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The new Italian National Immunization Technical Advisory Group (NITAG) and its commitment to endorse a new efficient National Immunization Plan in COVID-19 times

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Abstract
Among the objectives of the WHO Global Vaccination Action Plan 2020-2025, there is the establishment, in all countries, of a National Immunization Technical Advisory Group (NITAG), an independent body with the aim of supporting and harmonising vaccination policies. Italy firstly established a NITAG in 2017; it contributed to the nation's immunization policies but fell short of its goal of becoming a true reference group. The newly appointed NITAG, made up of 28 independent experts, has the ambitious goal to promote the new National Immunization Prevention Plan (PNPV), to harmonise the current vaccination schedule with the anti-COVID-19 campaign, and to recover the vaccination coverage decline that occurred during the pandemic. The contact with the ECDC EU/EEA, the WHO Global NITAG networks, and all the national stakeholders needs to be reinforced in order to accomplish these aims. This paper describes the structure, organisation, and strategy of the new Italian NITAG.

Key words
- NITAG
- vaccine preventable diseases
- vaccination policies
- national immunization plan
- COVID-19

INTRODUCTION

The rapid onset and harshness of COVID-19 pandemic has emphasised the importance of ensuring reliable and visible public health leadership, the need to improve people's trust in science, and to prevent misinformation [1]. Never in history has the vaccination been so much the focus of public attention. In particular, the increase of vaccine hesitancy represents an important issue to figure out [2].

Evidence-based decision making has constantly proven to be a successful means for countries to hold immunization programmes [3]. Currently, communication is crucial to increase awareness and coherence among countries throughout the world. To this end, special bodies called National immunization Technical Advisory Groups (NITAGs) are set up, with the aim of promoting and developing new national immunization policies [4, 5]. The Global Vaccine Action Plan called for all countries to establish or have access to such a NITAG by 2020 [6].

Vaccination represents an important part of primary health care and an undeniable human right [7], and contributes to individual health, community welfare and economic benefits [8]. Therefore, the World Health Organization (WHO) suggests the establishment and strengthening of NITAGs in all countries, as multidisciplinary groups of national experts whose role is to provide evidence-based recommendations to the Ministry of Health (MoH), supporting the decision making process on immunization policies and programmes [9, 10]. They have primarily a technical and advisory role with the aim of improving scientific rigour and credibility to the complex process of establishing immunization policies, without political, industrial, or personal interests [11, 12]. NITAGs systematically collect, review, and evaluate available evidence, for developing recommendations, even according to the social and epidemiological contexts [13].

WHO has defined six main criteria for characterising functional NITAGs, to ensure the systematic and comparable trend monitoring: i) a formal written terms of reference; ii) a legislative or administrative basis; iii) a

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minimum of five different areas of expertise in the core membership; iv) at least one meeting per year; v) circulation of the agenda and background materials at least one week prior to meetings; vi) a declaration of interests policy for all members [14].

NITAGs had to cope with the pandemic's fast changing COVID-19 knowledge, a dearth of data on vaccination product characteristics, and health misinformation. In this context, one of the most practical and effective ways for sharing and updating recommendations between countries was represented by the use of online platforms and the scheduling of updated webinars [13, 15]. Moreover, the decline in routine vaccination occurring during the pandemic exposed people at a higher risk of VPD [16].

Some NITAGs around the world serve as a model for the creation of a long-term operational work plan due to their long history of effective engagement and advocacy. The Australian Technical Advisory Group on Immunization (ATAGI), the German Standing Committee on Vaccination (STIKO), and the Canadian National Advisory Committee on Immunization (NACI) stand out for their experience. These ones have succeeded in adapting over time, gaining expertise through the production of evaluation reports, statements based on the most recent, accurate scientific knowledge, programs and campaigns aimed at improving health and forecasting the future issues the committee is likely to face.

HISTORY OF NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS IN ITALY

The first Italian NITAG was established in 2017 by the Minister of Health (Mrs Beatrice Lorenzin, the longest-serving health Minister of the Italian Republic). That year, when an innovative national vaccination plan came into force in Italy, is remembered for major awareness-raising and advocacy actions on the importance of vaccination due to the introduction of the Compulsory Vaccination Act with the aim of rapidly raising vaccination coverage after an increase in measles cases in the population [17-19].

In 2018, NITAG was revoked when all the technical bodies of the Italian MoH were renamed after the change of government. Despite the best of intentions, neither in the first nor in the second case did the Italian NITAG reach the target of becoming a reference point for Italian vaccination policies: the meetings were infrequent, and the number of documents produced was small. After a hiatus, due to the centralisation of vaccination decisions and policies related to the COVID-19 campaign to the institutional bodies of the MoH (i.e., National Health Council) and the Presidency of the Council of Ministers (i.e. National Technical and Scientific Committee on the COVID-19 pandemic), the new NITAG was appointed by the MoH in September 2021 and settled in early 2022 [20]. The main goals are linked to the achievement of the objectives of all the NITAGs set by the WHO, to the approval process of the new National Vaccine Prevention Plan (2022-2025) and to the recommendations of actions for the recovery of vaccinations not administered during the COVID-19 pandemic.

STRUCTURE AND MEMBERS OF THE ITALIAN NITAG

In Italy, NITAG composition is established by MoH Decree based on the proposal of the Director General of Health Prevention. Experts are chosen on their own merits, not as representatives of institutions, groups, or associations to which they belong. Hence, as soon as they are appointed, NITAG members are required to file an initial statement of conflicts of interest.

The overall composition of the NITAG includes core and non-core members. Core members are reputable professionals who do not represent a particular group or stakeholder. Non-core members are further divided into ex-officio members from governmental departments and liaison members, who represent immunization professional societies or organisations [21].

Currently, the new Italian NITAG includes different core members as follows: 10 public health physicians, 1 epidemiologist, 1 immunologist, 1 infectious diseases specialist, 1 communication expert, 1 psychologist and behavioural science expert, 1 forensic medicine expert, 1 expert in ethics, 3 paediatricians, 2 public health nurses and 1 general practitioner. Among non-core members, we can distinguish 3 ex-officio members and 2 liaison members.

The Italian NITAG has a chairperson and an executive secretariat. The three-year term of office is further prolonged if required. Furthermore, the nomination of one or more members may be withdrawn at any moment by the MoH or the Director General of Health Prevention. According to the WHO guidelines [13], the wide range of experience among NITAG members enables the committee to address several issues (vaccine recommendations, scheduling and prioritisation) that call for both scientific competence on vaccines and proficiency on public health policy matters. Currently, the Group consists of 28 members whose 23 are core members.

ITALIAN NITAG TASKS AND GOALS

According to the Decree, NITAG is expected to: 1) support the MoH in the monitoring of immunization programmes and assessment of their impact via annual reports; 2) provide information about epidemiological trends of diseases and about immunization coverage; 3) support elaboration of effective strategies detecting further data and useful information; 4) develop recommendations for immunization programmes, organisational models and control strategies for vaccine-preventable diseases, considering local epidemiology, vaccine efficacy and security, Health Technology Assessment (HTA), vaccine possible impact and social context; 5) provide recommendations for strategies, research, new vaccine development and technologies for the future; 6) to support regions in establishing relationships with Regional Vaccine Committees [20].

The main goals of the new Italian NITAG are summarized in *Table 1*.

Reinforcement of credibility and legitimacy of vaccination

Although vaccination is acknowledged as one of the most successful medical achievements of modern civi-

Table 1
Goals of the Italian National Immunization Technical Advisory Group (NITAG)

The Italian NITAG goals
Reinforcement of credibility and legitimacy of vaccination
Good governance
Proper management of Conflict of Interest
Reinforcement of institutional integration to promote sustainability and credibility
Increasing networking and regional collaboration: the global NITAG network

lization, an increasing number of people believe it to be unnecessary and life-threatening [22]. In fact, vaccine hesitancy poses the biggest threat to vaccination campaigns [23]. Research proved that trust in government is strongly correlated to vaccine acceptance and can promote public compliance with recommended actions [24]. Currently, enhancing the transparency of NITAG's decision-making process and supporting the development of best practices among the NITAGs is crucial to ensure people trust in recommended vaccination programmes.

To achieve this objective, NITAG must define terms of reference that are consistent with current NITAG practice. Moreover, the decision framework must adhere to a standardized approach, such as GRADE, and be evidence-based, structured, transparent, reproducible, and reliable [1]. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is an unofficial group of people who cooperate to deal with the shortcomings of grading systems in health care. Therefore, the methodology based on quality of evidence, which is applied by the GRADE working group, has been suggested as the operational mode. This operational mode is widely applicable in various contexts and helps in evaluating the strengthening of recommendations in healthcare [9, 25, 26].

Another step towards this goal is represented by the establishment of transparency in public communication with, agenda, decisions, and technical reports made available to those who request them. Meetings should ideally be accessible to everyone who desires to attend. Lastly, economic concerns (cost-effectiveness analysis and budget impact estimate) should be included in the framework analysis at NITAG level, while price and reimbursement should be handled by other bodies [27].

Good governance

To improve competent policymaking and eliminate vaccine hesitancy, good governance is essential. Notably, accountability, integrity, openness, accessibility, and proportionality are essential components of good governance. These ones are employed to evaluate NITAG operations and foundational tools, according to different criteria such as composition, member integrity, remit and values, organisation independence, practice procedures, evidence and policy, performance evaluation [28].

Proper management of conflict of interest

Once they are appointed, NITAG members should formally declare their interests in order to avoid conflict of interest (CoI). Identification of current, past, and potential future interests is necessary; besides this, regular updates on any new interest should be provided in order not to influence future recommendations. After declaration, interests are evaluated by the NITAG chair, possibly in consultation with the secretariat. The strength of each interest can be assessed on the basis of the amount of benefit considered, the frequency of the relationship with this source of interest, and the age and length of interest. Typically, the NITAG member has three outcomes: participation in the debate and decision-making, participation in the debate but not the vote, or exclusion from both the debate and the vote. [29, 30].

Reinforcement of institutional integration to promote sustainability and credibility

Raising awareness on NITAG's role as an advisory committee is one of the main and essential prerogatives to strengthen the relationship with the MoH and its technical scientific bodies (e.g., National Health Council). In fact, national authorities' misconception about NITAG role could represent an obstacle to the achievement of NITAG goals. These concerns could consist in NITAG's independence being seen as a threat which could undermine MoH's authority and could cast doubt on his prerogatives. Nevertheless, concerns could be allayed by improving awareness of their individual duties since MoH nominates NITAG members, designates the secretariat, takes part in the agenda and is the final decision-maker [14].

Increasing networking and regional collaboration: the global NITAG network

Executive secretariats should develop and maintain relationships with other NITAGs to constantly improve and compare outcomes [14]. That's why the Global NITAG Network (GNN) has been created. The rising initiative of this platform started in 2016 and officially established in Berlin in 2017. The GNN steering committee functions as an executive decision-making body. It is composed by two members of the NITAG secretariat and six NITAG members, who each represent one of the six WHO regions. The group's makeup represents the wide diversity of socioeconomic backgrounds, organizational experiences, and maturity levels present in the NITAG community. Fifty-three countries were part of the network in 2020. Based on priorities, meetings are organised by the network on a yearly basis in different locations and rotating WHO regions. GNN serves as a common ground in which experiences and practices are shared among NITAGs. Its mission is to improve efficiency in the development of evidence-informed recommendations on immunizations through global cooperation with input from regional networks [31]. The usage of webinars is a significant support for this endeavour as they enable more regular and timely information and guidance dissemination along with simpler participation of highly qualified worldwide experts [15].

THE NEW NATIONAL IMMUNIZATION PREVENTION PLAN

One of the first activities of the new NITAG has been the evaluation and promotion of the new National Immunization Prevention Plan (PNPV). Traditionally, the National Vaccine Plan (PNV), represented a multi-year planning tool to which the vaccination schedule, created with the contribution of both ministerial committees and the main scientific societies, was also linked [17]. Since 2012 it has been referred to as the National Vaccine Prevention Plan, equivalent to the worldwide National Immunization Programmes (NIPs). This time, the first draft, prepared by an *ad hoc* commission of the MoH, provided for some general four-year objectives along with an immunization schedule that may be updated annually. The NITAG, with its own skills, will have to integrate the proposal and favour rapid approval. The main objectives of the PNPV will be: I) to maintain polio-free status; II) to achieve measles-free and rubella-free status; III) to strengthen prevention of cervical cancer and other HPV-related diseases; IV) to reach and maintain target coverage through a fair and free vaccination offer among age groups and populations at risk; V) to counteract inequalities by promoting vaccination interventions in at-risk population for adverse socioeconomic status, occupational exposure or marginalization; VI) to complete the digitalization of a nationwide vaccination register that can be consulted from each region; VII) to improve the surveillance of vaccine-preventable diseases; VIII) to increase adherence to vaccinations; IX) to promote vaccinations among healthcare workers to achieve the target coverage [17, 31-33]. The COVID-19 pandemic's effects on vaccination coverage and the organizational lessons learned during the nationwide anti-SARS-CoV2 vaccination campaign are both considered in the latest version of the PNPV. Additionally, a patient-centered vaccination strategy is being emphasized, strengthening the role of the local healthcare network for the inclusion of vulnerable patients and their care.

RECOVERY OF VACCINATION COVERAGE DECREASED DURING THE PANDEMIC

The health emergency caused by COVID-19 has had a significant impact on the world population. National vaccination rates (about year 2020) have undoubtedly been impacted by the pandemic, which disrupted pediatric routine immunizations and caused parents to reschedule visits out of fear of infection or due to "stay-at-home" safety measures. The national immunization coverage levels for mandatory vaccinations slightly decreased during 2020 compared with the previous year, with only one exception that regards chicken pox, which underwent a significant increase (+2.2%). Almost all the recommended vaccinations showed a moderate decrease (range -1.4% to -2.7%). Particularly, anti-Men C revealed a remarkable drop (-8.5%) unlike vaccine coverage rates for anti-Men ACWY, anti-rotavirus and anti-HPV, that raised (+4.8%, +9.4% and +1.8%, respectively) [34].

One of NITAG's main goals is to propose the new PNPV (expired in 2019), to harmonise the current vaccination schedule with the anti-COVID-19 campaign and to recover the concerning vaccination drops that occurred during the pandemic. Interaction between the WHO Global NITAG networks and the ECDC EU/EEA networks can help to more effectively accomplish all of these objectives.

OTHER PERSPECTIVES OF THE ITALIAN NITAG

The new NITAG's mission is to advance and maintain the strategic goals established by the PNPV 2017-2019, with an emphasis on revising the current immunization schedule and formulating recommendations for coverage levels that are sustainable and attainable [35]. According to NITAG, these actions need to be continuously assessed using a system of indicators (to be developed) that can measure vaccination coverage and the accomplishment of preventative goals.

The introduction of new practices, such as the creation of a standard protocol for the introduction of vaccinations on the immunization schedule and a revision of the current essential levels of care (*Livelli essenziali di assistenza, LEA*), will be a key topic of debate [32].

There is still work to be done on two other crucial issues: the regional vaccine prevention gaps in Italy as well as the focus on at-risk groups, to whom specific vaccinations, free of charge, are offered (e.g., pregnant women, healthcare workers and subjects suffering from chronic diseases).

The new Italian NITAG holds another ultimate responsibility which is to complete the evaluation of the current law on mandatory vaccinations and to raise public confidence in the role of the latter during these trying times, via communication campaigns: after all, good communication could contribute to an increase in vaccination rates in Italy, which is essential to realizing the opportunity for everyone to live a healthy life [36].

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Conflict of interest statement

The Authors do not have any conflict of interest or financial interest.

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