# Advancing Procedures for the Development of Evidence-based Recommendations for Immunization: Report on the Second International Workshop

Berlin, September 15-16, 2011

Recommendations for human vaccine use by an independent, national expert advisory group to the health ministry are a key step in the implementation of immunisation programs. The assembly, collation, and interpretation of scientific evidence about each vaccine however, are an immense task and vary from country to country. Improvement in methods for recommendation making is a priority.

In November 2010, a first international meeting was held in Berlin, Germany, to discuss improved methods for the development of evidence-based vaccination recommendations. The objectives of the workshop were to review current procedures and experiences of National Immunization Technical Advisory Groups (NITAGs), discuss the applicability of methods like "Grading of Recommendations Assessment, Development and Evaluation" (GRADE), and to identify opportunities for international collaboration to support NITAGs in the development of vaccination recommendations at country-level. To continue the dialogue and to provide an update on recent experiences, the German Ministry of Health in collaboration with the Robert Koch-Institute (RKI) organized a second international workshop in Berlin on September 15-16, 2011.

The meeting brought together representatives of NITAGs or their scientific secretariats from the United States and Canada and several European countries including Austria, Finland, France, Germany, Ukraine, and the United Kingdom, as well as from Lebanon, Mozambique and Thailand. Furthermore, experts from international organisations such as the World Health Organization (WHO), the European Centre for Disease Prevention and Control (ECDC), the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative, and the GRADE Working Group participated in the workshop.

In this report, key messages from the plenary session and the group discussions are summarized.

In plenary sessions representatives of RKI, ECDC, WHO, SIVAC, the GRADE Working Group, CDC and Finland presented updates on national, regional and international vaccine decision making. Participants then divided into in working groups to discuss the applicability of GRADE for the development of vaccination recommendations ,challenges of developing vaccination recommendations at the country-level, and future possibilities for providing international cooperation and support for NITAGs. The presentations are online available at: http://www.rki.de/cln_109/nn_199596/DE/Content/Infekt/Impfen/Workshops/Workshops__node.html?__nnn=true

## SUMMARY OF THE PLENARY SESSION

**Ole Wichmann** (RKI) gave a short introduction into the topic. He described the objectives and main conclusions of the first workshop, which have been summarised in a meeting report and submitted for publication (Remark: in Vaccine, accepted for publication, see reference list). Based on the conclusions from the first workshop, he highlighted the objectives for the second workshop. Dr. Wichmann gave then an overview on the developments of the German Standing Committee on Vaccination (STIKO). STIKO developed a set of key questions in 2009, which need to be addressed when developing a vaccination recommendation, and decided in 2011 to test the applicability of GRADE. A first version of a document with a new

Standard Operating Procedure, which also includes GRADE, has been proposed by the STIKO working group on methods, and STIKO has decided to test this new procedure when developing the next major vaccination recommendation, which is a recommendation for the vaccination against rotavirus. Dr. Wichmann stressed the considerable resources that are needed especially when conducting systematic reviews of the literature, which is a prerequisite for any evidence-based driven approach. The sharing of systematic reviews or other important documents between NITAGs or international organizations such as WHO or ECDC would be an important step to support NITAGs and to avoid duplication of efforts. However, for this purpose it would be advantageous that these groups use a common methodology (e.g. GRADE) to guarantee that these reviews are useful to all groups and that all necessary criteria for decision making are addressed.

**Frode Forland** (ECDC) introduced main results of a working group at ECDC on evidence-based methods for public health. The mandate of the group of international experts, which were convened by ECDC, was to develop or adjust methods to strengthen evidence-based developments within the field of infectious diseases and to evaluate the usefulness of existing grading systems, standards and consensus methods. There is often a challenge to apply these systems to public health decisions, especially when time is limited and there is a lack of sound evidence. A conclusion of this expert group was that many methods, tools and templates for the development as well as for evaluation of recommendations have been already developed, are well suited for public health needs, and should be more widely used. However, in some areas there is still a need for further fine-tuning to better fit the needs of public health in the area of infectious diseases. There was a consensus, that the process of developing public health recommendations depends on the required timeline, and will differ for urgent rapid assessments (e.g. during public health emergencies) and non-urgent assessments (as it is the case for most vaccinations). The main results of this working group have been published in a report, which is available on the website of ECDC: www.ecdc.europa.eu

**Guillaume Dedet** (SIVAC) presented results from a survey conducted recently by SIVAC in 2011. The main objective of the survey was to gather information on the criteria used by NITAGs to make recommendations. Information on 1) the participant, 2) the NITAG, 3) the decision making process, and 4) the criteria used to formulate recommendations were collected during telephone interviews with a selection of 13 NITAGs or their executive secretariats. NITAGs from both low- and high income countries in 5 WHO Regions were included. A major finding was that there were fewer differences between high and low income countries than expected and that only 4 of 13 NITAGs reported to use a formal published framework. Mr. Dedet concluded that countries need more support to set a fair decision making process (e.g. how to identify and grade the level of evidence) rather than being given a list of criteria to use.

**Holger Schünemann** (GRADE-Working Group) gave a short introduction into the GRADE methodology and presented recent advances concerning GRADE, which are also relevant when developing vaccination recommendations. He stated that based on the GRADE framework conceptually, immunisation recommendations are not different from other recommendations related to interventions in public health or clinical conditions, for which randomised controlled trials (RCTs) are often lacking. In many settings RCTs might be either logistically very challenging (e.g. for very rare outcomes or population effects) or unethical (e.g. evaluation of strongly suspected harmful exposures). Therefore, in such instances best quality of evidence derives from observational studies. Observational studies enter the grading process as low-quality evidence, since inability to obtain evidence from RCTs does

not eliminate or minimize the risk for bias associated with observational studies. However, the quality of evidence from well-performed observational studies can be upgraded to moderate and even high quality evidence within the GRADE framework. Another way to conceptualize this framework is that all evidence starts at the same level of quality and that randomization, like the other three criteria used in GRADE for upgrading, can increase our confidence in estimates of effects (i.e. the quality of evidence). It is possible to apply the upgrading criteria also to observational studies in public health, for example by considering on a population level varying effects on disease burden depending on the coverage of the intervention (which can be regarded a population dose-response relationship). Dr. Schünemann pointed out, that in the GRADE system even if evidence for public health interventions is only of moderate or low quality, this can still lead to a strong recommendation if the other factors in the GRADE decision-making framework suggest so. He highlighted that the GRADE working group always welcomes suggestions to further develop the GRADE system, and invited the immunization community to provide examples where applying GRADE was challenging or criteria were incomplete. Indeed, an example presented by Dr. Philippe Duclos at one of the GRADE meetings has led to reconsideration of criteria that the GRADE working group had developed. These examples can then be discussed at the next meeting of the GRADE working group and the group welcomes participation.

**Philippe Duclos** (WHO) summarised recent advances in the methodological procedures applied by WHO's Strategic Advisory group of Experts (SAGE) on immunization. SAGE has established a discussion group to suggest –if needed– appropriate adjustments to the GRADE approach. This resulted in a guidance document that describes SAGE's approach when reviewing evidence to develop a vaccination recommendation. In August 2011 the "Guidance for the development of evidence-based vaccine related recommendations" was posted online at: http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf.

In this guidance document the GRADE methodology and the criteria for up- and downgrading have been described in the context of vaccination recommendation. Specific criteria (e.g. dose-response) can be used from a population perspective and need therefore no adjustments. Only a few minor changes in the GRADE approach were suggested by SAGE to better accommodate observational studies, especially on vaccine safety when no (negative) effect was shown (which creates the problem that upgrading due to strength of effect is not possible) or e.g. when long-term surveillance data from numerous countries show consistently a dramatic decrease in disease burden after the introduction of vaccines. Furthermore, SAGE decided to use no formal scoring in terms of weak or strong recommendations, since SAGE provides guidance to countries and weak recommendations are of little value to country immunization programs. SAGE will continue interaction with the GRADE working group to refine and further adjust its methodology as necessary. It was noted by SAGE that for successful evidence review and grading WHO would need to ensure that adequate resources were available. Dr. Duclos asked for a pragmatic approach to GRADing and the review of evidence, and he highlighted the need to share information between NITAGs and other groups who work on vaccination recommendation.

**Faruque Ahmed** (US CDC) presented the new evidence framework of the U.S. Advisory Committee on Immunization Practices (ACIP), which is also based on GRADE. ACIP uses 2 categories of recommendations: Category A recommendations will be made for all persons in an age- or risk-factor-based group, with the exception of persons who have a contraindication. These recommendations can be for or against a vaccination. Category B recommendations will be made for individual clinical decision making; they do not apply to all members of an

age- or risk-factor-based group, but in the context of a clinician-patient interaction, vaccination may be found to be appropriate for a person in an age- or risk-factor-based group. The body of evidence will be categorized into four levels: (1) randomized controlled trials (RCTs), or overwhelming evidence from observational studies; (2) RCTs with important limitations, or exceptionally strong evidence from observational studies; (3) observational studies, or RCTs with notable limitations; (4) clinical experience and observations, observational studies with important limitations, or RCTs with several major limitations. As suggested by GRADE, besides evidence type (i.e. confidence in the estimated effect of vaccination) ACIP also considers the balance between benefits and harms, the values of the people affected, as well as health economic data (e.g. cost-effectiveness) when formulating a recommendation. Finally, Dr. Ahmed presented some examples of applying GRADE to vaccine recommendations.

**Hanna Nohynek** (National Institute for Health and Welfare, Finland) gave an overview on the minimum requirements and procedures when developing vaccination recommendations in Finland. She highlighted that in Finland, the national vaccination program is completely financed by the government. Since 2000, Finland has adhered to a so called "four-step approach" when evaluating the need and deciding to introduce a vaccine into the national program. The elements of this decision making process are: 1) expected considerable impact of the vaccine on a significant public health disease burden; 2) demonstrated safety of the vaccine on individual level; 3) demonstrated/expected safety of the vaccine when used on large scale; 4) reasonable cost effectiveness of the intervention to justify the public spending. Dr. Nohynek stated that the overall process is rather strict, and that universal introduction of a vaccine is only performed when sufficient national data and/or reliable assumptions are available. A strength of the system in Finland is that it can built on long-term, truly evidence based prevention strategies as well as gives an incentive to develop nationwide register-based research that supports the design and evaluation of the vaccination program. A point of criticism has been that cost-effectiveness is weighed disproportionately and that the process takes a long time in comparison to the decision making process of other Western countries. For example, despite key licensure studies on the pneumococcal conjugate vaccine (PCV) having been carried out in Finland, PCV was introduced only in 2010. On the other hand, Finland was among the first to introduce universal childhood influenza and rota vaccination.

## RESULTS FROM THE WORKING GROUPS

## WORKING GROUP 1

### Topic: “The application of GRADE for the development of immunisation recommendations. Which challenges have to be faced and which solutions are possible?”

The working group pointed out the advantages and key benefits of GRADE for the development of vaccination recommendations. GRADE helps to make the decision-process more transparent and to explain possible country-specific differences in the decisions since it takes into account also national/regional values, preferences, and if the net benefits are worth the costs.

Participants of the working group discussed also aspects of the **terminology** of GRADE. Some institutions and NITAGs have problems with the wording for the type of

recommendation (weak and strong). There is concern that in the public health field a "weak" recommendation is not easy to communicate, especially since usually healthy people need to get motivated to receive a vaccination and therefore communication of recommendations is even more sensitive (in contrast to –for example- a recommendation for a specific treatment in a sick patient). However, the GRADE working group already suggests using as an alternative to “weak” the term “conditional”.

There was consensus in the group that a glossary would be helpful that covers the terminology and gives specific examples for various settings where recommendations are being developed including the public health and immunization field. Misperceptions by different users could be avoided and consistency between NITAGs could be achieved if GRADE users do not create their own terminology but stick to the official GRADE terminology.

A topic intensively discussed in the group was how to deal with evidence related to the “efficacy” of a vaccine derived from RCTs in contrast to the “effectiveness” of a vaccine, which is usually assessed in **post-marketing observational studies**. The group agreed that both data sources can be used. It has to be decided on the basis of the PICO-question which outcomes (e.g. efficacy and effectiveness to prevent hospitalization) will be relevant for decision making in respect to a recommendation, or if maybe only one of the study designs is suitable to answer the PICO-question. If the outcome is very rare (e.g. death in a usually mild disease) or difficult to study in RCTs (e.g. indirect effects or replacement phenomena) observational studies are often better suited.

It was noticed that RCTs can often be assumed “close to real life conditions”, and that there is often no need to conduct a systematic review of observational studies if data from well performed RCTs are available and adequately represent the population under consideration. In case there is limited quality of published RCTs, effectiveness data from observational studies should be added for evaluating the overall quality of evidence. In any case, a non-systematic pragmatic screening of effectiveness studies should be performed. If there are relevant discrepancies, further evaluation would be necessary. If the results from the observational studies confirm the RCT findings, there is no need to formally grade also the evidence derived from these observational studies. It was proclaimed that data from different study designs (RCTs, case-control or cohort studies) should not be merged.

The group discussed if **upgrading** is allowed **after downgrading**. It was stated that evidence derived from both, RCTs and observational studies, should usually not be upgraded if there was already a significant mistrust in the data which has led to downgrading. A theoretical exception would be the downgrading of the quality of evidence of a body of RCTs due to inappropriate randomization (e.g. risk of bias). Under those circumstances and if there is no other serious concern about other factors, the body of evidence from RCTs could be re-classified as observational evidence (and should therefore be handled like observational studies, which can be upgraded if the relevant criteria are fulfilled). However, there is no example available yet).

Furthermore the question was raised if **passive surveillance** can be regarded as an “observational study” and enters the same evidence level as e.g. case-control or cohort studies. There was an agreement that passive surveillance data can be used to evaluate the vaccine impact in e.g. (controlled) before-and-after or (interrupted) time series analyses. Evidence from these kind of analyses can be handled as observational data, and the quality of them should be evaluated accordingly (e.g. risk for bias due to a change in the reporting system).

In rare diseases (e.g. meningococcal disease) a clinical outcome can not be assessed in RCTs and, as a consequence, **surrogate markers** (e.g. immunological response) serve to assess vaccine efficacy. If clinical outcomes are available, the use of surrogate markers should be

avoided. When using surrogate markers downgrading for indirectness should be considered. In contrast, if the confidence in a surrogate marker is high, upgrading for a large effect (e.g. if a large proportion of participants develop protective antibodies) is possible. In this case the explanation of judgement in footnotes is essential for the transparency and understanding of the evaluation. If the degree of correlation between surrogate marker and clinical outcome is unknown or only moderate/low, quality of evidence should be downgraded.

**Herd immunity** can be achieved by several vaccines if the vaccination coverage is high. This effect adds additional benefit to a vaccine and should be taken into consideration in the decision-process for a vaccination recommendation. However, it is unlikely that herd effects can be considered when initially developing the recommendations, because evidence on herd protection usually derives from large observational studies or surveillance data after the introduction of the vaccine. Cluster-randomization is a study design that would allow studying indirect vaccination effects, but it is logistically challenging and rarely used by manufacturers in pre-licensure studies. Therefore, herd protection is more likely to be chosen as a critical outcome when re-assessing a vaccination recommendation. If data on herd immunity is available from other countries, this evidence can be used after evaluation for indirectness. An assessment of the potential magnitude of herd effects based on mathematical modelling should not be formally graded, but can be taken into consideration during the development of the recommendation (when evaluating the balance between benefits and harms). Herd immunity is also an important key factor when conducting cost-effectiveness analyses, which is also integrated in the decision-making process for the development of vaccine recommendations in many countries.

At the end of the session it was discussed how to best approach and **continue an exchange with the GRADE Working Group**. Holger Schünemann (co-chair of the GRADE working group) stated that GRADE meetings are open to everybody and usually 2 to 3 meetings are taken place every year. Some meetings of GRADE are attached to the Cochrane-, GIN or other meetings on EBM. Everybody can become a member of the GRADE Working Group by sending an e-mail to the GRADE secretary. Communication of the Working Group members is organized via e-mailing, where everybody is welcome to participate. Agendas of the next meetings are published on the GRADE-webpage. Holger Schünemann noted that, although much progress has been made, the development of GRADE will remain, as most areas in science, an ongoing process, and that -if there are challenges when applying GRADE to vaccination recommendations- these specific examples should be collected to better illustrate the problem and to discuss it with the GRADE working group.

The Journal of Clinical Epidemiology provides a 20-part guide for systematic review and health technology assessment authors, guideline panelists and methodologists on how to apply the GRADE methodology framework

Finally, it was suggested that GRADE users in the immunization field (e.g. ACIP, SAGE, STIKO) should implement a joint working group for the cooperation with GRADE and among each other. Furthermore, **sharing systematic reviews and other supporting evidence** (e.g. mathematical models) was regarded beneficial by the group to avoid duplication of work. There was consensus that -at a minimum- a better link to organizations that perform systematic reviews should be encouraged to ensure that the products are useful for NITAGs. There are unfortunately many systematic reviews available in the published literature that do not fit the requirements (e.g. reporting exclusion / inclusion criteria) or do not provide the relevant information for the NITAGs. As a consequence, they are often forced to conduct their own systematic review which is very time- and resource consuming.

**WORKING GROUP 2**

The objectives of the **Working Group 2** were:

A) To summarize **experiences and challenges** of NITAGs when developing country-level immunization recommendations and applying EBM tools

B) To identify **country needs** for the support in developing evidence-based immunization recommendations

Representatives of NITAGs from the UK (JCVI), Thailand (NCIP), and Ukraine as well as from Mozambique (CoPI) presented their experiences in developing vaccination recommendations to open the discussion, and illustrated the completely different challenges NITAGs are facing worldwide.

To address the objectives and to facilitate the discussions some key questions where proposed to the participants:

- Which challenges do the international immunisation committees face when developing national vaccination recommendations?
- How can work / resources be shared (and with whom?) to develop evidence-based vaccination recommendations on a country-level? (including transmission and health economics models)
- How can international cooperation be improved to better support NITAGs in their decision-making processes?
- Which elements / approaches in international guidance documents on immunisations are the most valuable from the national perspective?
- What approach should be taken if there is little or no data for some key indicators / outcomes on a country-level?

**The working group identified some of the challenges that NITAGs are facing** when developing vaccination recommendations are partly numerous:

– Lack of financial and human resources, especially as EB decision-making processes (literature review) are “costly and time consuming”

– Lack of training of NITAG members regarding EB decision-making processes (e.g. GRADE, understanding methodology of health economics and modelling)

– Difficulty to prioritize between various vaccines

– Lack of data (especially as surveillance systems are weak) and lack of data of a reasonable quality

– The reluctance to use neighbouring countries data on burden of illness when local data are not available

– The impact of the political context in the activities of a NITAG (local but also international pressure or an often missing national political commitment to the commission)

– The difficulty to ensure the independence of experts, especially in Low and Middle Income countries

– Limited number of experts of experts to serve on NITAGs and limited NITAG secretariat human resources, especially when their tasks include operational issues

Overall, the group agreed that it seemed feasible to share resources, results and skills between the different countries when developing immunisation recommendations, despite the diversity

in NITAGs. The working group discussed several procedures or experiences that could be shared in order to facilitate these processes at national level and then decided to rank them. The proposed **ranking of the different procedures or experiences** that could be shared across NITAGs was:

1. Systematic reviews: literature searches (search strategy, method of abstraction, etc as well as results) and grading results (e.g. repository of GRADE evidence tables)

2. Background of decisions could be shared, what is the decision strategy (on request)?

3. Cost-effectiveness: health-economic models could be shared and then adapted and populated with local values

4. Mathematical modelling: models, assumptions

5. Risk groups / target groups for vaccination

6. Methods (protocols) of epidemiological studies (e.g. for burden of disease studies)

7. Models of structure and ways of working of well established NITAGs (ToR, SOPs) – it was noted that this is already happening in NITAG Resource Centre website

8. Formulation of what other important elements are taken into account in addition to graded evidence when recommendations are produced?

9. Experience in vaccine procurement

10. Experience with off label schedules

Participants agreed that the 3 first activities (Systematic reviews, background documents and Cost effectiveness models) should be the highest priority for NITAG collaboration at this time..

In order to **further develop procedures and cooperation** the working group discussed possible ways to strengthen an international development of evidence review methods. It was proposed that WHO was one of the most feasible institutions to support further efforts, perhaps by creating a “Permanent Working Group for Evidence-based Vaccine Policy (at national level)”. Furthermore it might be feasible to use existing structures of the Cochrane Collaboration and build up or join a Vaccination Working Group within this collaboration. Closer cooperation with the GRADE Working Group seemed to be helpful to discuss challenges and successes in developing population-based vaccination recommendations. In addition to an international working group for evidence-based vaccine policy, the idea of “twinning” between NITAGs in order e.g. to share data and models or to have the possibility of sending observers to other NITAG meetings was discussed. An interactive, restricted, web platform was thought to be an important virtual venue for discussions; it was noted that the SIVAC NITAG web resource centre was a good platform to share documents and procedures.

The participants of the working group identified possible institutions that should be involved in the coordination and development of an international collaboration (especially between European NITAGS), for example:

- WHO Headquarters
- Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC)
- Cochrane Collaboration
- International Vaccine Institute (IVI)
- WHO Office for Europe (pending discussion with management)

- ECDC (pending discussion with management and the European Commission)
- European Medicines Agency (EMA)
- National Immunisation Technical Advisory Groups (NITAGs) themselves
- National Regulatory Authorities (NRAs)
- Educational institutions (Schools of Public Health)
- Other professional associations

At the end of the two working group sessions, some participants emphasized some challenges like the language issues and the confidentiality issues linked to some documents used for the decision-making. Some participants also suggested that a regular NITAGs workshop should be in place to ensure that NITAGs have the opportunity to exchange informally on their recommendations.

## MAIN CONCLUSIONS OF THE WORKSHOP

- NITAGs face numerous similar challenges irrespective of the legal background, function, and responsibilities concerning the development of evidence-based recommendations
- It seems to be feasible to share resources, results, and skills between the different countries when developing immunisation recommendations
- Independent from the methodology that a NITAG decides to apply for the grading of evidence, systematic reviews are the prerequisite for all evidence-based decisions and pose the biggest workload to NITAGs
- A common methodology like GRADE would be an advantage to better understand the decision processes of NITAGs and to facilitate the sharing of relevant documents (e.g. evidence tables, systematic reviews)
- GRADE was regarded suitable to account for issues relevant in the immunization field such as herd immunity, surrogate markers, passive disease surveillance, and post-marketing observational studies on vaccine effectiveness and rare adverse events following immunization.
- Using the GRADE system to establish the quality of evidence related to vaccine effectiveness and safety and then separately developing a precise recommendation based as well on country specific issues was favoured by many participants. In the second step country-specific issues like values, preferences, and costs need to be considered individually by each NITAG. The first step –the evaluation of the existing evidence on the effectiveness and safety of a vaccine– can be conducted in a cooperative international effort.
- An international institution or working group (maybe on a regional level) is needed to coordinate these efforts and to identify minimum requirements for the preparation of relevant documents (such as systematic reviews) to be of value for each NITAG
- WHO has been considered to be one of the most feasible institutions to support further efforts and create a “Permanent Working Group for Evidence-based Vaccine Policy”

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