The role of national immunisation technical advisory groups in the national immunisation policy making process
Content

 National immunization policy-making

 What are National Immunization Technical Advisory Groups (NITAGs)?

 Why is a systematic approach needed?

 Characteristics and roles of NITAGs in the EU – results of two surveys 2013/14

 Conclusions
From licensure to recommendation

**Licensure**

= is the vaccine safe and effective for the intended use?

Product-specific

1) safety
2) potency (incl. efficacy, immunogenicity)
3) purity

**Recommendation**

= how to best make use of the vaccines in a given population (public health)

Additional aspects, e.g.

1) local disease incidence / severity / epidemiology
2) potential indirect effects
3) cost-effectiveness
4) best schedule/target group
5) implementation aspects
Challenges in introduction decisions

- **Dynamic / complex vaccine market**
  - different product profiles (efficacy, safety, valency)
  - often target mild/common or severe/rare diseases
  - limited financial resources

- **Data issues** (how much evidence is needed?)
  - systematic review of evidence is time-consuming
  - several key aspects only known after widespread use

- **Implementation issues**
  - public acceptance
What is a NITAG?

- A body of national experts that provides technical and scientific guidance to the government on immunization policy, norms, and practices

- A NITAG should ideally
  - be independent from government
  - eliminate real or apparent personal conflicts of interest
  - minimize pressure from outside interest groups
What should a NITAG do?

- Advise the Ministry or National Program on:
  - optimal immunization policies and strategies
  - vaccine introduction decisions
  - monitoring immunization program impact

- Conduct the best possible review of scientific evidence

- Provide timely, evidence-based recommendations on vaccine policy

- Identify need for additional data or research for evidence-based decision- and policy-making
Why is a systematic approach needed?

- Helps to improve quality of the recommendation
- Reduces anticipated or actual arbitrariness
- Contributes to acceptance of recommendation in the professional community and the public
- Improves transparency
  - facilitates critical appraisal
  - builds trust
- Helps to compare recommendations endorsed by different countries / states
Same evidence - different conclusions

- Considerable differences in vaccination schedules in EU countries

- Differences exist in
  - number of vaccines included in the National Immunization Program (NIP)
  - number of vaccine doses
  - target age-groups

- E.g. in the EU/European Economic Area member states, 4 to 16 vaccines are recommended to adults

(Kanitz et al. Vaccine 2012)
Two surveys on NITAGs in the EU

- To better understand in EU member states
  - the qualities and processes within NITAGs
  - factors considered and processes for the inclusion of vaccines in NIPs

- To identify reasons for the differences in NIPs in EU member states

- To identify opportunities & challenges for future collaborations

Two surveys on NITAGs in the EU

- ECDC-funded surveys conducted within VENICE infrastructure 2013/2014
  - Network of nominated gatekeepers from all 28 EU member states and 3 EEA countries
- Online questionnaire & data validation round
  - the 2014 survey included also individual interviews
- Participants: VENICE gatekeeper (2013) and/or NITAG chair/representative (2014)

- VENICE: Vaccine European New Integrated Collaboration Effort
Two Surveys on NITAGs in the EU

- 28 of 30 countries participated in the 2014 survey
- 26 (93%) have a NITAG or equivalent expert group
- Established
  - >40 years: Germany, Luxembourg, Netherlands, UK
  - <5 years: Czech Republic, Romania, Slovenia
- Number of NITAG members: 7-35 (median 14)
- Declaration of conflict of interest: 20 (77%)
- Meeting open to public: 1 (Latvia)
## Key factors considered by NITAGs

<table>
<thead>
<tr>
<th>Key factor</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine efficacy/effectiveness</td>
<td>100</td>
</tr>
<tr>
<td>Vaccine safety at population level</td>
<td>100</td>
</tr>
<tr>
<td>Severity of disease</td>
<td>100</td>
</tr>
<tr>
<td>Method of vaccine administration</td>
<td>58</td>
</tr>
<tr>
<td>Disease burden in neighboring country</td>
<td>29</td>
</tr>
<tr>
<td>Disease burden in home country</td>
<td>100</td>
</tr>
<tr>
<td>Feasibility of recommendation</td>
<td>92</td>
</tr>
<tr>
<td>Priority of vaccine related to other VPDs</td>
<td>84</td>
</tr>
<tr>
<td>Results from <strong>economic evaluations</strong></td>
<td>80</td>
</tr>
<tr>
<td>Results from <strong>mathematical modeling</strong></td>
<td>46</td>
</tr>
<tr>
<td>Public perception about the disease</td>
<td>44</td>
</tr>
</tbody>
</table>

- Largely context-free aspects
- Context-sensitive aspects (i.e. country specific)
## NITAG evidence assessment

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of <strong>systematic reviews</strong> in the recommendation development process is for NITAG/expert group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- required</td>
<td>15</td>
<td>58</td>
</tr>
<tr>
<td>- optional</td>
<td>11</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usually/ often conducted/ if resources permit</td>
<td>10</td>
<td>38</td>
</tr>
<tr>
<td>Transmission modelling considered as part of the recommendation development process</td>
<td>18</td>
<td>69</td>
</tr>
<tr>
<td>Health economic evaluations considered as part of the recommendation development process</td>
<td>20</td>
<td>77</td>
</tr>
</tbody>
</table>
Decision-making structure

Vaccine introduction into the national vaccination schedule/programme

NITAG/Expert group

Ministry of Health

in combination with other stakeholders (e.g. regional authorities, Ministry of Finance)

Parliament/Government

National Institute of Public Health (or equivalent)

4% (n=1)

62% (n=16)

35% (n=9)

4% (n=1)

8% (n=2)

46% (n=12)

12% (n=3)

35% (n=9)
Views on interests & barriers

- High degree of interests in collaboration
  - Possibility of joint conduct or sharing of systematic reviews for context-free aspects (efficacy/safety/impact)
    - but to be based on agreed guidelines/methodologies
    - also sharing of models & epi-assessments beneficial

- Potential barriers
  - Structural concerns (n=16; 59%)
    - differences in the countries‘ healthcare systems
    - differences regarding the respective role of NITAGs
  - Lack of funding / resources (n=10; 37%)
  - Language barriers & cultural differences (n=5; 19%)
Discussion I

Reasons for differences in national recommendation

- Differences in context-sensitive factors
  - E.g. local disease epidemiology
  - Cost-effectiveness (vaccine price, disease costs)
  - Integration of schedule in the local health system

- Factors not considered or weighted differently
  - Priority of the target disease / public perception
  - Results from health economic evaluations

- Other reasons
  - Different vaccination systems / funding schemes
Discussion II
NITAGs in the EU/EEA & opportunities for collaboration

- Majority of EU countries with NITAG
  - but other entity takes final decision on NIP inclusion
- Independent if a formal framework is in place or not, common key factors are considered
- Vast majority sees potential for collaboration
  - Scientific collaboration to support NITAG decisions useful
  - Joint conduct or sharing of systematic reviews
- Challenges to collaboration
  - Frameworks/extent of evidence review differ widely
  - Different structures & limited resources
Conclusion

- Majority of EU/EEA member states have a NITAG
- NITAGs consider context-free AND context-sensitive (i.e. country-specific) aspects
- Duplication of efforts occur if every NITAG conducts own systematic reviews on the same vaccine / body of evidence
- Synergies might be possible when jointly assessing or commissioning the assessment of evidence as a basis for decision-making

→ but decision-making remains within each NITAG
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