

Concept Note: Establishment of National Immunization Technical Advisory Groups (NITAG) and National AEFI Committee

NITAG

The Global Vaccine Action Plan calls for all country to establish or have access to such a NITAG by 2020 and the WHO has recommended that countries should establish National Immunization Technical Advisory Groups (NITAGs) to empower governments to formulate rational policies and to increase the use of evidence-based decision-making to adapt global recommendations on immunization to their local context. The World Health Assembly (WHA) reinforced those recommendations in 2012 when Member States endorsed the Decade of Vaccines Global Vaccine Action Plan (GVAP).

In 2012, according to the WHO–UNICEF Joint Reporting Form, among 57 countries eligible for immunization program financial support from the GAVI Alliance, only 9 reported having a functional NITAG.

Also, the 2015 Epi Program Managers' Meeting Recommendations for East and Southern Africa Countries include Rwanda in countries which should align their cMYP and EPI operational activities with the AFRO Immunization Strategic Plan 2014 – 2020 and 10 countries which should accelerate the establishment (NITAGs) in order to guide national immunization policies and strategies.

Terms of Reference (TOR) of the National Immunization Technical Advisory Group (NITAG)

A NITAG is a technical resource that provides guidance to national policy makers and immunization program managers to enable them to make evidence-based decisions on immunization and vaccines.

The role of NITAG includes developing recommendations on new vaccine introduction, appropriated vaccine schedules, determination of high-risk groups, vaccine formulation, research priorities, and implementations of adverse events.

A NITAG is both a technical resource and a deliberative body to empower the national authorities and policy makers to make evidence-based decisions

The following terms of reference will guide the activities of National Immunization Technical Advisory Group (NITAG):

- Conduct policy analyses and determine optimal national immunization policies.
- Guide the national government and the national immunization programme on the formulation of strategies for the control of vaccine preventable diseases through immunization.
- Advise the national authorities on the monitoring of the immunization programme so that impact can be measured and quantified.
- Advise the government on the collection of important disease and vaccine uptake data and information.
- Identify the need for further data for policy making.

Guide, where appropriate, organizations, institutions or government agencies in the formulation of policies, plans and strategies for research and development of new vaccines and vaccine delivery technologies for the future.

Proposed membership (core members)¹ for NITAG

Specialties/field of work	Proposed members
Paediatrician(s)	Prof. BARIBWIRA Cyprien Dr. TETERI Raissa
Adult Medicine Specialist(s)	Dr. Osee SEBATUNZI
Epidemiologist(s)	Prof. Manasseh NZAMURAMBAHO
Infectious Diseases Specialist(s)	Dr. MANZI Olivier
Public health Advisors/Specialist(s)	Dr. MANZI Emmanuel
Immunologist(s)	Dr. MAMBO Claude
(Clinical) Research Adviser(s)	Dr. Brenda KATEERA
Health systems and Delivery Adviser(s)	Ines BUKI
Health Economist(s)	KAMANDA David

AEFI Committee

The Regional Strategic Plan for Immunization 2014-2017 whose aim is to ensure that the goal to provide universal immunization coverage within the WHO African Region is achieved mentions that all countries

¹ Non-core members representing either government (ex-officio) or non-government (liaison) entities will be selected/nominated from their respective institutions. A document detailing the process of establishing NITAG can be found on this link:

http://www.who.int/immunization/sage/RegionalActionPlanforImprovingDecisionMaking_UpdatedDec2009.pdf

are to regularly report adverse events following immunization by the end of 2020 in accordance to objective 1 which is to improve immunization coverage beyond the current levels.

Key approaches for implementation of the strategic plan include ensuring “Promotion of safe injection policies and practices and improved surveillance of adverse events following immunization.” Requiring a strengthened National AEFI committees that rapidly respond to AEFI reports and crises and disseminate evidence-based information to counteract mis-information about vaccines and immunization.

Terms of Reference (TOR) of the National AEFI Committee

Only the most necessary cases with public or national concern, particularly where causality needs to be assessed, are to be referred to this committee.

This AEFI Committee plays a critical role in confirming the causality assessments of selected investigations and in determining causality when not established with confidence by the investigator. Expert committee may use the WHO Aide-Memoire on causality assessment as a resource material, which is available at www.who.int/immunization/safety/en . Also the committee is encouraged to guide comprehensive case definitions developed by the Brighton Collaboration.

The committee should include a wide range of specialists whose expertise may add to the task of reviewing the AEFIs. Areas of expertise would include paediatrics, neurology, general medicine, forensic medicine, pathology, microbiology, immunology and epidemiology.

Medical experts in particular areas should be invited for the review of special clinical events. It also needs support from the both EPI and NRA to ensure its functions.

The following TOR will guide activities of the committee:

- assessing potential causal links between AEFIs and a vaccine;
- monitoring reported AEFI data for potential signals of previously unrecognized vaccine-related adverse events;
- reviewing all reported serious AEFI presented for expert opinion and making arrangements to investigate further to establish causality and to make necessary recommendations to rectify issues;
- making final decisions on causality assessment of inconclusive investigations and ensuring quality control on immunization surveillance system;
- communicating with other national and international experts when requirements arise in establishing causality and vaccine quality issues;
- advising the national immunization programme (manager) and NRA about AEFI-related issues when requested by these institutions;

- Provide recommendations for further investigation, education, corrective action and communication with interested parties, including the media,
- Record its deliberations and decisions and feedback on each reviewed case to all relevant stakeholders; and
- advising the Ministry of Health about vaccine and immunization safety-related matters when requested by the Ministry.

A few point on expert committee content and function:

• **Independence and transparency:** Complete independence from government and industry-associated experts may not be possible to achieve as that may result in losing too much of the potential expertise needed. Therefore, it is encouraged that the committee explore what transparency means, i.e. discuss how to declare conflicts of interest/competing interests and decide which conflicts may hinder an individual expert from taking part in causality assessment of a specific event for a given vaccine, etc. and which conflicts may not.

• **Role of immunization programme and NRA:** Staff of the immunization programme and regulatory authority are critical to the process and should serve the role of a Secretariat to facilitate the committee's review (including preparing the documentation to be reviewed) but should not influence in deciding on the causality. Their role may be advisory.

• **No industry participation:** It is important to emphasize that employees of the vaccine manufacturing companies cannot sit on these committees. Such a conflict is too flagrant and could undermine the credibility and acceptance of the committee's conclusions.

Proposed membership² for AEFI Committee

Specialties/field of work	Proposed members
Pharmacist	Phn. KABATENDE Joseph
Pediatrician	Dr. Lisine TUYISENGE
Pediatrician	Dr. KARAMBIZI Angelique
Neurology	Dr. Francois Xavier NSHIMIYIMANA
General Medicine	Dr. MUTAGANZWA Avite
Forensic Medicine	Dr. HAKIZIMANA Francois Xavier
Pathology	Dr. Emile MUSONI
Microbiology	Dr. Claude BAYINGANA

² Member representing either government (ex-officio) or non-government (liaison) entities will be selected/nominated to serve in the committee in from their respective institutions.

Action to take

The establishment of NITAG has become one of the requirement from GAVI and the process of its establishment was even requested before the review of the submitted MR follow up campaign application. Also, in 2015, the establishment of NITAG was requested officially (in writing) by the WHO country office.

Rwanda is now in need to establish the National Immunization Technical Advisory Groups (NITAG) and the National AEFI Committee to deliver in their respective roles in implementing national, regional and global initiatives and recommendations pertaining to the vaccination program as it expands; the ICC Meeting of 12th May 2017 urged the vaccination programme to expedite the establishment of the committees.

Approved by:

Jeanine U. CONDO, MD, PHD
Associate Professor of Public Health
Director General/RBC

