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India's National Technical Advisory Group on Immunisation

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ABSTRACT

The National Technical Advisory Group on Immunisation in India (NTAGI) fulfils a need for informing decision-making concerning the introduction of new vaccines and strengthening the Universal Immunisation Programme (UIP). The role and membership of NTAGI have expanded over the years in tune with the emerging needs and priorities of the Government of India. Current challenges include institutionalizing mechanisms to follow-up and monitor recommendations, to support research needs to fill information gaps, and to provide technical assistance for monitoring and periodically reviewing the UIP.

1. Description and background

India adopted the Expanded Programme on Immunisation (EPI) in 1978, targeting 80% coverage of infants with Bacillus Calmette-Guérin, diphtheria, tetanus and pertussis vaccine, oral polio vaccine and typhoid–paratyphoid (whole cell, killed) vaccine. EPI was revised as the Universal Immunisation Programme (UIP) during 1985–1990, targeting 100% coverage; also typhoid–paratyphoid vaccine was dropped and measles vaccine was added. Tetanus toxoid vaccination of pregnant women was part of EPI and was retained in UIP.

The UIP is managed by two senior officers (Deputy and Assistant Commissioners) in the Immunisation Division of the Department of Family Welfare (DFW) under the Ministry of Health and Family Welfare (MoHFW) of the Government of India (GoI). The functional responsibility is shared between GoI and State Governments: GoI provides funds, policy formulation, training of staff, cold chain support and procurement and supply of vaccines and injection equipment while the States are responsible for the implementation of the program.

Earlier, there was no mechanism established within EPI/UIP for regular technical reviews. When technical inputs were required, ad hoc consultations with experts (identified on the basis of issues needing to be discussed) were undertaken. In 1985, measles vaccine was introduced as recommended by the Planning Commission under the 7th Five-year Economic Plan. From about that time it had been recognized that there was a need for a mechanism for continuous and sustained availability of technical inputs regarding implementation of the vaccination program, regulatory aspects, new vaccine introduction as well as for research. To fill this need, the National Technical Advisory Group on Immunisation (NTAGI) was established in August 2001 by the DFW [1]. The NTAGI was intended to provide technical advice to inform decision-making on both technical and operational matters pertaining to immunisation and choice and scheduling of existing and planned vaccines.

The NTAGI thus is meant to be the primary advisory committee (hereafter also referred to as the Committee) advising the MoHFW on all immunisation-related issues. The Office Order, issued by the Ministry in August of 2001 to constitute the NTAGI, designated the Secretary to the GoI (in the Department of Health Services and DFW) to be its Chair and the Deputy Commissioner (Immunisation Division) as its Member-Secretary. It had representation from a wide spectrum of relevant constituencies (Table 1). They included national organizations involved in health-care policy and research, such as the Indian Council of Medical Research and the National Institute of Health and Family Welfare; professional organizations such as the Indian Academy of Paediatrics and the Indian Medical Association; representatives of GoI agencies such as the Child Health Division, Department of Biotechnology, Planning Commission, and the National Regulatory Authority (Drugs Controller General of India); representatives of five State Governments (Madhya Pradesh, Maharashtra, Orissa, Tamil Nadu and Uttar Pradesh); and five independent experts. Although not formal members, representatives of UNICEF, the World Health Organization (WHO) and the World Bank are invited to attend committee meetings. Care has been taken for members to represent a range of expertise including pediatricians, epidemiologists, public health specialists, infectious disease experts, virologists/microbiologists, vaccinologists, immunisation programme experts, logisticians and regulatory experts.

Abbreviations: EPI, Expanded Programme on Immunisation; DFW, Department of Family Welfare; GoI, Government of the India; MoHFW, Ministry of Health and Family Welfare; NTAGI, National Technical Advisory Group on Immunisation; TOR, Terms of Reference; UIP, Universal Immunisation Programme; WHO, World Health Organization.

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Table 1
Members of the National Technical Advisory Group on Immunisation constituted in August 2001 with the approval of the Secretary of the Department of Family Welfare (DFW), Government of India.

Chairman
Secretary (DFW)
Members:
Department of Family Welfare
Joint Secretary (Maternal and Child Health)
Deputy Commissioner (Immunisation)
Assistant Commissioner (Universal Immunisation Programme)
Representative of National Organizations
Indian Council of Medical Research
National Institute of Virology, Pune
National Institute of Communicable Disease, Delhi
National Institute of Health and Family Welfare
National Institute of Immunology, Delhi
Representatives of Professional Organizations
Indian Academy of Pediatrics
Indian Medical Association
Indian Association of Preventive and Social Medicine
State Government Representatives/Program managers
Secretary (DFW), Orissa
Secretary (DFW), Uttar Pradesh
State Director/State RCH Officer, Tamil Nadu
Director (DFW), Maharashtra
Director (DFW), Madhya Pradesh
Representatives of Government Departments
Department of Women and Child Development
Internal Finance Division, Ministry of Health and Family Welfare
Department of Bio-Technology
Planning Commission
Drug Controller General of India
Experts
Dr. Jacob John
Dr. Ranjit Rai Choudhary
Dr. Shanti Ghosh
Dr. K.B. Banerjee
Dr. Jotna Sokhey
Representative from UNICEF
Representative from World Health Organization
Representative from World Bank

One independent expert is mandated to function as Co-chair of the NTAGI.

The NTAGI is essentially a standing committee under the DFW in the MoHFW. As a specially established committee its official administrative position and status within the GoI is unclear, except that it was created by a formal Office Order from MoHFW. The current membership and Terms of Reference (TOR) of the initial NTAGI (2001) are detailed in Tables 1 and 2. While non-government members are paid expenses to attend meetings, no remuneration is paid to government employees. So far no requirement for members to declare actual or potential conflicts of interest has been defined. However, members have been selected on the basis of a reputation for integrity in addition to expertise. Industry representatives may be invited to present data but they do not participate in other discussions. The development of a tool to ensure lack of, or to document any specific, conflict of interests is being considered for the future.

2. Operation of the NTAGI

The first meeting of the NTAGI was on 19 December 2001 with the following objectives:

1. Identification of reasons for declining immunisation coverage.
2. Involvement of the private sector to improve coverage levels.
3. Plans for expansion of the cold chain system.
4. Standardized monitoring and evaluation of the UIP.
5. Setting criteria for the introduction of new vaccines.
6. Identification of research needs.

Based on deliberations at this first meeting, it was decided that sub-groups would be established to examine the following specific issues:

1. Operational issues including injection safety.
2. Monitoring and surveillance.
3. Introduction of new vaccines.
4. Vaccine quality and coordination with the National Regulatory Authority.
5. Research needs—future studies.

3. Meeting schedules and format

In its early years the NTAGI met infrequently, but currently it meets more often (see below). The Immunisation Division acts as the Secretariat for scheduling meetings, preparing minutes and taking follow-up actions. The meeting agenda is based on the needs of the Immunisation Division as well as requests from the States. Meetings are "close-door" with additional observers attending by invitation only. However, the NTAGI has the ability to invite or co-opt experts in specific fields according to need and the topics to be discussed. Manufacturers of vaccines do not play any role in NTAGI but have been invited on occasion. The decisions (resolutions) and recommendations of the NTAGI are reached by general agreement among members and Chair and to date there has been no need for members to vote.

On an ad hoc basis, NTAGI sub-groups and Expert Advisory Groups (outside NTAGI) are constituted through the Secretariat to address specific issues and to submit their summary assessments, suggestions and recommendations. In addition, the existing disease-specific working groups on measles and polio established through 'Partner Networks' (WHO, UNICEF, and other bilateral/international agencies) may forward their recommendations to the NTAGI for consideration.

For recommendations regarding the introduction of a new vaccine into the UIP, the NTAGI may directly make resolutions, or assign the task to a Sub-group to bring its proposals to the NTAGI meeting. The decision-making process is based on disease epidemiology, disease burden, cost-effectiveness analyses and priority of vaccine introduction related to other public health interventions. When data are inadequate, the opinions of experts and the collective wisdom of the members may be applied.

4. Evolution of NTAGI

Since its formation in August 2001, the NTAGI has met six times (December 2001, October 2004, March 2006, July 2007, June 2008 and August 2009). A number of important interventions, namely introduction of vaccines against Japanese encephalitis, hepatitis B, rubella (in combination with a second opportunity for measles vaccine, as measles rubella vaccine) and *Haemophilus influenzae* type b (as a combination pentavalent vaccine) and introduction of auto-disable syringes in the UIP, were recommended by the NTAGI and have been accepted by the MoHFW [2].

More recently the NTAGI has made extensive deliberations on several issues—development of a Multi-Year Strategic Plan for the UIP (GoI, 2002–2007), the pros and cons of introduction of rotavirus and pneumococcal vaccines, enhanced measles control activities, the safety of thiomersal in vaccines, introduction of vaccine vial monitors on all vaccine vials, review of the human resource needs for immunisation at GoI and State levels and the re-engineering of the UIP as a system. For several issues the NTAGI has made

Table 2
Major roles and terms of reference of the National Technical Advisory Group on Immunisation in India.

Major roles
To be an advisory body to assist the Government of India in developing a nation-wide policy framework for vaccines and immunisation
To prioritize immunisation activities and set attainable targets
Identify critical gaps in policy and programme and identify studies, assessment and research areas to be addressed
To review periodic assessment of the national immunisation programme, including immunisation performance and disease incidence
Terms of reference
Identify reasons for the decline in immunisation coverage levels, identify bottlenecks and suggest measures to revitalize the routine immunisation activities
Establish criteria for ensuring a cost effective expansion/renewal plan for the cold chain
Set up norms for periodic evaluation of the immunisation programme (e.g., frequency surveys, methodology to be adopted, and mechanism for data dissemination)
Examine the current status of surveillance under the Reproductive and Child Health Programme and suggest mechanism for integrating the National Polio Surveillance Project network with the existing surveillance system once the polio is eradicated
Firm up guideline for epidemic/outbreak control measures for vaccine-preventable diseases
Establish standards and criteria for introduction of new vaccines under the Universal Immunisation Programme
Guide policy for introduction of injection safety technology into the immunisation programme
Suggest innovative strategies for introducing demand generation strategies in the programme
Examine the role of private sector vis-a-vis immunisation and suggest measures for a more effective programme with private sector partnership
Identify strategies, which would be required under special circumstances for instance (a) in under served areas like urban slums and tribal areas (b) immunisation during natural calamities
Identify areas that need research studies including cost effectiveness analysis, burden of diseases studies, operations research, etc., and suggest modalities for conducting the same
Suggest mechanisms and modalities for improving the vaccine quality assurance through the National Regulatory Authority (Drug Controller General of India)
Examine the need for decentralization of programme implementation and suggest the degree and modalities for affecting the same

specific recommendations, many of which have been acted on by the MoHFW. On some issues, the recommendations are still being considered.

Over the years, the role of the NTAGI (and consequently the membership) has evolved to meet the changing requirements at the national level. Other issues pertaining to immunisation have also been taken up for ongoing discussions such as improving coverage and access, promoting vaccine security, monitoring of adverse events following vaccinations, vaccines beyond childhood (like human papilloma virus, seasonal influenza and meningitis vaccines), public–private partnerships in the UIP, and measuring and monitoring the impact of immunisations. Currently, the minutes and recommendations (http://mohfw.nic.in/dofw%20website/june.pdf) of the NTAGI are published on the MoHFW website (http://mohfw.nic.in/dofw%20website/dofw.htm), to promote transparency and facilitate access to everyone. At the last meeting of the NTAGI it was resolved to increase the frequency of meetings to twice annually initially, progressing to meeting every quarter.

5. Future directions and challenges

Recognizing the need to strengthen the functioning of the NTAGI, a number of issues have been proposed. The need for regular meetings of the NTAGI has been clear. Earlier meetings were announced on an ad hoc basis but in the future meetings are to be pre-scheduled. This will help to strengthen the NTAGI as an institution and to allow better monitoring of the implementation of recommendations. To achieve these goals the NTAGI has a critical need for full-time support services to provide a secretariat, as well as technical assistance for data review and developing norms and standards. A mechanism and funding for generating data (e.g., disease burden, vaccine efficacy, and cost effective studies) are needed to support the NTAGI's decision-making and recommendations. Since health personnel are the backbone of the immunisation program, there is a critical need for the NTAGI to widen its scope to include human resource issues in its agenda. Similarly, the expertise of the NTAGI may be used to monitor the progress of the UIP as well as to deliberate and provide recommendations on other important issues for strengthening childhood immunisation like improving access and coverage; optimizing utilization of resources; strengthening monitoring and supervision; reducing immunisation drop out rates by tracking children through full immunisation; and strengthening the surveillance of vaccine-preventable diseases and adverse events following immunisation.

6. Conclusion

The NTAGI has evolved from an ad hoc decision-making process to one that is transparent, collective and systematic using the best available evidence for decision-making. However, wide gaps between the available and optimal evidence required have been noted. This has occurred in part because available evidence often comes from research that was not necessarily conducted to provide specific data to inform decisions such as on the choice of vaccines and their inclusion in the UIP. A more serious gap is the lack of quantitative data on the frequency of diseases or mortality from the GoI agencies concerned with disease control, such as the National Institute of Communicable Diseases and the Central Bureau of Health Intelligence.

Recently there has been debate in local medical journals regarding the Indian NTAGI recommendations, e.g., the recommendation for a phased introduction of the combination pentavalent vaccine. This is seen as a healthy trend. Major weaknesses in the UIP remain that affect its efficiency. These include: the time taken by national and state governments to implement NTAGI recommendations; lack of an institutional mechanism to follow-up and monitor recommendations; and differing perceptions about the respective roles and responsibilities of GoI, State Governments and other stakeholders. The lack of comprehensive data on disease burden and the lack of surveillance systems for vaccine-preventable diseases add to the difficulty that India has in achieving the full potential of its Immunisation Division.

Conflict of interest statement

The authors state that they have no conflict of interest.

References

[1] John TJ. National Technical Advisory Group on Immunization: a major step forwards for child health. (Editorial). Indian Pediatr 2002;39:327–30.
[2] Subcommittee on introduction of Hib vaccine in Universal Immunisation Programme, National Technical Advisory Committee on Immunisation, India. NTAGI Subcommittee recommendation on Haemophilus influenzae type b (Hib) vaccine introduction in India. Indian Pediatr 2009; 46: 945–954.