RESEARCH ARTICLES

Characteristics and practices of National Immunisation Technical Advisory Groups in Europe and potential for collaboration, April 2014

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In many countries, national vaccination recommendations are developed by independent expert committees, so-called national immunisation technical advisory groups (NITAG). Since the evaluation of vaccines is complex and resource-demanding, collaboration between NITAGs that evaluate the same vaccines could be beneficial. We conducted a cross-sectional survey among 30 European countries in February 2014, to explore basic characteristics and current practices of European NITAGs and identify potential modes and barriers for collaboration. Of 28 responding countries, 26 reported to have a NITAG or an equivalent expert group. Of these, 20 apply a systematic approach in the vaccine decision-making process, e.g. by considering criteria such as country-specific disease epidemiology, vaccine efficacy/effectiveness/ safety, health economics, programme implementation/logistics or country-specific values/preferences. However, applied frameworks and extent of evidence review differ widely. The use of systematic reviews is required for 15 of 26 NITAGS, while results from transmission modelling and health economic evaluations are routinely considered by 18 and 20 of 26 NITAGS, respectively. Twenty-five countries saw potential for NITAG-collaboration, but most often named structural concerns, e.g. different NITAG structures or countries' healthcare systems. Our survey gathered information that can serve as an inventory on European NITAGS, allowing further exploration of options and structures for NITAG collaboration.

Introduction

The number of vaccines available on the market has grown in recent years. At the same time, national healthcare systems have faced financial constraints and sought to maximise protection for those who benefit most in a given population. It has thus become increasingly important to assess the available evidence regarding a range of aspects before introducing a new vaccine into national immunisation programs. The assessment usually takes into account the vaccine characteristics and expected population-level effects which can be considered as context-free aspects, e.g. vaccine efficacy/effectiveness or safety. Local disease epidemiology, cost-effectiveness and societal or cultural values and preferences, which are considered as context-specific aspects, are also factors often or always considered by responsible authorities. Assessments of vaccine recommendations should ideally be standardised, transparent and evidence-based: evidence-based being defined as 'the process of systematically finding, appraising, and using contemporaneous research findings as the basis for (...) decisions' [1].

To help appraising evidence gathered in such systematic manner, a number of tools are available for quality appraisal of single studies, e.g. the Critical Appraisal Skills Programme (CASP) [2], Assessing the Methodological Quality of Systematic Reviews (AMSTAR) [3], and the Cochrane risk of bias tool [4], as well as for entire bodies of evidence, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology [5,6].

In the majority of industrialised countries, national vaccine recommendations are developed by a national immunisation technical advisory group (NITAG) [7]. A NITAG is an independent expert advisory committee, providing 'evidence-based recommendations to the Ministry of Health (MoH), policy makers and program managers to guide policies and formulate strategies'

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TABLE 1

General characteristics of National Immunisation Technical Advisory Groups and equivalent expert groups, European Union and European Economic Area countries, April 2014 (n=26)

| Parameter | Countries (n) |
|---|---------------|
| Expert body for national vaccine recommendations in place | 26 |
| Self-designation ^a as NITAG | 21 |
| Self-designation ^a as expert group | 5 |
| Number of NITAG/expert group meetings per year ^b | |
| ≤2 | 2 |
| 3-5 | 16 |
| >5 | 5 |
| No fixed number | 3 |
| Years since NITAG/expert group was established | |
| <5 years | 5 |
| 5–20 years | 12 |
| >20 years | 9 |
| NITAG/expert group members have to declare potential conflict of interest | 20 |
| NITAG/expert group chair is | |
| Appointed by Ministry of Health or other/subordinate institution | 20 |
| Selected by NITAG/expert group members | 5 |
| No official chair | 1 |
| NITAG/expert group has voting members from ^c | |
| National public health institute (or equivalent) | 15 |
| Ministry of Health | 13 |
| Neither Ministry of Health nor national public health institute (or equivalent) | 5 |
| NITAGs/expert groups with Executive Secretariat or administrative office | 17 |
| NITAGs/expert groups with additional persons/institutes scientifically supporting their work | 20 |
| NITAGs/expert groups with official website | 11 |
| Providing English translations of NITAG/expert group information or materials (only non-English speaking countries) | 2 |

NITAG: National Immunisation Technical Advisory Groups.

- ^a Classification as NITAG or expert group by respondent.
- b Might not include additional, ad hoc meetings.
- ^c Multiple answers possible.

[8]. The World Health Organization (WHO) Global Vaccine Action Plan 2011–2020 stated as first strategic objective that all countries should as a priority commit to immunisation, e.g. by strengthening national capacity through creating or strengthening existing independent bodies such as NITAGs to formulate evidence-based policies [9].

During the '1st international workshop on procedures for the development of evidence-based vaccination recommendations' in Berlin in 2010 [10], a working group of international experts involved in vaccine decision-making processes discussed the need for international cooperation in the development of evidence-based vaccine recommendations and how such cooperation could be organised. Participants pointed out that, for example, systematic reviews of the same body of evidence are performed by NITAGs of several countries, thereby duplicating efforts and that this could be avoided by sharing those reviews and making them publicly available.

However, NITAG mode of operation, role and procedures in the decision-making processes can differ substantially from country to country [11, 12]. Therefore, it is a prerequisite for the potential establishment of an international cooperation to examine in detail similarities and differences in NITAGs' structures and modes of practice. The survey conducted by Nohynek et al. in 2013 was a first step taken to comprehensively explore key characteristics of NITAGs in the European Union (EU) and European Economic Area (EEA) countries and to explain obvious differences in immunisation policies between these countries even though decisions were based on the same or similar body of evidence [12]. In 2014, as part of the Vaccine European New Integrated Collaboration Effort (VENICE) [13], an EU/EEA Member States network of experts in vaccine-preventable diseases, we conducted a follow-up survey in order to (i) systematically collect basic characteristics of EU/ EEA countries' NITAGs or immunisation expert groups, (ii) explore in detail their current practices for vaccine recommendation and, if applicable, framework characteristics, and (iii) identify potential synergies and

resource sharing as well as potential barriers and limitations for collaboration in the vaccine recommendation development processes of NITAGs.

Methods

The VENICE gatekeepers in all 27 EU countries (except for the new Member State Croatia) and in the three EEA countries Iceland, Liechtenstein and Norway were contacted via email and asked to nominate and provide contact information of an expert in their respective country involved in the national vaccine recommendation decision-making process. The criterion for nomination was being a member of the NITAG (preferentially the NITAG chair) or alternatively, being a staff member of the NITAG Executive Secretariat (if existing). If the country had no NITAG, the gatekeeper was asked to nominate an expert involved in the development of national vaccine recommendations.

An electronic questionnaire was developed, piloted by staff of the Executive Secretariat of the German NITAG, and sent out via email to the nominated contact persons in February 2014. The questionnaire consisted of four sections: (i) general NITAG characteristics, (ii) vaccine recommendation process, (iii) potential for collaboration between NITAGs in the vaccine recommendation development process, and (iv) an open section for further explanations. Completed questionnaires were sent back to the Robert Koch Institute by the end of April 2014, assessed for completeness and consistency, and in case of unclear answers or open questions a follow-up telephone interview was conducted or an email was sent if only minor clarifications were necessary.

For each country a two to three-page country profile was constructed with all information on the NITAG characteristics and decision-making processes, which was then supplemented with additional data regarding NITAG characteristics (year NITAG/expert group was established, voting-member composition, declaration of conflict of interest, number of meetings held, meetings opened to public, minutes published online) from the first survey of Nohynek et al. [12] and then sent back to each respondent for validation [14].

Answers provided in response to the first two sections as well as parts of the third section were analysed quantitatively to obtain aggregated results describing key parameters of NITAGs/expert groups in Europe. The remaining data from the third section (open questions on potential and barriers/limitations for collaboration), and if applicable answers from the last section were analysed qualitatively.

Results

In total 28/30 countries responded to the questionnaire: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Malta, the Netherlands, Norway, Poland,

TABLE 2

Professional expertise represented among National Immunisation Technical Advisory Groups and equivalent expert groups, European Union and European Economic Area countries, April 2014 (n = 26)

| Field of expertise/institution ^a | Countries (n) |
|--|---------------|
| | |
| Epidemiology | 25 |
| Paediatrics | 24 |
| Clinical medicine | 22 |
| Public health | 21 |
| Vaccinology | 21 |
| Immunology | 20 |
| Microbiology including virology | 17 |
| University faculty/various disease specialists | 6 |
| Health economics | 5 |
| General practice | 5 |
| Regulatory authority on medicines | 3 |
| Evidence-based medicine/systematic reviews | 2 |
| Non-governmental organisations | 2 |
| School health medicine | 2 |
| Social sciences | 2 |
| Ethics | 1 |
| Health insurance system | 1 |
| Law | 1 |
| Lay members | 1 |
| Transmission modelling | 1 |
| Pharmaceutical company ^b | 1 |
| 'Well-baby clinics' | 1 |

NITAGs: National Immunisation Technical Advisory Groups.

- ^a Multiple answers possible.
- b Representative from the Association of Pharmaceutical Companies

Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (UK). Hungary and Luxembourg did not participate in the survey. Of the 28 responding countries, 26 reported having a NITAG or an equivalent expert group in place. Liechtenstein did not have a NITAG or expert group but adopted vaccination recommendations from the neighbouring Switzerland without additional in-country assessments. Liechtenstein was therefore not included in the final analysis of NITAGs. For Cyprus whose NITAG was discontinued in 2013, only data from the section regarding potential NITAG collaboration (see Attitudes towards and potential modes and barriers for collaboration) were included in the result section. At the time of our survey only a temporary, ad hoc committee was in place and new Terms of References for the future NITAG were under internal discussion. Of the 27 countries (including Cyprus) overall participating in the survey, the respondents were either members of the respective NITAG or staff of the NITAG executive secretariat (n=19), or staff of the National Public Health Institute or MoH (n = 8) involved in NITAG work or national immunisation policy.

TABLE 3

Elements of the vaccine recommendation development processes in National Immunisation Technical Advisory Groups and equivalent expert groups, European Union and European Economic Area countries, April 2014 (n=26)

| Parameter | Countries (n) |
|---|---------------|
| Systematic reviews | |
| Use of systematic reviews in the recommendation development process is for NITAG/expert group | |
| Required | 15 |
| Optional ^a | 10 |
| Systematic reviews not used | 1 |
| NITAG/expert group usually uses | |
| Self-conducted systematic reviews and published systematic reviews by others (e.g. Cochrane Collaboration) | 17 |
| Data used | |
| Peer-reviewed data | 17 |
| Unpublished/non-peer reviewed data | 9 |
| Quality appraisal tools used | 5 |
| GRADE [5,6] | 4 |
| CASP [2] | 2 |
| Cochrane risk of bias tool | 1 |
| Only published systematic reviews by others | 8 |
| Quality appraisal tools used | 3 |
| AMSTAR [3] | 2 |
| PRISMA | 1 |
| No reviews | 1 |
| NITAG/expert group is allowed to outsource reviews to a third party (e.g. institution, private company) | 8 |
| Quality of evidence appraisal is performed | 5 |
| Contract allows to share results with other parties (e.g. foreign NITAGs or national public health institutes) | 5 |
| Transmission modelling | |
| Transmission modelling considered as part of the recommendation development process | 18 |
| Transmission modelling outsourced (e.g. national public health institute or similar institute) | 15 |
| Transmission modelling developed within NITAG/NITAG executive secretariat | 8 |
| Experiences exist with adopting existing models to own local setting | 7 |
| Health economic evaluations | |
| Health economic evaluations considered as part of the recommendation development process (e.g. cost-effectiveness analyses) | 20 |
| Level at which the economic evaluation is considered | |
| NITAG/expert group | 16 |
| Ministry of Health or government or parliament or Ministry of Finance (or similar) | 14 |
| Economic assessment contains cost-effectiveness threshold | 5 |
| Cost-effectiveness threshold is final/decisive criterion | 2 |

AMSTAR: Assessing the Methodological Quality of Systematic Reviews; CASP: Critical Appraisal Skills Programme; GRADE: Grading of Recommendations Assessment, Development and Evaluation; NITAG: National Immunisation Technical Advisory Groups; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

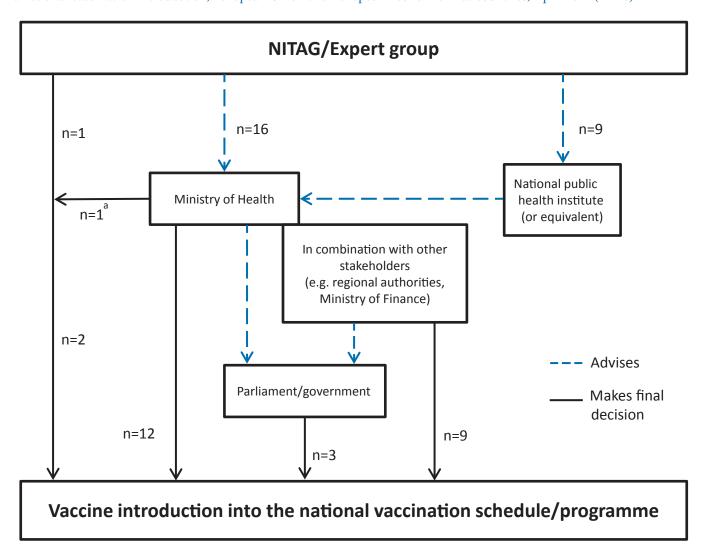
Characteristics of NITAG/expert groups and funding of recommended vaccinations

Table 1 depicts general characteristics of the 26 NITAGs/ expert groups such as number of years since its establishment, whether members have to declare potential conflicts of interest, or if the NITAG is supported by an executive secretariat. A large range of professional expertise is usually represented among NITAGs/expert groups (Table 2). In 15 countries staff from the National Public Health Institute or an equivalent institution is also represented as a voting member in the committee (Table 1).

The role of NITAGs/expert groups can be different during the decision-making process of a national vaccine introduction in EU/EEA countries (Figure). Most commonly, NITAGs/experts groups provide advice to the National Public Health Institute or the MoH. The latter, often together with other stakeholders, usually makes the final decision whether or not a new vaccine

^a Usually or often conducted or if resources permit.

Role of National Immunisation Technical Advisory Groups and equivalent expert groups in the decision making process of a national vaccination introduction, European Union and European Economic Area countries, April 2014 (n = 26)



NITAG: National Immunisation Technical Advisory Groups.

^a Ministry of Health is obliged to introduce the vaccine if it is recommended by the NITAG and is cost-effective.

is introduced in the national immunisation programme or vaccination schedule.

Funding of vaccinations that are adopted into the national vaccination schedule is in 19 countries through tax revenue, in three through social insurance, and in four based on a mixed scheme. In some countries, the funding can be restricted to mandatory vaccinations only and other recommended (but non-mandatory) vaccinations have to be paid out-of-pocket. Twenty-three of the 26 participating countries have a tender system for vaccine procurement in place, either at national (n=20), regional (n=4) and/or at local level (n=2).

Frameworks/processes for evidence assessment

Of the 26 countries that participated in this survey section, 20 indicated that their NITAG/expert group applies

a systematic approach (e.g. framework or standard operating procedure) and 13 stated that the approach contained a fixed list of key criteria. Elements of those systematic approaches and fixed lists of key criteria, respectively, were the consideration of country-specific disease epidemiology and burden (n=20), vaccine efficacy/effectiveness and safety (n=16), health economic evaluations (n=12), vaccine implementation, logistics and availability (n=11), country-specific values and preferences and acceptability in target groups (n=9), alternative preventive measures (n=4), as well as experiences of other countries or WHO guidelines (n=4).

Despite the consideration of these common key criteria, the working process or sequences varied, from e.g. one NITAG with an assessment of the local disease

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epidemiology and WHO recommendations to another NITAG that uses an approach with two prerequisites that have to be fulfilled i.e. vaccine is available and vaccine should induce more than a short-term immunity, followed by the assessment of three criteria and 13 aspects set by law. Further details of the different systematic approaches by country have been made publicly available in country-specific profiles [14].

Nine of the 20 countries with a framework had it published [15-25], two of them in peer-reviewed journals [16,23].

The use of systematic reviews is required in 15 of the 26 of NITAGs/expert groups, for the remaining this is optional (Table 3). Most NITAGs/expert groups (n=17) make use of self-conducted and published systematic reviews, and quality appraisal tools are used by five NITAGs/expert groups. The majority incorporates transmission modelling (n=18) and health economic evaluations (n=20) in their decision-making process. A background paper with the decision rationale is usually published by 13 NITAGs/expert groups. Of those published background papers, nine usually contain references of literature used, eight a narrative summary, six detailed results of systematic reviews including meta-analysis and six other materials (multiple answers possible); two contain all of the above. It has to be noted that background paper publications may be either peer-reviewed or non-peer reviewed online publications, e.g. on the NITAG's/expert group's own website.

Attitudes towards and potential modes and barriers for collaboration

Of the 27 countries that responded, 25 thought that there is 'potential for a collaboration/resource-sharing between NITAGs to support the individual country's process of developing vaccination recommendations'. Regarding areas or aspects for collaboration, five of them named systematic literature reviews in general. Fourteen of the 25 countries explicitly mentioned collaborating in the evidence review of context-free aspects like vaccine efficacy/effectiveness or safety, and 19 of context-specific aspects (e.g. local disease burden or local cost-effectiveness).

Regarding the latter, one country stated that 'there is always a value to also share the context-specific aspects', another that 'context-specific material may be illustrative of possible interpretations, assessments and recommendations'. Cost-effectiveness and/or transmission modelling were explicitly named by 15 countries and disease burden assessment by 11 countries. It was suggested that 'mathematical models and cost-effectiveness models could be shared in order to be adapted to every specific country' and that '(...) burden assessment templates and mathematical modelling templates [should be shared] in which specific assumptions and country data could be introduced'.

When asked about minimum requirements for conducting joint systematic reviews, transmission modelling and/or economic evaluations, 18 of 25 countries favoured agreed methodologies and written guidelines. However, while most only mentioned that there should be such agreed methodologies, some countries voiced more detailed ideas about the optimal content of those agreements: 'Collaborating NITAGs should have the possibility to give input in the beginning of the process, e.g. which outcomes should be considered in the review or inclusion/exclusion criteria of studies', and a common methodology should include 'e.g. a search strategy, paper selection, and exclusion criteria of publications', make '(...) use of the same tools, e.g. GRADE, AMSTAR etc.' and should '(...) guarantee high quality of the work, for better comparability and to make the review process more transparent'. Finally, one country mentioned that there should also be 'a plan for peer review/publication' of those collaborative/shared systematic reviews to make transparent what is currently being worked on.

Regarding barriers and limitations for collaboration, responses could be grouped into the different categories (i) structural concerns, (ii) lack of funding and/ or lack of (human) resources and/or lack of available expertise, and (iii) possible language barriers and cultural differences, mentioned by 16, 10 and two countries, respectively.

In terms of structural concerns the countries highlighted either limiting differences in the countries' healthcare systems/vaccine delivery structures or differences among countries regarding the respective role of the NITAG and NITAG (working) structures. Concern was expressed 'when the collaboration exceeds the technical level' or that 'tasks of the vaccination recommendation development process can be in different institutions; close collaboration [among those intracountry institutions] would be necessary which is often yet not present'. Furthermore, 'NITAGs/MoH put different value on the methodological requirements in the process of developing NITAG recommendations due to differences in the available resources but also due to different consequences of the NITAG recommendations. ... [If the NITAG decision] automatically triggers a coverage decision by health insurances, there is much more of a need to apply rigorous methodologies and be transparent as much as possible'. Another point made by countries was that NITAGs might not always work on the same topic(s): '(...) countries might be in a different process, one is considering a vaccination while another one is considering another one. However, this should still not hinder collaboration. When a country is considering to assess [a specific] vaccination, a request could be sent out for collaboration. And the result of the assessment should be shared.'

Lack of funding, lack of human resources or lack of available expertise was mostly mentioned by smaller countries or countries with fewer resources. Concern was expressed that countries with no/little resources will not be able to contribute much and might therefore not be part of a common collaborative effort.

In respect to possible language barriers and cultural differences one country e.g. expressed the view that different values and preferences might lead to a different assessment of available evidence and consequently different recommendations: 'This [vaccination recommendations including assessments of several subquestions, each of them with their own value judgments], in our opinion, not only precludes grading of the recommendation, it also means that any assessment can only partially rely on a systematic review or an economic model. Although it will be stimulating and useful to participate in any such collaborative effort, that effort will cover only part of the assessment.' Finally, the survey assessed the countries' interests in sharing information on current NITAGs' activities or outputs, asking to rate its helpfulness on a scale from 1 (not necessary at all) to 5 (very helpful). An institutional platform hosting 'Systematic reviews jointly conducted or outsourced by a group of European NITAGs' scored a median of 4, 'Information on vaccine recommendations/assessments of the different European NITAGs currently in progress' and 'Information on European NITAGs' priorities for vaccine recommendations that need to be dealt with' both scored a median of 5.

Discussion

This survey gathered information from 28 of 30 EU/EEA countries, thereby allowing for a detailed and representative inventory of NITAGs and equivalent expert groups involved in the process of developing national vaccination recommendations in the EU/EEA. In our survey, 26 of the participating countries reported having a NITAG or equivalent expert group, and the number will rise further once Cyprus has finished the process of re-establishing its NITAG. Liechtenstein relies on the evidence-based recommendations of the Swiss NITAG [26], an alternative approach for very small countries also proposed by the WHO [8].

Twenty of the surveyed countries indicated that they apply a systematic approach when developing a vaccination recommendation. The approaches reported by all/most of countries include an assessment of country-specific disease epidemiology/burden and vaccine efficacy/effectiveness and safety. About half also assess context-specific questions regarding programme implementation and vaccine logistics as well as potential acceptability in the target population. However, some countries have, as part of their specific formal requirements, a comprehensive set of questions or topics that need to be addressed in a predefined sequence. Furthermore, five countries use quality of evidence assessment tools. The extent and specifics that NITAGs/expert groups apply such systematic approaches, rely on systematic reviews, and consider results from transmission modelling and health economic evaluations differ between countries. Reasons

for these differences are diverse and may be rooted in the role of the NITAG/expert group decision-making process. For example, if the NITAG is the final decision-maker for inclusion of a vaccine in the national programme, the NITAG might feel a stronger responsibility to apply rigorous methodologies and to be as transparent as possible. Other reasons for these diversities might be cultural variations among countries regarding societal or governmental value/demand of transparency and evidence-based approaches vs trust in expert opinion as well as different resources for the NITAGs (e.g. the existence of an executive secretariat, own budget, or other contributing institution) or historical developments.

Less than half of the countries with a framework had it published, which makes it difficult to assess their differences in detail. Of those countries with a published framework, only Finland and the Netherlands [16,23] published it in English in peer-reviewed journals, thereby making it accessible for a wider audience. The remaining frameworks were published on websites associated with the NITAG/expert group or government, making it necessary to know specifically what and where to look for. Furthermore, four of those remaining seven frameworks are only available in the country's language. In comparison, NITAG frameworks of Canada, Switzerland and the United States [26-30] and WHO SAGE [31] can easily be found in English in peer-reviewed journals.

Despite those framework differences and respondents' concerns especially about structural differences among NITAGs or country systems posing essential barriers for collaboration, all but two saw potential for collaboration or resource-sharing to support the individual countries' processes of developing evidence-based vaccination recommendations. The great majority would favour to collaborate in systematic reviews regarding context-free and context-specific aspects. Fundamental for such collaboration is to recognise, that - as suggested by the GRADE working group - two steps can be separated when developing a recommendation: The assessment of the body of evidence and the process when moving from evidence to recommendation [5, 6]. Collaboration between NITAGs should focus on the first step. The strength of such an effort would be that it does not aim to harmonise vaccination recommendations across Europe and that it acknowledges that final decisions lie in the mandate of each country, with country-specific particularities being considered in their decision-making process.

Fifteen of the NITAGs/expert groups are required and ten optionally use systematic reviews in the recommendation process. Thus it is not surprising that countries saw potential for collaboration in conducting systematic reviews, a time and resource consuming undertaking, often requiring at least 12 months per review [32]. Though the majority favoured agreed methodologies and written guidelines as a minimum requirement,

only a small number of countries suggested possible concrete requirements, most likely to make the review process more transparent or applicable to their own framework requirements. Furthermore, so far the use of quality appraisal tools is not yet common among NITAGs/expert groups and is currently only performed by five countries. By definition, cooperation regarding context-free aspects will be less of a challenge as results are usually easily transferrable across countries. Regarding context-specific aspects, respondents found it valuable to share tools or generic models, rather than results, so countries could then apply their own country-specific assumptions or epidemiological data to these models. However, such adaptations of existing models could require special skills - so far seven countries have experiences of adopting existing models to their own local setting. Nevertheless, as one respondent stated, sharing context-specific information could still be helpful in the decision-making process, as it can provide an illustration of other countries' assessments and interpretations.

Our survey has two main limitations. Though answers in the questionnaire were followed up by a telephone interview or email, language barriers or differences in cultural perception may have led to misunderstandings of interview questions or responses. For example, the fact that in two countries transmission modelling was not named as part of the recommendation process but health economic assessments was (though transmission modelling is usually necessary to conduct cost-effectiveness analyses) might indicate that respondents could have interpreted the two terms and what they comprise in different ways. However, to avoid misunderstanding, summarised answers by country were given to the respondent for final validation to minimize interview misunderstandings. Second, the views and attitudes towards collaboration were retrieved usually only from one expert per country and might not necessarily represent the view of the entire NITAG or other stakeholders involved in NITAG work. However, we believe that these views and information constitute an important starting point for further discussions and stakeholder involvement with the aim to develop a draft roadmap for NITAG collaboration and resource-sharing in the EU/EEA as currently envisioned by ECDC and the VENICE project partners.

In 2008, the Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC) initiative has founded a platform to support the establishment of NITAGs in low- and middle income countries by providing information, tools and short-learning modules [33]. In our survey, respondents showed great interest in an institutional platform that would go beyond what SIVAC is currently offering. Besides hosting a share point for already published materials, this platform could provide information on vaccine recommendations and assessments currently in progress and on future priorities of European NITAGs/expert groups, could allow the sharing of not yet published outputs (if

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needed under specific confidentiality agreements), or could host or organise systematic reviews jointly conducted (or outsourced) by NITAGs/expert groups. When provided with such a platform, NITAGs or expert groups could collaborate more easily, form small groups to conduct systematic reviews, share generic models, or benefit from work already done. However, such an approach requires addressing and solving a number of practical issues, e.g. finding a consensus on guidelines for systematic reviews, the application of quality appraisal tools, the issue of data protection and code of conduct for considering unpublished data, or who would host and, very importantly, maintain such an institutional platform. Furthermore, questions may arise about contribution equity or compensation, particularly concerning the conduct of resource-intensive systematic reviews or the development of transmission models. Small countries and countries with fewer resources have already identified a lack of expertise and/or human resources in their country as an important potential barrier for collaboration. However, even countries with more resources or greater expertise will not be able to constantly provide output for all EU/EEA Member States. A conference with interested representatives of all NITAGs/expert groups in the EU/EEA countries could provide a forum to discuss and start to resolve those challenging issues and thereby to define common standards for advancing and achieving future NITAG collaboration in Europe.

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Conflict of interest

None declared.

Authors' contributions

OW, PCS, SC, FDA, DLB, IPS, PVB defined the research theme; OW and AT developed the study design and survey questionnaire; SC, FDA, DLB, IPS, PVB and ECDC staff reviewed the survey questionnaire; members of the NITAG Survey Group identified eligible survey respondents and/or completed the questionnaire; AT analysed the data and drafted the manuscript; all co-authors reviewed and assisted in the editing of the final version of the manuscript.

References

- Rosenberg W, Donald A. Evidence based medicine: an approach to clinical problem-solving. BMJ. 1995;310(6987):1122-6. http://dx.doi.org/10.1136/bmj.310.6987.1122 PMID:7742682
- Critical Appraisal Skills Programme (CASP). 2013. [Accessed 11 July 2014]. Available from: http://www.casp-uk.net.
- Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007;7(1):10. http://dx.doi. org/10.1186/1471-2288-7-10 PMID:17302989
- Higgins JT, Altman DG, Gotzsche PC, Jüni P, Moher D, Oxman AD, et al. Cochrane statistical methods group: the cochrane collaboration's tool for assessing risk of bias in randomized trials. BMJ. 2011;343:d5928. http://dx.doi.org/10.1136/bmj. d5928 PMID:22008217
- GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ. 2004;328(7454):1490-7. http://dx.doi.org/10.1136/bmj.328.7454.1490 PMID:15205295
- Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al.; GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-6. http://dx.doi.org/10.1136/bmj.39489.470347.AD PMID:18436948
- 7. Duclos P, Ortynsky S, Abeysinghe N, Cakmak N, Janusz CB, Jauregui B, et al. Monitoring of progress in the establishment and strengthening of national immunization technical advisory groups. Vaccine. 2012;30(50):7147-52. http://dx.doi.org/10.1016/j.vaccine.2012.04.015 PMID:22521845
- Duclos P. National Immunization Technical Advisory Groups (NITAGs): guidance for their establishment and strengthening. Vaccine. 2010;28(Suppl 1):A18-25. http://dx.doi.org/10.1016/j. vaccine.2010.02.027 PMID:20412991
- World Health Organization (WHO). Global Vaccine Action Plan 2011-2020. Geneva: WHO. [Accessed 7 January 2015]. Available from: http://www.who.int/immunization/ global_vaccine_action_plan/en/.
- 10. Matysiak-Klose D, Ahmed F, Duclos P, Falck-Ytter Y, Forland F, Houweling H, et al. Report on the 1st international workshop on procedures for the development of evidence-based vaccination recommendations, Berlin, Germany, 22-23 November 2010. Vaccine. 2012;30(14):2399-404. http://dx.doi.org/10.1016/j.vaccine.2011.12.004 PMID:22178723
- Bryson M, Duclos P, Jolly A, Cakmak N. A global look at national Immunization Technical Advisory Groups. Vaccine. 2010;28(S):A13-A17.
- Nohynek H, Wichmann O, D Ancona F; VENICE National Gatekeepers. National Advisory Groups and their role in immunization policy-making processes in European countries. Clin Microbiol Infect. 2013;19(12):1096-105. http://dx.doi. org/10.1111/1469-0691.12315 PMID:23957860
- Vaccine European New Integrated Collaboration Effort (VENICE). The Project. [Accessed 11 July 2014]. Available from: http://venice.cineca.org/the_project.html.
- 14. European Centre for Disease Prevention and Control (ECDC). Technical report. Current practices in immunisation policymaking in European countries. Stockholm: ECDC. Mar 2015. Available from: http://ecdc.europa.eu/en/publications/ Publications/Current-practices-on-immunisation-policymakingprocesses-Mar-2015.pdf
- 15. Health Technology Assessment. Toolbox. [Accessed 11 July 2014]. Available from: https://sundhedsstyrelsen.dk/en/health/quality-and-guidelines/centre-for-health-technology-assessment.

- 16. Nohynek H. The Finnish decision-making process to recommend a new vaccine: From vaccine research to vaccination policy. J Public Health. 2008;16(4):275-80. http://dx.doi.org/10.1007/s10389-008-0204-y
- 17. Finnish National Institute for Health and Welfare. [Systematic approach for development of national vaccine recommendations]. Helsinki: National Institute for Health and Welfare. [Accessed 11 July 2014]. Finnish. Available from: http://www.thl.fi/fi_Fl/web/rokottajankasikirja-fi/ kansallinen-rokotusasiantuntijaryhma.
- 18. Robert Koch Institute (RKI). The German Standing Committee on Vaccination (STIKO). Standard Operating Procedure (SOP) of the German Standing Committee on Vaccination (STIKO) for the development of vaccination recommendations. Version 1.0. [Accessed 11 July 2014]. Available from: http://www.rki. de/EN/Content/Prevention/Vaccination/methodology/SOP. pdf?__blob=publicationFile
- Italian Ministry of Health. Piano Nazionale Prevenzione Vaccinale (PNPV). [National Plan for Vaccine Prevention 2012-2014]. Rome: Ministry of Health. [Accessed 11 July 2014]. Italian. Available from: http://www.salute.gov.it/imgs/C_17_ pubblicazioni_1721_allegato.pdf.
- 20. Portuguese Ministry of Health. Diário da República. Portaria n

 º 243/2013, 11/04/2013; DR, 2ª série, nº 78. O [Official Journal. Ordinance 243/2013]. 22 Apr 2013. [Accessed 11 July 2014].
 Portuguese. Available from: https://dre.pt/application/dir/pdf2sdip/2013/04/078000000/1310313104.pdf
- 21. Ministerio de Sanidad, Política, Social e Igualdad. Criterios de Evaluación para Fundamentar Modificaciones en el Programa de Vacunación en España. Criterios de Evaluación para Fundamentar Modificaciones en el Programa de Vacunación en España. [Evaluation criteria for the amendments to the Vaccination Programme in Spain. September 2011]. Madrid: Ministerio de Sanidad, Política, Social e Igualdad. 2011. [Accessed 11 July 2014]. Spanish. Available from: http://www.msssi.gob.es/ciudadanos/proteccionSalud/vacunaciones/docs/Criterios_ProgramaVacunas.pdf
- 22. Socialstyrelsen. Modell för framtagande av underlag till regeringen inför beslut om nationella vaccinationsprogram. [Model for preparing support material for the Government before decisions on the national vaccination programme]. [Accessed 11 July 2014]. Swedish. Available from: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19243/2013-11-9.pdf.
- Houweling H, Verweij M, Ruitenberg EJ; National Immunisation Programme Review Committee of the Health Council of the Netherlands. Criteria for inclusion of vaccinations in public programmes. Vaccine. 2010;28(17):2924-31. http://dx.doi. org/10.1016/j.vaccine.2010.02.021 PMID:20189486
- 24. Health Council of the Netherlands. The future of the National Immunisation Programme: towards a programme for all age groups. Report nr. 2007/02E. The Hague: Health Council of the Netherlands, 2007. [Accessed 11 July 2014]. Available from: http://gr.nl/sites/default/files/200702E_0.pdf.
- 25. Public Health England. Joint Committee on Vaccination and Immunisation (JCVI). Code of Practice June 2013. London: JCVI. [Accessed 11 July 2014]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI_Code_of_Practice_revision_2013_-_final.pdf.
- 26. Spicher VM. The Federal Vaccination Commission in Switzerland: an officially appointed independent commission ensuring evidence-based recommendations and transparent procedures. Vaccine. 2010;28(Suppl 1):A48-53. http://dx.doi.org/10.1016/j.vaccine.2010.02.033 PMID:20412997
- 27. Ismail SJ, Langley JM, Harris TM, Warshawsky BF, Desai S, FarhangMehr M. Canada's National Advisory Committee on Immunization (NACI): evidence-based decision-making on vaccines and immunization. Vaccine. 2010;28(Suppl 1):A58-63. http://dx.doi.org/10.1016/j.vaccine.2010.02.035 PMID:20412999
- 28. National Advisory Committee on Immunization (NACI). Evidence-based recommendations for immunization methods of the National Advisory Committee on Immunization. An Advisory Committee Statement (ACS). Can Commun Dis Rep. 2009;35(ACS-1):1-10.
- Erickson LJ, De Wals P, Farand L. An analytical framework for immunization programs in Canada. Vaccine. 2005;23(19):2470-6. http://dx.doi.org/10.1016/j.vaccine.2004.10.029 PMID:15752833
- 30. Ahmed F, Temte JL, Campos-Outcalt D, Schünemann HJ; ACIP Evidence Based Recommendations Work Group (EBRWG). Methods for developing evidence-based recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC). Vaccine. 2011;29(49):9171-6. http://dx.doi.org/10.1016/j. vaccine.2011.08.005 PMID:21839794

- 31. Duclos P, Durrheim DN, Reingold AL, Bhutta ZA, Vannice K, Rees H. Developing evidence-based immunization recommendations and GRADE. Vaccine. 2012;31(1):12-9. http://dx.doi.org/10.1016/j.vaccine.2012.02.041 PMID:22391401
- 32. Ganann R, Ciliska D, Thomas H. Expediting systematic reviews: methods and implications of rapid reviews. Implement Sci. 2010;5(1):56. http://dx.doi.org/10.1186/1748-5908-5-56 PMID:20642853
- 33. Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC). [Internet]. [Accessed 14 October 2014]. Available from: http://www.sivacinitiative.org/

www.eurosurveillance.org