MEETING OF THE NATIONAL TECHNICAL ADVISORY GROUP ON IMMUNIZATION

2:00pm -3:30 pm, Tuesday, 25 August, 2015

Nirman Bhawan, New Delhi

AGENDA

Chair : Shri Bhanu Pratap Sharma, Secretary MoHFW ***Co-chairs: Dr K. VijayRaghavan, Secretary DBT & Dr Soumya Swaminathan, Secretary DHR***		
Introduction		
1400-1405	Introduction	Chair and Co-chair
1405-1415	Updates: • national roll-out of pentavalent vaccine • strengthening of the AEFI surveillance Action Taken Report on previous meeting of the NTAGI, June 12, 2014 • Progress report on new vaccine introduction- rotavirus, IPV and MR	MoHFW
Agenda item 1: Potential Introduction of Pneumococcal Conjugate Vaccine in India's UIP		
1415-1430	Summary: STSC discussion and recommendations on PCVs • Global, regional and national burden of pneumococcal disease in India • Available evidence on safety, efficacy and impact of PCVs • Programme and operational considerations for introduction of PCVs in India	Dr VijayRaghavan, Secretary DBT
1430-1450	Discussion	
1450-1500	Recommendations	Chair and Co-Chairs
Agenda item 2: Code of Practice		
1500-1510	Proposed Code of Practice	Dr NK Arora, INCLEN
1510-1520	Discussion	
1520-1530	Recommendations	Chair and Co-Chair

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LIST OF ATTENDEES

Chair & Co- Chairs	
Shri Bhanu Pratap Sharma	Secretary, Ministry of Health and Family Welfare, Chair
Dr K. VijayRaghavan	Secretary, Department of Biotechnology & Co- Chair , NTAGI
Dr Soumya Swaminathan	Secretary, Department of Health Research & Co- Chair , NTAGI
Core Members, Independent Expert	
Dr Parvez Kaul	Professor & Head, Department of Internal & Pulmonary Medicine, Sher-i-Kashmir Institute of Medical Sciences, Srinagar
Dr Dileep Mavalankar	Director, Indian Institute of Public Health, Gandhinagar
Dr Arun Kumar Agarwal	Professor of community medicine, School of Public Health, Postgraduate Institute of Medical Education & Research, Chandigarh
Dr Dileep Kumar Das	Professor and HOD, Community Medicine, Burdwan Medical College, Burdwan, West Bengal
Dr D.K Taneja	Ex. Vice President IPHA& Director Professor of Community Medicine, Maulana Azad Medical College, New Delhi
Dr Y K Gupta	Professor and Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi
Dr MD Gupte	Professor, National Institute of Virology, Pune
Dr Indrani Gupta	Professor and Head, Health Policy Research Unit, Institute for Economic Growth Delhi
Dr J Puliyel	Consultant pediatrician and Head of Department, St Stephen's Hospital, Delhi
Dr NK Arora	Executive director, INCLEN, New Delhi
Dr G Sridharan	Consultant Virologist, Christian Medical College, Vellore
Core Members, Ex- Officio	
Dr S Venkatesh	Director, National Centre for Disease Control

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Representatives from International Partners	
Dr Pankaj Bhatnagar	National Professional Officer (Immunization), World Health Organization , New Delhi
Dr Satish Gupta	Health Specialist, UNICEF, New Delhi
Representatives of Professional Organization	
Dr Vipin M. Vashishtha	Co-Chair, IAP Advisory Committee on Vaccines & Immunization Practices, Indian Academy of Paediatrics.
Dr K K Aggarwal	Honorary Secretary General, Indian Medical Association
Liaison Members	
Dr Rakesh Kumar	Joint Secretary, Reproductive and Child Health , MoHFW
Dr M.K. Agarwal	Deputy Commissioner, Universal Immunization Programme, MoHFW
Dr Pradeep Haldar	Deputy Commissioner, Immunization, MoHFW
Dr VG Somani	Joint Drugs Controller, Central Drugs Standard Control Organization
Others	
Dr NV Kamath	Principal Advisor, Indian Medical Association
Prof Ramanan Laxminarayan	Vice-President, Research & Policy, Public Health Foundation of India
Dr Jyoti Joshi	Senior Advisor- Immunization Safety Surveillance, ITSU- NTAGI Secretariat
Dr Ambujam Nair Kapoor	Senior Advisor- Strategic Planning and system Design, ITSU- NTAGI Secretariat
Ms Apoorva Sharan	Program Manager, Evidence to Policy Unit, ITSU- NTAGI Secretariat
Ms Suchi Kapoor	Program Associate, Evidence to Policy Unit, ITSU- NTAGI Secretariat
Mr Manish Sharma	Administrative Assistant, ITSU- NTAGI Secretariat

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MEETING MINUTES

The National Technical Advisory Group on Immunization (NTAGI) met 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).

Joint Secretary, Reproductive and Child Health (JS, RCH) welcomed all members and participants to the meeting, and provided a brief introduction regarding the history and evolution of the NTAGI in India. He highlighted the progress made in the strengthening of evidence based decision making on immunization policy in the country. Following a round of introductions, the chair welcomed the new co-chair, Secretary DHR as well as the participants to the meeting and called the meeting to order. As per the agenda, the following items were discussed:

Agenda item 1: Potential introduction of Pneumococcal Conjugate Vaccines (PCVs) in India's Universal Immunization Programme

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 had deliberated on three key issues: the potential inclusion of PCVs in India's UIP, the available evidence of burden of Hepatitis A in India and the proposed draft of the Code of Practice for the NTAGI and its STSC. Three working Groups, comprising of members from the STSC and independent subject matter experts had been established for undertaking detailed technical review for each of these agenda items. While work on Hepatitis A review is still on-going, the STSC presented finalized recommendations on PCVs and Code of Practice.

b) Over the course of 4 meetings, the STSC had deliberated on pertinent issues regarding the potential inclusion of PCVs in India's UIP:

   1) In its December 22, 2014 meeting, the STSC reviewed available evidence on burden of pneumococcal disease in India and recommended the establishment of a Working Group under the leadership of Dr MD Gupte for collating evidence on the burden of pneumococcal disease in India, including estimates of mortality and morbidity caused by the pathogen in the country.

2) The Working Group met on April 6, 2015 to conduct critical appraisal of evidence on burden of disease, serotype prevalence, prevalence of antibiotic resistance and surveillance of pneumococcal disease in India.

3) In its June 10, 2015 meeting, the STSC reviewed the report collated by the Working Group and deliberated upon available global and regional evidence on safety and impact of PCVs in averting the burden of pneumococcal disease. While there was general consensus regarding the potential of Pneumococcal Conjugate Vaccines (PCVs) to reduce pneumococcal disease burden in India, the STSC requested for further evidence on impact, dosing schedules and economic considerations prior to finalizing recommendations for introduction of PCV in India's Universal Immunization Programme (UIP)

4) To discuss issues regarding the potential impact of PCVs in India and programmatic and operational considerations for PCV introduction, the STSC met on July 8, 2015. Following detailed deliberations, the committee recommended a phased introduction of PCV in India's UIP using a 2p+1 dosing schedule, to be given at 6 weeks, 14 weeks and 9 months. The STSC recommended that PCV must be introduced in high priority (high under 5 mortality) areas with quality controlled surveillance systems to conduct impact assessment of the vaccines.

c) The NTAGI deliberated on the recommendations made by the STSC. Some of the members expressed concern over the findings of the STSC Working Group, particularly regarding the absence of reliable national level population estimates of pneumococcal disease burden estimates. The chairperson of the Working Group clarified that, this issue was discussed in detail in the STSC working group meetings and despite the absence of population level estimates, available evidence from hospital based surveillance studies and impact of PCV vaccines witnessed in other parts of the globe, PCV is likely to be effective in reducing the burden of pneumococcal disease in India.

d) The importance of strengthening systems for surveillance of both, potential impact of the vaccine and any potential AEFIs was stressed. Members highlighted that, the proposed introduction of multiple new vaccines must be planned per system readiness with proper mechanisms in place to monitor and evaluate the impact of these vaccines. It was suggested that based on horizon scanning of potential new vaccine candidates, surveillance for vaccine preventable diseases may be initiated at last 3 years in advance, in order to ensure adequate baseline information is collected.

e) It was clarified that while PCV10 provides protection against approximately 66% of the prevalent serotypes, PCV13 provides protection against nearly 70% of the prevalent serotypes in the South East

Asia Region. With regards to duration of protection of PCV vaccination, it was clarified that PCVs are relatively new, having existed for only 10-15 years, data on duration of protection is limited. Current evidence seems to suggest that once immunized, PCV confers life time immunity against specific pneumococcal strains.

f) The indirect benefits of PCV vaccination were highlighted. Introduction of PCV in routine immunization programmes is linked to reduction in nasopharyngeal carriage rates of Streptococcus pneumoniae, which in turn reduces transmission of the disease in the unvaccinated and elderly population as well.

g) The introduction and subsequent impact of PCV in over 120 countries globally was also discussed in detail. There was general consensus over the safety of PCVs. With the South East Asia Region (SEAR) Nepal and Bangladesh have introduced PCVs in their routine immunization programmes.

Recommendation: The recommendations of the STSC from its June 10, 2015 meeting were endorsed by the NTAGI with one dissenting vote. The recommendations adopted by the NTAGI are as follows:

- **The NTAGI recommends a phased introduction of Pneumococcal Conjugate Vaccine (PCV) in India's UIP. A dosing schedule of 2 primary doses at 6 weeks and 14 weeks, followed by a booster dose at 9 months is recommended. This dosing schedule also aligns with the UIP schedule.**
- **Based on efficacy data, either PCV10 or PCV13 may be used in the programme. However, PCV13 provides protection against three additional serotypes, potentially covering an additional 4% of the prevalent serotypes in the country, PCV13 is preferable.**
- **In the first phase, the vaccine should be introduced in at least some high priority areas (i.e. high under five mortality areas) with quality controlled surveillance systems and carefully designed and conducted impact assessment with appropriate oversight. Systems for surveillance of *Streptococcus pneumoniae* must be strengthened. The methodology for surveillance and the design of impact studies with appropriate external monitoring should be decided by an expert group.**
- **Additionally, efforts must be made to establish national capacity to model disease burden and the impact of vaccination.**

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Agenda item 2: Update on agenda items from previous NTAGI meeting on June 12, 2014

a) The JS, RCH presented an update on key agenda items from the minutes of the previous NTAGI meeting, held on June 12, 2014. The committee was informed about the progress made on the nationwide scale up of pentavalent vaccines and strengthening of systems for AEFI surveillance and investigation. The committee was also apprised of the progress made in the introduction of the IPV, MR and rotavirus vaccines in India's UIP.

b) Some members were of the view that high mortality states should be selected first for pilot introduction of new vaccines. It was clarified that the selection of states for piloting of new vaccine introduction was decided upon by an independent committee, based on a number of different criteria, including the population cohort, availability of vaccines, immunization coverage, demand from states for the vaccines and health system readiness.

c) Additional data on AEFIs reported following pentavalent vaccination were requested by some of the members. It was clarified that details of all AEFIs for which causality assessment has been done has been put up on the Ministry of Health and Family Welfare website.

d) The need for greater involvement of the private sector paediatricians in reporting of AEFIs were stressed. Chairman National AEFI committee informed the NTAGI about the membership of the Indian Academy of Paediatrics and the Indian Medical Association in the National AEFI committee.

e) It was suggested that as newer more expensive vaccines are introduced, efforts must be undertaken to minimize vaccine wastage by optimizing systems for vaccine logistics and cold chain management, as well as addition of management capacity at state level for ensuring good Routine Immunization (RI) services. In this regard, members were apprised of the numerous efforts undertaken by the MoHFW to augment capacity for vaccine logistics and cold chain management, including the piloting of temperature logger technology and the Electronic Vaccine Intelligence Network (eVIN) systems, putting in place an Open Vial Policy (OVP) to ensure use of multi-dose vial as well as augmenting the existing cold chain points. Members were apprised that the eVIN has helped eliminate vaccine stock-outs in two pilot districts and this technology is now being scaled-up nationwide.

f) Similarly to augment state RI programme management capacity, the large states have been encourage to appoint three consultants with the National Health Mission (NHM) Programme Implementation Plans (PIP) to monitor logistics, AEFI surveillance, cold chain etc.

g) Secretary DHR suggested that the NTAGI may consider the available evidence on the burden and strategies to avert the burden of Human Papillomavirus (HPV) in India.

Agenda item 3: Proposed draft of the Code of Practice for NTAGI and STSC:

a) Dr NK Arora, member of the Working Group on Code of Practice presented an overview of the proposed draft of the Code of Practice:

1) A brief history of the evolution of the draft Code of Practice was presented. Members were apprised that the initial draft of the Code of Practice had been prepared by the secretariat following detailed review of best practices at similar global and national scientific advisory committees. This draft was approved (for further circulation and finalization) following review by the chair, co-chairs and liaison members of the NTAGI in September 2014. Subsequently, the STSC has reviewed and amended the Code of Practice in two meetings (Dec, 2014 and March, 2015).
2) In order to learn and implement global best practices in decision making on immunization policy issues, the secretariat coordinated a visit of a delegation of STSC members and MoHFW representatives to the Advisory Committee on Immunization Practices (ACIP) meeting in Feb, 2015. The ACIP is the American equivalent of the NTAGI.
3) A teleconference was also organized between members of the NTAGI secretariat and the Sri Lankan Advisory Committee on Communicable Diseases (ACCD) with the same objective.
4) A Working Group, comprising of three independent STSC members (Drs Kang, Taneja and Arora) was then tasked with reviewing and incorporating lessons learnt from these exchanges into a revised draft of the Code of Practice.
5) The Working Group presented the revised draft to the co-chair and MoHFW representatives in April, 2015

6) A detailed overview of the key topics covered by the proposed Code of Practice was also presented, including the scope of activities of the NTAGI and its STSC, terms of reference for the members, guidelines for recording and disseminating proceedings the NTAGI, policies for declaration of interests and confidentiality agreements.

b) Members highlighted the need to establish systems for grading of the quality of evidence considered whilst drafting policy recommendations, along the lines of the GRADE methodology adopted by the ACIP. It was clarified that the proposed STSC standing Working Group on research and capacity building may undertake the creation of such an evidence review framework in the coming years.

c) The terms for declaration of interests were discussed in detail. Members remarked that the granting of voting rights to members with declared pecuniary interests in vaccine related issues is a marked departure from global best practices. Members also suggested revisions of the timelines for recording, dissemination and publication of the minutes of the NTAGI meeting. There was general consensus that minutes may be circulated to NTAGI with a 2 week deadline for comments, which can be deliberated upon by the chair and co-chairs prior to the finalization of the meeting minutes.

d) It was recommended that the head of ICMR Epidemiology and Communicable Disease Division may be added as an ex-officio member to the NTAGI.

Action Point: A draft of the Code of Practice may be circulated to members of the NTAGI for their feedback with a time-bound deadline. Comments received by members will be reviewed by the chair and co-chairs of the NTAGI to finalize the Code of Practice.

The chair thanked all the participants for their invaluable contributions to the committee and concluded the meeting.