Challenges and solutions in making evidence-based national vaccination policies and recommendations

Developing vaccination policies through National Immunization Technical Advisory Groups (NITAGs)

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Overview

- Context
- About NITAGs
- Challenges
- Solutions
How to make the best evidence-based national vaccination policies and recommendations? Challenges!

- Who is/should be driving the call (e.g. industry or public health need, global or country perspective)?

- Very complex scientific field (many vaccines, diversity of vaccine providers, interactions, missing data, need to adjust overtime, future vaccines,…)!!!

- Multiple health priorities, limited human resources and logistical capacities - expensive vaccines with limited funds available – other health interventions

- How to take the local situation into consideration?

- Is there room for off-license recommendations?

- Recommendations for the public sector or all vaccinators?
Answer to the challenges:

Evidence-based recommendations

- Policy brief
- National Technical Advisory Group on Immunization
NITAGs
An old global recommendation


- *World Health Assembly 61.15* (2008), “WHA requests the Director-General to…strengthen national capacity for making evidence-based policy decisions to adopt new vaccines”


- Several specific recommendations from regional technical advisory groups on immunization (2009-2012)

NITAGs within the Strategic Objectives of the Global Vaccine Action Plan

1\textsuperscript{st} strategic objective $\rightarrow$ All countries commit to immunization as a priority

"National legislation, policies and resource allocation decisions should be informed by credible and current evidence regarding the direct and indirect impact of immunization. Much of the evidence base exists but does not reach policy-makers, as those who generate the evidence are not always those who interact with these decision-makers. . . ."
"Independent bodies such as regional or national immunization technical advisory groups (NITAGs) that can guide country policies and strategies based on local epidemiology and cost effectiveness should be established or strengthened, thus reducing dependency on external bodies for policy guidance.

…It is important that NITAGs or their regional equivalents, engage with academia, professional societies, and other national agencies and committees..to ensure a cohesive and coordinated approach to achieving national health priorities….."
Immunization Policy Advisory Framework

- **Safety**
- **Standards**
- **Practice**
- **Burden assessment/modelling**

Other WHO Technical Advisory Committees

Strategic Advisory Group of Experts (SAGE)

- Global policy recommendations & strategies
- Support regional/national challenges

- Regional policies & strategies
- Identify & set regional priorities
- Monitor regional progress

National Technical Advisory Group on Immunization

- National Policies & Strategies
- Prioritize problems & define optimal solutions
- Implement national programme & monitor impact
Purpose of NITAG

Technical resource and deliberative body to Guide/enable policy makers and program managers to make evidence-based immunization (all ages, all vaccines - new ones or those that are already included in the programme) related policy decisions

Empowers government:
- comprehensive and integrated approach
- neutral forum
- credibility (acceptance and support)
- help resist pressure from interest groups
Functions

Advise on:

- **Optimal policies and strategies formulation** that take into account the local epidemiologic and social contexts,

- **Need for surveillance and collection** and **identification of** important data,

- **Latest scientific development** in the area of vaccines and vaccine preventable diseases.
Key Points

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

NITAG is about ownership and cohesion

Interagency Coordinating Committees (ICCs) are NOT equivalent to NITAGs
NITAG composition

Membership

- Core members (10-15 members involved in decision making, own independent expertise, broad range of disciplines)
- Ex-officio (Government agencies) & liaison (Other stakeholders)

Technical and administrative support

- Secretariat
  - Institution with scientific staff
  - Linked to the Ministry of Health (MoH)
What does “independent expertise” mean?

- Experts should provide independent expertise (unbiased)
  - From manufacturers
  - From MoH (or at least from line of authority)
  - But also from WHO, UNICEF, BMGF, …

- Does not mean disconnected from MoH
- All members should declare relevant interests
- The main goal is transparency
- Depending on reported interests, conflicted members could:
  - participate but not be involved in final decision making
  - not participate at all in the meeting/session
Membership: Nomination

- Standard Operating Practices to specify nomination process, duration of term, rotation process and termination clauses
- Appointed formally by MoH
- Chair should be senior and widely respected with no direct accountability with MoH immunization program and/or interest-group affiliation
- Prior to appointment, members should complete a declaration of interests and sign a confidentiality agreement
Functioning

- Standard Operating Practices to specify mode and conduct of meetings
  - Frequency
  - Open versus closed meetings
  - Decision making process (consensus or voting) and basis for review of evidence and decision making – establishment of working groups
  - Administrative support
  - Recording and adequate communication on declarations of interest
  - Agenda setting
  - Report writing
  - Communications and reporting of recommendations

- Direct communication with senior officials in MoH

- Evaluation
Principles for Issuing Evidence-Informed Recommendations on Immunization

- Development of recommendations based on the best available data applying the principles of scientific reasoning
- Thorough and transparent search for data, using a rigorous, standardized and reproducible approach (systematic use of data and information systems)
- Go beyond traditional "science" to consider socio-economic and programmatic considerations
Steps for the development of evidence-based recommendations once agenda item agreed

Before the NITAG meeting

1. Consider establishment and if useful establish a Working Group
2. Define the questions to inform the recommendations
3. Assess and summarize the evidence
   - Conduct a systematic review of the literature with or without meta-analysis and, where necessary, commission research to address gaps in evidence.
   - Review the quality of evidence (assessment of risk of bias and confounding) - Grading of Recommendations Assessment, Development and Evaluation (GRADE)
Steps for the development of evidence-based recommendations

During the NITAG meeting

4. Present proposed recommendations with their supporting evidence

5. NITAG discussion, deliberation and decision regarding the proposed recommendations

After the NITAG meeting

6. Submission of the policy brief to the competent authorities
Issues to be taken into consideration in developing recommendations

**Disease epidemiology**
- Disease burden including age specific mortality, morbidity, and societal impact; projections for future disease burden; specific risk groups; epidemic potential; disease occurrence over time; serogroup or serotype distribution; and changes in epidemiology over time

**Clinical characteristics**
- Clinical management of disease, disease severity, primary/secondary/tertiary care implications, long term complications of disease and medical requirements
Issues to be taken into consideration in developing recommendations

Vaccine and immunization characteristics
- efficacy, effectiveness and population impact of vaccine; indirect effects; vaccine safety; cold chain and logistics concerns; vaccine availability; vaccine schedules; schedules acceptability and ability to deliver

Economic considerations
- disease, vaccine and vaccine delivery costs, perspective for vaccine price reduction, vaccine cost and cost-effectiveness of immunization programmes and affordability of immunization
Issues to be taken into consideration in developing recommendations

- Health system opportunities and existence of, and interaction with, other existing intervention and control strategies
- Social impacts
- Legal considerations
- Ethical considerations
Evidence-to-recommendation framework

- Assists in making evidence-informed recommendations
- Increases transparency
- Criteria
  - Problem Statement
  - Benefits and harms (plus GRADE)
  - Values and preferences
  - Resource use and cost-effectiveness
  - Equity impacts
  - Acceptability
  - Feasibility
  - Other considerations
- Concludes with:
  - Balance of Benefits and Harms, Type of Recommendation and Recommendation Text
Off-label recommendations: a communication challenge!

Four main reasons why NITAGs recommendations may differ from the labelled indications issued by regulators:

1. NITAGs and regulators do not use exactly the same information to inform their decisions.
2. NITAGs decisions are not based exclusively on the scientific evidence of efficacy and safety.
3. NITAGs have a different perspective than regulators, as public health recommendations are intended to achieve the optimal health benefits possible in the population.
4. NITAGs will usually not make a product-specific recommendation.
6 “basic” indicators defined by WHO (Joint Reporting Form)

- Formal written terms of reference
- Legislative or administrative basis establishing the committee
- Core membership with at least 5 main expertise areas represented among members
- Committee meeting at least once a year
- Agenda and background materials distributed ahead of meetings
- Declaration of interests by members

To be reported every year by Member States to WHO

GVAP annual report to the World Health Assembly

Additional process, output and outcome indicators available for use by regions and countries
NITAGs status report 2014 – Provisional Data

- 59% of countries with a NITAG with an administrative or legislative basis
- 83 (43% of countries) NITAG complying with the 6 basic process indicators** (>93% increase compared with 2010) including 53 developing countries
- Mandatory DoI for members still a big limiting factor

*Based on the JRF
**Formal ToRs, legislative or administrative basis, at least 5 areas of expertise, at least one meeting a year, agenda distributed >= 1 week ahead of meetings, mandatory declaration of interests
National Immunization Technical Advisory Groups (NITAGs) in 2014 by WHO regions

- 83 Countries meeting the 6 NITAG criteria
- 114 Countries having a NITAG with administrative or legislative basis
- 119 Countries Reporting the Existence of a NITAG with ToRs
- 131 Countries Reporting the Existence of a NITAG
- Not available
- Not applicable

Data Source: Joint Reporting Form, 2015 (Provisional data)
Map production: Immunization Vaccines and Biologicals, (IVB), World Health Organization
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The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.
What is a «well-functioning» NITAG?

- Basic process indicators not sufficient: do not assess the effectiveness and impact of NITAGs

- This is not because a NITAG meets regularly with well represented expertise that it has a real impact!

- Who will evaluate the NITAG? Which perspective?

- Is the NITAG responsible for the non-implementation of its recommendations?
Self assessment tool for NITAG Performance Processes, Outputs and Outcomes

17 indicators

Criteria: understandability, ease of collection and perceived usefulness.

3 categories including:

- 10 process or activity indicators to monitor functionality of a NITAG, based on recommendations and best practices.
- 3 output indicators to assess the quality and relevance of evidence-based recommendations.
- 4 outcome indicators to evaluate the impact of technical recommendations on government policies and strategies.

New approach to evaluating NITAG performance

NITAG performance is a combination and balance of three elements

1. NITAG ability to function regularly and issue recommendations in a timely manner

2. NITAG ability to use the best available evidence and produce relevant recommendations in a given national context

3. NITAG ability to influence immunization policy decisions
NITAG performance evaluation tool

Performance Dimensions

Evaluation questions

• Do the NITAG’s structure and operations foster the timely generation of recommendations?

• Has the NITAG developed, formalized and implemented appropriate processes to ensure quality recommendations?

• Is the NITAG fully integrated into the decision-making system?
Establishment and strengthening of NITAGs: Challenges

- Recognition by the MoH
- Process takes time
- Context – Build on the infrastructure
- Independence and transparency of processes
- Quality of the recommendations & complexity of processes
  - methodology, systematic reviews, Grading of Recommendations Assessment, Development and Evaluation (GRADE) versus experts opinions
- Availability of data (particularly local data)
- Human resources
  - Experts availability (persons and time)
  - NITAG secretariat
- Small countries need for a sub-regional structure
What support for NITAGs?

- Not one size fits all
- Direct technical support
  - Evaluations, NITAG twinings, field visits
- Strengthening capacities of members and secretariat
  - Guidance documents, training tools, orientation workshops, and participation in vaccinology courses, SAGE, RTAG, other NITAG meetings, …
- Collaboration and fostering of peer-learning between NITAGs (global and bilateral)
- NITAG Resource Centre → One stop shop!
- International network!!
NITAG Resource Center

http://www.nitag-resource.org
Thank you