community based studies and surveillance especially for VPDs and this will also give information on emerging diseases. It is an immediate priority to start surveillance for VPDs.
- A member commented that monitoring of Hepatitis A outbreaks is needed and to do surveillance via ICMR sites. Also, it is important to establish aetiology and it is important to establish sero-prevalance for Hepatitis A. WG chair, Dr. Gupte shared that in Himachal Pradesh, there was an epidemics of Hepatitis A in 2006 and there are current sites that needs to be taken up seriously for epidemic investigation and action. Concerns were expressed about figures on Hep A that have been shared and he believed that they are underestimated.
- The IMA offered its support through its presence in 1700 districts and 30 states to support MoHFW program in immunization and surveillance of VPDs.
- A member requested for greater availability of data on AEFI surveillance and rotavirus vaccine related intussusceptions. It was felt that there is a need to explore a common pharmacovigilance platform to increase reporting of adverse events.
- Chair, NTAGI commented that decisions taken on enhancing surveillance systems need to be followed up to ensure effective implementation.
- In response to comments on shortage of IPV and forward planning for new vaccine introductions, the Chair, NTAGI clarified that prior to new vaccine introduction, all measures are taken to check and ensure availability of vaccine stock, cohort size for introduction, and that shortage of IPV is a unique situation of global shortage and India is taking all steps to ensure optimal utilization of available vaccine stocks.

The Chair and Co-Chairs thanked all the participants for their invaluable contribution and concluded the meeting.