



Editorial

Recommendations for strengthening NITAG policies in developed countries



Vaccination constitutes one of the most significant public health advancements protecting millions of people from infectious diseases worldwide and contributing to the socio-economic development of nations on a global scale. Preventative in nature, vaccines have been traditionally used with the aim of directly avoiding or reducing overall incidence, morbidity, and mortality in healthy individuals, proving vaccination is a highly cost-effective public health intervention [1]. Yet, time to effective populations' access to new vaccines is heterogeneous and lengthy in developed countries, with an average of 6.4 years between European Marketing Authorization and effective populations' access to new vaccines [2]. The delay in access is mainly driven by the time taken by National Immunization Technical Advisory Groups (NITAG) to issue vaccination recommendations guiding the executive policy-decisions [2]. Ricciardi et al. reported the heterogeneity in NITAG terms of reference and analytical decision frameworks that may contribute to the disparity in access to vaccination and immunization programs across developed countries [3]:

- In a study of 13 countries, publicly available information on NITAGs' policies and processes was very limited in most countries, but more documented in the UK, US and Germany.
- The decision analysis frameworks that are critical for transparent, structured, reproducible and reliable decision-making, were available for a limited number of NITAGs with only two countries (Germany and the US) using a detailed and standardized methodology for reliable, robust, and reproducible assessments (the Grades of Recommendation, Assessment, Development and Evaluation – GRADE) [4–7].
- The lack of transparency in NITAGs' interaction with the general public and healthcare professionals deserves improvement. Few NITAGs published their meeting agendas and minutes and only the US had open meetings.

Throughout Europe, the decision-making process to include vaccines in national immunization policies is evolving in order for governments to find optimal ways to facilitate timely and equitable access for populations to innovative vaccines. Countries like Sweden, the Netherlands [8], Italy or France [9] have initiated debates with the various stakeholders including the vaccine industry in charge of developing and producing effective vaccines, the NITAGs, in charge of evidence-based decisions regarding the vaccinations strategies and the public health authorities in charge of

the effective implementation to discover new methods of improving the system. As an illustration of this, the French Public Health Council recently highlighted the complexity and inequality of the current organization of vaccination in France proposing concrete suggestions for change involving all key stakeholders, especially regarding the need for a public consultation on compulsory vaccination and for a strong public communication on the importance of vaccination in France [9]. Concurrently, the Italian Superior Health Council started the preparation of a National Plan aiming to reduce the huge variability of immunization services between and among the regions.

To ensure public trust in vaccination programs recommended by health authorities, there is a need to enhance the transparency of NITAGs' decision-making process and to support the development of best practices among the NITAGs, in view of strengthening the reliability of immunization policies and programs. To meet this objective the following four steps seem unavoidable from a short term perspective:

- All NITAGs should have well defined terms of reference that are consistent with the actual NITAG practice.
- The decision framework should be evidence based, transparent, structured, reproducible, reliable, and should follow a standardized process such as GRADE.
- Transparency of communication should be established with, at the very least, an agenda, decisions and technical reports that are available to the public. Ideally, meetings should be open to the public.
- Economic considerations, such as cost-effectiveness analysis and budget impact estimate should be part of the framework analysis at NITAG level. However, pricing and reimbursement should be dealt with through another body.

Experience in the US and Germany supports the applicability of evidence based structured process for NITAG vaccine recommendation. Moreover, in the US, availability of meetings to the public did not hinder NITAG recommendations.

At this time of booming communication, the lack of transparency and of NITAGs' recommendations will give ammunition to vaccine detractors that are gaining space every year. The implementation of the four recommended steps seems to be the only way to reinforce credibility and legitimacy of vaccination, one of the most effective public health interventions to date.

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Conflict of interest

Mondher Toumi, Professor at the public health department of University Aix-Marseille, Faculty of Medicine, has undertaken consulting projects for pharmaceutical companies, including companies manufacturing vaccines.

Dr. Poland is the chair of a Safety Evaluation Committee for novel investigational vaccine trials being conducted by Merck Research Laboratories. Dr. Poland offers consultative advice on vaccine development to Merck & Co. Inc., CSL Biotherapies, Avianax, Sanofi Pasteur, Dynavax, Novartis Vaccines and Therapeutics, PAXVAX Inc, and Emergent Biosolutions. Dr. Poland holds two patents related to vaccinia peptide research. These activities have been reviewed by the Mayo Clinic Conflict of Interest Review Board and are conducted in compliance with Mayo Clinic Conflict of Interest policies. This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and was conducted in compliance with Mayo Clinic Conflict of Interest policies.

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