

Indonesian TAGI Activities

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Description and background

The National Immunization Technical Advisory Group (NITAG) in Indonesia is officially recognized as “The Indonesian Technical Advisory Group on Immunization” (ITAGI) - is established in 2007 (Ministry of Health Decree, December 15th 2006 No.1418/Menkes/SK/XII/2006). The current mandate of ITAGI is “to provide advice to MOH through the Director General of the Communicable Disease Control (CDC) with ongoing timely medical, scientific, and public health advice relating to vaccines”. ITAGI recommendation has not been published to the public until this time. There are limited new recommendations submitted to the MOH through the Director General of the CDC.

Membership on ITAGI consists of eighteen core members. They are recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine, Health Economic, and Epidemiologist. Members are appointed for a term of three years and may be requested to renew their membership for a second term of three years. The Chair of ITAGI is appointed by the Director General of CDC for a three-year term. Selection of the Chair is based on expertise and knowledge in the field of immunization practices, public health, and use of vaccines and prophylactic agents for the prevention of vaccine-preventable diseases. A General Secretary selected from existing membership is also appointed for a three year term.

There are liaison members from various organization with interests in immunization, such as IDAI (Indonesian Pediatrics Society), PAPDI (Indonesian Internal Medicine Society), IDI (Indonesian Medical Association), WHO, and UNICEF. Liaison members of ITAGI are representatives from groups identified by the Chair of ITAGI to provide expertise on vaccine safety and effectiveness, and/or provide input to ensure appropriate interpretation of ITAGI’s advice, and/or have access to relevant research on specific issues. Liaison members are selected by their organizations, and are expected to bring knowledge and input into the ITAGI discussions, express the views of the organization, and communicate ITAGI’s advice to the organization as permitted.

Ex officio representatives on ITAGI are assigned by the Director General of the CDC of Indonesia. The role of the *ex officio* members is to support the work of ITAGI by providing additional knowledge and expertise, communicating the views of the Department/Agency/Division they represent and communicating ITAGI’s advice as permitted by the Director General of CDC.

Vaccine industry representatives cannot be members of ITAGI, and do not participate in group discussions. Industry experts do provide information about vaccines to the Committee, and may be invited to make presentations to the full committee or its working groups. ITAGI is not funded by any means related to vaccine manufacturers..

ITAGI Working Groups are established to address specific vaccine and immunization issues. These groups review evidence and draft Advisory Committee Statements on specific vaccines, including options for vaccine recommendations for the full committee to consider. Working groups may prepare guidance in response to specific inquiries or other issues as they arise, and are also required to contribute and revise relevant chapters of the Indonesian Immunization

Guidelines. Working Groups comprises of core, liaison, *ex officio* members and external experts as necessary.

Secretariat is to assist with the technical analysis, literature review, and drafting of Advisory Committee Statements in addition to other roles and responsibilities, such as responding to medical inquiries to ITAGI. External content experts or other consultants may be invited to serve on a Working Group as necessary to provide broader input.

Terms of reference, meeting processes, and declaration of conflicts of interest

Terms of reference

Information on ITAGI's structure and processes is contained within its Terms of Reference, which may be amended at any meeting by consensus or by vote.

Tasks and functions mentioned below are only in general.

- Conduct policy analysis and determine the most optimal national immunization Policy
- Advise the national government on the formulation of strategies for the control of vaccine preventable diseases through immunization
- Assist the national authorities in the monitoring of national immunization program so that impact can be measured and quantified
- Keep the national authorities updated on the latest scientific development in the area of vaccines and vaccine preventable diseases
- Advise, where appropriate, organizations, institutions or government agencies in the formulation of policies, plans and strategies for research and development in new vaccines and vaccine delivery technologies of the future
 - Promote vaccine production to meet national and, where possible, even global needs for vaccines that are of high quality, in sufficient quantity and at affordable prices
 - Promote collaboration between vaccine industries, national policies makers and national regulatory authorities to foster regional and national vaccine security
 - Foster inter-departmental linkages for those disease that may already have a vaccine or a potential vaccine in the pipeline
 - Promote partnership between government, civil society, industry and donors to promote immunization in a sustainable, scientifically and credible manner
 - Be a link between national government and the regional and international technical bodies that work in immunization

Meeting process

The ITAGI has four internal meetings annually which occur over 2 days. Email correspondence occurs regularly. Meetings are not open to public. Experts, including representatives from vaccine manufacturers, may be invited to make presentations as needed. For each meeting, detailed Minutes and a succinct Summary of Discussions are prepared by the Secretariat, reviewed by the Executive Secretary and Chair of ITAGI, and approved by ITAGI. Summary of Discussions will be used for information sharing beyond ITAGI however the detailed Minutes are considered as confidential document for internal use only..

Agenda for ITAGI meetings is created based on changes in the epidemiology of vaccine-preventable diseases, new products, or new evidence about existing products. Potential topics may be submitted by committee members and other stakeholders, and are accepted for addition to the agenda by the Executive Secretary, in consultation with the Chair. An executive committee (consisting of the Chair, Executive Secretary, and the limited core ITAGI members and ITAGI Secretariat) meets regularly between meetings to oversee the progress of the Working Groups, plan full ITAGI meetings and deal with inter-current issues that may arise.

Declaration of conflicts of interest

Members, liaison representatives and consultants are required to submit annual conflict of interest declarations to the Executive Secretary, based on Conflict of Interest Guidelines. Any circumstances that may place, or be seen to place the member in a real, apparent or potential conflict of interest should be disclosed on a written form. It is incumbent upon the member to update this disclosure should his/her personal situation change. Members, representatives and consultants are expected to conduct themselves in an appropriate manner and in accordance with the ITAGI guidelines. In situations where there is a conflict of interests or the appearance thereof arises in the course of the work of the committee, the individual involved must declare its existence and either work with the Executive Secretary to resolve the conflict, or if necessary, disqualify himself/herself from participation in the discussion or from further participation on the committee according to the circumstances of specific situations.

Development of recommendations and the basis for decision-making

The stages for the development of ITAGI recommendations are:

1. Knowledge synthesis (retrieval and summary of individual studies on vaccine safety, efficacy, immunogenicity, effectiveness, ranking of the level and quality of evidence of each study).
2. Synthesis of body of evidence of benefits and harms, considering the relevance, quality of the evidence and magnitude of effects observed.

The final ITAGI Advisory Committee Statement, incorporating committee discussion and vote, is circulated by email for approval. After this approval and final review by the ITAGI Chair and Executive Secretary, the document is sent to the Director General of the CDC Officer for final approval.

Training and Workshop practices

SIVAC (*Supporting Independent Immunization and Vaccine Advisory Committees*) and WHO-SEARO assisted ITAGI conducting a workshop towards - enhancement for establishing or improving the role of ITAGI on National decision making process and capabilities. It has been successfully conducted on Oct 7-8, 2010. Workshop participants consists of ITAGI members, *ex-officio* members are representative of Government: DC-EH – Disease Control & Environmental Health (Expanded Programme Immunization), representatives from Indonesian Drug Control (Badan POM or NRA) and NIHRD - National Institute Health Research Development (Puslit Biomedis Farmasi & Health Economic division), technical support representative from WHO-SEARO and Indonesia WHO representative plus one UNICEF representative as an observer.

Challenges and limitations

Like most immunization advisory committees, ITAGI has faced challenges in a rapidly evolving and complex immunization environment. Limited funding for activities, limited resources data and person to review & analyze supported data.

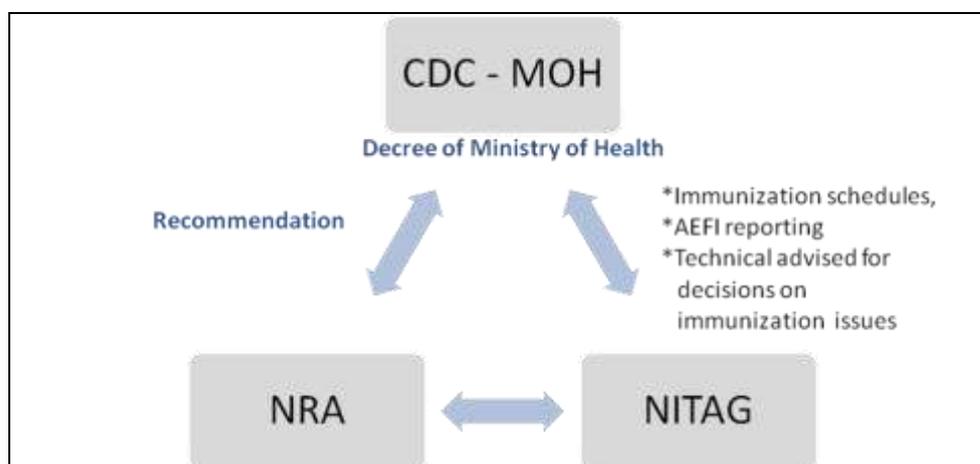
Key Points

Indonesian TAG has a technical advisory role for all vaccine preventable diseases and should NOT serve as an implementing, coordinating or regulatory body.

ITAGI activities during **2007-2011** are:

No	Year	Date	Activity
1	2007	June	The 1 st Plenary Indonesian TAG - Recommendations on <ul style="list-style-type: none"> ▪ Introduction Hib vaccination into NIP (support by GAVI) ▪ Influenza vaccination for health working in Hajj Program Attending the SAGE meeting in Geneva, invited by WHO HQ, Geneva
2	2008	February	Core team's meeting : <ul style="list-style-type: none"> ▪ Planning for introduce Td vaccine to school children (TT change to Td) ▪ Introducing JE vaccine in Indonesia (Bali as a pilot project) ▪ Workshop on Strengthening the Capacity of NCIPs for Pandemic Influenza Preparedness on 25-28 March
		March	SEARO Workshop on Strengthening the Capacity of NCIP For Pandemic Influenza Preparedness, Jakarta
		July	Introducing of typhoid vaccine in school children
		August	Update of influenza H5N1 vaccine
3	2009	March	<ul style="list-style-type: none"> ▪ Socialization on <i>Material Transfer Agreement</i> (MTA) ▪ Justification on introduction of HPV vaccination
		May	Attended the WHO Regional Workshop on Vaccines Prioritization (delegate)
		August	<ul style="list-style-type: none"> ▪ Recommendation on influenza H1N1 vaccination for hajj ▪ Recommendation on use influenza H1N1 vaccine (donation from WHO)
		October	Justification on rotavirus vaccination
4	2010	January	Attending SIVAC (<i>Supporting Independent Immunization and Vaccine Advisory Committees</i>) meeting in Paris– delegate
		March	<ul style="list-style-type: none"> ▪ Meeting with SIVAC ▪ Recommendation Hib vaccination to national immunisation program (an up-date)
		May	Strengthening networking NRA-MOH-ITAGI <i>Developing Countries' Vaccine Regulators Network</i> (DCVRN), Bali
		May	<ul style="list-style-type: none"> ▪ Rabies Vaccine regimen intradermal ▪ Support SIVAC to Strengthening Indonesia TAG
		October	<ul style="list-style-type: none"> ▪ Update of Hib Vaccine ▪ Outbreak Report of diphtheria in Indonesia
		November	Update Hepatitis B immunization
	2011	March	Update Pneumococcal vaccination
	Next plan		Justification of Rotavirus, IPV & JE vaccination

Networking Between Indonesia NRA and NITAG



Therapeutic product that is intended to be marketed in Indonesia has to hold a marketing authorization. Under Decree of Minister of Health No. 1010/2008 dated 3 November 2008 on Drug Registration (Revision of Decree of MoH No. 949/PER/MENKES/VI/2000), the National Agency of Drug and Food Control (NADFC) Indonesia has got mandate as NRA to control drug registration in Indonesia. Therefore, in order to get the marketing authorization, the product should be registered to NADFC, at this stage the applicant should submit a registration application to the Head of Agency to be reviewed. MOH, NRA and NITAG work together for vaccine availability in Indonesia. NRA may seek scientific opinion from NITAG during vaccine development (Investigational New Drug/IND process for new vaccine), during vaccine registration, as well as during post marketing surveillance. During vaccine development, when vaccine is going to be investigated under clinical trial, NITAG involves in NRA review in clinical trial (CT) protocol, consultation on result of GCP inspection, and advice for immunization schedule for CT and target population. As part of vaccine submission review during registration, NRA may seek scientific advice from NITAG before issuing a decision for marketing authorization of which NITAG may also look at pre-market evaluation on clinical data of new vaccines.

Furthermore, NRA gets involved in NITAG's meetings and discussion about current vaccine or any new issues of particular vaccine as well as when developing guidance.

Regarding to the EPI program or introduction of new vaccines which is under MOH roles, NRA gets involved in sharing scientific opinion, Marketing authorization process and approval for any vaccine to be used in EPI program. Furthermore, MOH, NRA, and NITAG work together for the AEFI reporting.

Liaison members

- *Pre-market evaluation on clinical data of new vaccines
- * Introduction & evaluation of new vaccines
- *AEFI reporting

The role of NRA in the Networking of NRA – NITAG

- NRA seeks scientific advice from NITAG's with regards to:
 - Decision making for vaccine's Marketing Authorization.
 - IND process for new vaccine
 - Post marketing surveillance

- Involvement in NITAG's meetings or discussions for developing guidance and scientific opinions.
- NRA advise on Marketing Authorization process and approval for vaccines used as EPI program.

The role of NITAG in the networking of NRA – NITAG

- Involvement in the stage of IND (investigational new drug/vaccine):
 - Evaluation of CT protocol
 - Consultation on result of GCP inspections
 - Advise for immunization schedule for CT and target population
- Pre-market evaluation on clinical data of new vaccines
- Introduction & evaluation of new vaccines
- AEFI reporting

The role of WHO in supporting the ITAGI

WHO Indonesia has been providing technical guidance for the establishment and strengthening of the ITAGI. They regularly provide ITAGI with global and regional guidance documents and **policy recommendations** with references and other background material that constitute the evidence for such recommendations. They also provide regular **updates** and latest developments on the vaccine pipeline, guidance about recommend immunization schedules, vaccine delivery technology, vaccine preventable disease surveillance, safety and quality data/information, etc. WHO also facilitates **exchange** between other regional TAGS and participation of ITAGI's chairperson at regional immunization meetings.

Acknowledgement

We wish to acknowledge our highest appreciation towards MoH -who has issued the ITAGI decree - ex-officio members (DC&EH, Indonesian NRA, NHIRD), SIVAC who intensively support us for ITAGI strengthening , and also towards WHO and UNICEF . Our deep gratitude towards ITAGI secretariat for assistance during task assignment and to all ITAGI members for their supports & dedication.

DC & EH - Disease Control and Environmental Health
 NRA - National Regulatory Authority
 NHIRD – National Health Institute for Research & Development.

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