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Evidence-informed vaccination decision-making in countries: Progress, challenges and opportunities

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ABSTRACT

Countries face an increasingly complex vaccination landscape. As well as ever-changing infectious disease epidemiology, the number and diversity of vaccine-preventable diseases, vaccine products, and vaccine technologies continue to increase. To ensure that vaccination decision-making is transparent, country-owned and informed by sound scientific evidence, many countries have established national immunization technical advisory groups (NITAGs) to provide independent expert advice. The past decade has seen substantial growth in NITAG numbers and functionality, and there is now a need to consolidate this progress, by further capacity building, to ensure that NITAGs are responsive to the changing face of immunization over the next decade.

1. Introduction

Globally, enormous progress has been made since the 1970s in the development of national immunization programmes in low- and middle-income countries, driven initially principally by WHO's Expanded Programme on Immunization (EPI). Initial priorities included expanding countries' access to a small number of relatively affordable vaccines of well-proven efficacy and safety. These investments are highly cost-effective [1] and there was little need for detailed national-level evaluation of programme options. As additional vaccines were licensed and commercialized at much higher prices, national decision-making became more challenging. Global funding mechanisms such as Gavi, the Vaccine Alliance supported the introduction of new vaccines in low- and middle-income countries, while schemes such as the Pan-American Health Organization/WHO's Revolving Fund facilitated pooled procurement of vaccines at significant lower prices and thus also increased access to new vaccines.

With the breadth of vaccines expanding and programmatic capacity and resourcing inevitably constrained, it is essential that decisions are based on the best available evidence. In vaccination, global advisory bodies such as the Strategic Advisory Group of Experts on Immunization (SAGE) have established mechanisms to synthesize evidence and make global recommendations. However, these general recommendations need to be interpreted at the regional level, usually by regional immunization technical advisory groups (RITAGs), and even more importantly at the country level by national immunization technical advisory groups (NITAGs). They need to take account of factors such as local disease epidemiology, acceptability of vaccination strategies to local populations, equity in local populations, and programmatic and financial constraints.

Vaccination decision-making in countries is becoming increasingly complex, for a range of reasons:

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1.1. Increasing numbers of diseases prevented by vaccines

The original EPI programme focused on six vaccine-preventable diseases – tuberculosis, poliomyelitis, diphtheria, tetanus, pertussis and measles. Since then, the number of vaccine-preventable diseases has grown significantly, and now encompasses diseases such as rubella, hepatitis B, invasive pneumococcal, Haemophilus influenzae type b and meningococcal disease, influenza, mumps, yellow fever, rotavirus diarrhoeal disease, Japanese encephalitis, cervical cancer (human papillomavirus, HPV) and varicella zoster virus. New vaccines against Ebola, typhoid fever, cholera, malaria and dengue have been approved and are used in outbreak situations or particular settings. The first COVID-19 vaccines have been approved and are beginning to be rolled out globally. Furthermore, promising vaccines are under clinical evaluation for multiple other infections, including HIV, tuberculosis, respiratory syncytial virus, group B streptococci, enterotoxigenic E. coli, Shigella, norovirus and cytomegalovirus [2].

1.2. Increasing diversity of vaccine products and technologies

For each pathogen, countries typically face an increasingly diverse range of products, including multiple vaccine combinations, formulations and schedules. As the development of COVID-19 vaccines has illustrated, innovative new technologies such as mRNA and non-replicating viral vector platforms are being used to generate vaccines, and to rapidly modify them as pathogens evolve [3].

While guidance documents such as WHO Vaccine Position Papers (based on SAGE recommendations) [4] provide pathogen-specific recommendations for vaccine use, and mechanisms such as WHO pre-qualification assure the quality and programmatic suitability of vaccine products [5], options need to be carefully assessed at the national level to identify those best meeting a country's needs. The protection conferred by vaccines at a population level may be influenced by multiple biological, epidemiological and product-specific factors, necessitating complex risk–benefit and value-for-money assessments. Community acceptance must also be considered.

The diversity of vaccine combinations, such as the pentavalent/hexavalent and measles, mumps and rubella (MMR) vaccines, requires detailed assessment of the programmatic, logistical and economic advantages and challenges of each option.

Multiple new delivery technologies and delivery devices are also being developed, such as microneedle array patches or vaccines for use in a controlled temperature chain [6]. These may offer benefits but also increase costs, and potentially add programmatic complexities.

1.3. Greater programmatic complexity in a changing environment

National decision-making needs to take account of programmatic constraints. Decision-making increasingly has to consider use in particular subpopulations or geographic areas based on disease epidemiology or to address inequities. The epidemiology of many vaccine-preventable diseases is also changing, and climate change and environmental degradation are likely to drive further major shifts [7]. The age range of vaccination now extends across the life-course, into the second year of life, adolescence and adulthood, including maternal immunization, and COVID-19 vaccination will add further complexity to adult vaccination strategies.

With more vaccines available during infancy, in many countries infants need to get multiple injections (at up to four sites) over one to four visits. Dose scheduling is thus a further important issue to consider.

1.4. Increasingly complex decision-making criteria

In addition, decision-making is now seldom based on a pathogen-by-pathogen approach. Low- and middle-income countries may have to make difficult choices on which vaccines to prioritize for introduction. In addition, it is increasingly important to incorporate an ethical dimension into vaccination decision-making [8], such as how to balance cost-effectiveness with equity goals when reaching underserved populations. Prioritization of groups for COVID-19 vaccination illustrates the growing complexity of decision-making. SAGE has developed global guidelines for allocation and prioritization for COVID-19 vaccination, which need to be adapted to each country's specific context [9].

1.5. Growing volumes of global data and limited availability of local data

The amount of information being generated on vaccines continues to grow, and syntheses of evidence are becoming increasingly challenging. Furthermore, countries would ideally like to base decisions on locally generated evidence, but this may not be available [10], and it may not be easy to determine the most relevant data to inform decision-making.

1.6. Transparency

Globally, there are increasing concerns about public confidence in vaccination, which has the potential to be further undermined by lack of transparency in vaccination decision-making. Without a clear foundation for decision-making, vaccination policies could be seen as subject to bias and undue influences or based on financial interests or political whims.

1.7. COVID-19

Many of these issues are brought into sharp focus by COVID-19. As COVID-19 vaccines progressively become available for use in countries, decisions on priority target populations and choices on products and strategies will likely be complex. Immunization programmes will probably be targeting a range of age groups with COVID-19 vaccines, specific occupational subpopulations, and high-risk or high-transmission groups. Decisions will be made in accelerated timeframes with significant data gaps, Furthermore, immunization programmes will potentially face the challenges of new pathways of delivery, for example to older groups, integration with other vaccines or services, and maintaining existing vaccination activities while a COVID-19 vaccine is introduced.

To different degrees, all countries face these issues. They are particularly acute for middle-income countries, which lag behind Gavi-eligible and high-income countries in their introduction of new vaccines [11], and for countries that are transitioning out of Gavi support and moving to greater self-financing of vaccines.

2. Independent evidence-based advice: The role of NITAGs

NITAGs advise health authorities on the definition and, in certain cases, implementation of national immunization policies and strategies, including new vaccine introductions across all age groups and updates to existing vaccination schedules. Other key areas of focus include monitoring vaccine-preventable disease epidemiology and determining evidence gaps (for example, in disease surveillance) and response to outbreaks. NITAGs can also have an important public-facing role, advocating for vaccines on behalf of populations and providing an authoritative and independent voice on issues such as vaccine safety or vaccine hesitancy.

Ideally, therefore, NITAGs maintain a close dialogue with national health authorities, enabling them to respond to national needs and also pro-actively offer advice when appropriate. On the other hand, they also need to maintain a position of independence to ensure that advice provided is impartial and underpinned by evidence. NITAGs are advisory bodies and a clear separation with implementing bodies is essential. While ministry of health staff can attend NITAG meetings as *ex officio* members, they should not vote on recommendations.

In 2017, SAGE made a series of recommendations to assist NITAGs [12], stressing the importance of initiatives such as the Global NITAG Network (GNN) and the Global NITAG Resource Centre. Moreover, the World Health Assembly adopted a resolution urging countries to strengthen country commitment to NITAGs [13]. In Africa, the African Union's 2017 high-level framework identified NITAGs as a major contribution to national ownership of immunization policies [14].

To support the work of NITAGs, the GNN is free to join and provides a forum enabling NITAGs to exchange information, identify common challenges and future priorities [15], and to discuss issues of common interest (such as off-label use of products, addressing conflicts of interest, or implementing NITAG evaluations [16]). The Global NITAG Resource Centre (www.nitag-resource.org) offers a wealth of training materials and other useful resources, including country-specific documentation provided by NITAGs in the network (such as terms of reference, meeting agendas and minutes/recommendations).

3. The growth of NITAGs

The Global Vaccine Action Plan (GVAP) placed great emphasis on evidence-based decision-making [17]. Specifically, NITAGs were seen as an indicator of national commitment to immunization. Before GVAP, a limited number of countries had established NITAGs. Guidance was therefore produced to support their development [18]. In addition, between 2008 and 2017 the Supporting Independent Immunization and Vaccination Committees (SIVAC) initiative, funded mainly by the Bill and Melinda Gates Foundation, provided major impetus, helping low- and middle-income countries to establish and strengthen NITAGs [19,20]. The PAHO ProVac initiative played a similar role in the Americas [21].

In GVAP's monitoring and evaluation framework, the activities of NITAGs were assessed through six process indicators mapping their administrative foundation and functioning [22]. These covered areas such as the existence of formal written terms of reference, a legislative or administrative basis, core membership covering at least five areas, meetings held at least once a year, agenda and meeting-related documents distributed in advance, and a declaration of interests' policy. Great progress has been made in the creation of NITAGs since 2010, with the numbers of NITAGs meeting these criteria increasing from 41 to 120 between 2010 and 2019 (Fig. 1) [23].

The emphasis on NITAGs in GVAP, backed up by SIVAC and other activities, led to a stronger national focus on evidence-based decision-making and raised the profile of NITAGs. WHO country and regional offices were also instrumental in stimulating national government interest in NITAGs. In many countries, NITAGs have increased the capacity of countries to make informed decisions on vaccine introductions and other key aspects of immunization programme function. Some new NITAGs have rapidly established themselves as core elements of national immunization landscapes [24].

However, GVAP indicators provide little insight into the functioning and impact of NITAGs [25]. Evaluation tools have been developed to provide a more detailed picture of NITAG performance, across three levels: functional capacity; quality of NITAG processes and outputs; and integration into national immunization decision-making systems. Depending on the required granularity, the tools support simple self-assessments [26] as well as more in-depth evaluations [27]. Increasing numbers of countries have engaged in evaluation of their NITAGs in recent years.

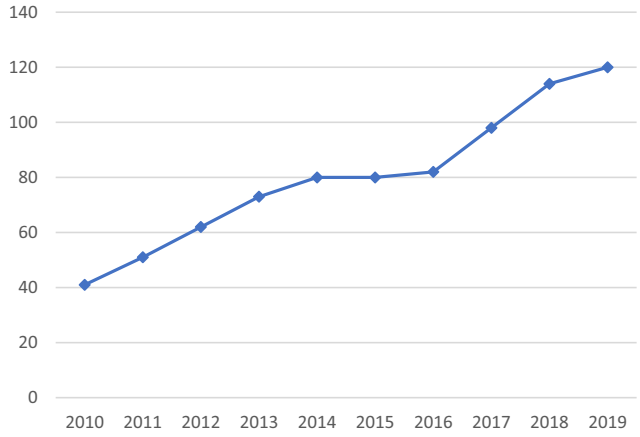

Fig. 1. Number of countries served by a NITAG meeting all 6 process criteria, (2010 to 2019). Source: Global Vaccine Action Plan. Monitoring, evaluation & accountability report, 2020 [23].

The capabilities of NITAGs vary globally. NITAGs with limited experience and resources can still add value by adapting global and regional recommendations to the country context. As their capacities develop, they can begin to more actively organize evidence syntheses and expand their role according to national needs.

A survey of immunization stakeholders in low- and middle-income countries found broad support for NITAGs, and a recognition of their importance for promoting evidence-based vaccination decision-making and contributing to more effective and sustainable national immunization systems [28]. Key challenges included shortage of funding, availability of expertise, management of conflicts of interest, transparency, expertise in evidence syntheses, and integration with national health authorities. The need for continued long-term coordinated support for their development was widely recognized [29]. A detailed look at six countries with relatively new NITAGs found promising signs of effective practice and good integration into national decision-making systems [30]. However, there were concerns about long-term sustainability.

4. NITAGs in the 2021–2030 decade

More than 80% of countries now have NITAGs, covering 87% of the world's population and providing a solid foundation for further strengthening of national evidence-informed decision-making [31]. One key priority is to ensure all populations benefit from decisions informed by a competent NITAG. For many countries, though, the priority is to strengthen the capacity of NITAGs, particularly with regard to their ability to provide solid recommendations, and to ensure closer integration into national decision-making.

The GVAP review strongly recommended that NITAGs should be prioritized in a future global immunization strategy [25]. Indeed, NITAGs have been identified as central to national immunization systems in the successor to GVAP, the Immunization Agenda 2030 [32], which recommends strengthening of evidence-based decision-making. Under the umbrella of WHO's 13th General Programme of Work (GPW13), WHO remains committed to providing technical support for NITAG development, promoting coordination and exchange of information, monitoring progress, and exploring

innovative ways to enhance national evidence-based decision-making. The latest strategy from Gavi (Gavi 5.0) also sees NITAGs as fundamental to the long-term sustainability and performance of national immunization programmes in middle-income countries [33], in particular those that have recently transitioned out of Gavi support.

COVID-19 will present NITAGs with an opportunity to demonstrate their value. Firstly, before COVID-19 vaccines become available, NITAGs can provide valuable advice on minimizing impacts on routine immunization programmes and disease surveillance, avoiding the resurgence of vaccine-preventable diseases due to immunity gaps. As COVID-19 vaccines become available in countries, decisions on introductions, target populations, choice of strategies and products will likely be complex and benefit from expert advice to achieve recommendations that take into account local epidemiologic and social context. The transparency of the decision-making process, based on evidence and involving independent experts, will also help to maintain public trust.

5. Challenges and opportunities

NITAGs carry great responsibilities. Their recommendations underpin major and long-term investments, with significant implications for public health. It is therefore essential that they operate effectively and efficiently.

Countries' needs and health systems vary, so there is no one-size-fits all solution that dictates what a NITAG should look like or how it should operate. Nevertheless, there are core functions any NITAG-like body needs to fulfill and important principles that need to be adhered to if it is to provide impartial, evidence-based and policy-relevant advice to national decision-making authorities.

5.1. Capacity building

5.1.1. Technical capacity and processes

The capacity of many NITAGs still needs to be strengthened. Some NITAGs need to broaden their range of expertise, and many need to enhance their capacity to make best use of complex evidence syntheses and systematic reviews and to undertake country-tailored assessments to develop recommendations. Many still need to refine their processes (particularly with regards to management of conflicts of interest). Multiple demands on committee members' time are a further challenge, and emphasize the need for greater investment in secretariat capacities. Targeted training implemented at regional or national levels [34] and follow-up support will remain an important tool to build and sustain those capacities, particularly given high turnover of experts and secretariat staff. External technical assistance is provided by WHO, the US Centers for Disease Control and Prevention (CDC) and other global or regional technical partners to develop NITAG capacities.

In the current COVID-19 context, WHO regional offices have been regularly organizing webinars to support the key role of NITAGs in issuing and revising regularly COVID −19 vaccination policies. Additionally, face-to-face training curricula are currently being adapted to distance learning. NITAG members will be able to follow the e-courses at their own pace and they will be offered periodic touchpoints with facilitators and other trainees.

5.1.2. Networking and resource sharing

Multiple opportunities exist for NITAGs to exchange information, share good practice and evidence syntheses, and learn from longer-established advisory bodies. The GNN provides a forum for global networking [35], while several regional and subregional networks have been set up. For example, subregional networks have been set up in West Africa under the auspices of the West Africa Health Organization (WAHO) and more recently across ASEAN (Association of South-East Asian Nations) countries. In Europe, two initiatives have been established, one coordinated by the European Centre for Disease Prevention and Control (ECDC) [36] and one by the Robert Koch Institute [37]. The African region is currently establishing a regional hub to provide technical support throughout the continent more consistently. The Eastern Mediterranean region is also seeking ways to establish a virtual platform for sharing experiences and exchange among NITAGs.

More localized informal networks have been set up to promote peer-to-peer learning and coordinated capacity development, while twinning enables newly established NITAGs to learn from those with greater experience. Productive collaborations have been established between, among others, Mozambique and Angola, Sweden and Norway, and Timor Leste and Australia [38].

RITAGs offer additional opportunities for dialogue, with NITAGs increasingly involved in RITAG meetings. For instance, in the Americas, all NITAGs attend RITAG meetings every other year. In the South-East Asia region, all NITAGs attend annually the RITAG meeting.

5.1.3. Structured capacity development

To systematically identify development needs, a 'maturity model' is being developed, led by the CDC, to characterize the development status of a NITAG. The model enables maturity to be assessed across a set of domains and indicators. These results can then be used to prioritize interventions to build capacity in less well-developed areas.

Multiple e-learning tools have been developed to support NITAG capacity development and are being made available through the NITAG Resource Centre. Other resources include case studies and reference documents, in multiple languages [39].

5.1.4. Monitoring and evaluation

The six criteria in the GVAP monitoring and evaluation framework have enabled progress in NITAG set up to be tracked. More sophisticated frameworks are now required to measure outputs and impact more precisely, such as influence on national decision-making. Regular in-depth evaluation and a renewed set of functionality indicators encompassing measures of output will help countries improve the performance of their NITAGs over time.

5.2. Evidence synthesis and formulation of recommendations

5.2.1. Data

Many NITAGs face a twin challenge of information overload, due to the increasing volumes of information published on an ever-growing set of vaccines, alongside a lack of crucial local data, for example on disease epidemiology in local settings or vaccine effectiveness in specific populations. Some also struggle to access data behind academic journal paywalls.

5.2.2. Formalizing and documenting the decision-making process

Many NITAGs still need to gain a better understanding of widely used tools for supporting and documenting evidence-based decision-making, such as the GRADE and Evidence to Decision frameworks [40,41]. While not all NITAGs will be able to carry out systematic reviews using these frameworks, it is essential that they are familiar with the processes and methods behind such tools so that they can interpret existing data reviews according to their specific national contexts.

5.2.3. Knowledge sharing

Independent assessment of the same data by multiple countries is not an efficient use of resources, particularly when such duplica-

tion is at the expense of consideration of local programmatic data and issues.

Efforts are being made to streamline and coordinate evidence syntheses. For example, the Robert Koch Institute in Germany and WHO are developing a global repository of systematic reviews, as well as an associated e-learning course to enable NITAGs to make best use of systematic reviews [42]. In addition, the ECDC is coordinating an EU-wide project to explore the potential for joint assessment of scientific evidence on vaccines and immunization practices. The project is comparing two models – one in which experts from EU member states undertake the evidence synthesis and one in which this activity is outsourced. Webinars are also being used to communicate the findings of systematic reviews undertaken within individual member states.

5.2.4. Comparative assessments

In resource-constrained settings, hard choices need to be made between interventions. The decision facing policymakers may not be simply whether to introduce a vaccine but which of a range of new products should be prioritized. This adds further complexity to evidence syntheses, requiring comparisons between products targeting different diseases, different age groups, and with differing impacts on morbidity and mortality. Moreover, vaccine-related interventions might be in competition for funding with other public health interventions.

Tools are under development to support comparative analyses. These include use of deliberative stakeholder consultations to clarify assessment criteria[1] and an online tool to support a multicriteria decision analysis approach, an early version of which was used in Uganda to prioritize five potential vaccine introductions [43].

5.2.5. Learning from others

Immunization is not the only field facing challenges in assimilation of evidence. NITAGs also stand to gain by engaging with other bodies evaluating new medical interventions and technologies, such as national regulatory agencies and organizations with responsibility for health technology assessment. Conversely, well-functioning NITAGs can be a model for national advisory bodies in other areas of health.

5.3. Integration into government decision-making

5.3.1. Integration and recognition

In many countries, NITAGs are not yet fully embedded in national immunization systems. Not all ministries of health and national immunization programmes appreciate their role or the value they can add, and NITAGs are not utilized as fully as they should be. Interaction with other national immunization stakeholders (such as medical professional associations or academic institutions) is sometime limited and can offer opportunities for additional resourcing and greater recognition of NITAGs.

5.3.2. Resourcing

Many NITAGs in countries across all income settings remain under-resourced, often receiving little or no governmental support. Long-term sustainability requires stable and ring-fenced domestic funding. As NITAG members are not paid, the main costs arise from the need for a secretariat to provide dedicated support and for capacity development. In some countries, secretariat support is shared with other health system functions, limiting the dedicated support available to NITAGs.

[1] CAPACITI project, unpublished

5.4. Diversification and innovation

5.4.1. Tailoring solutions to geopolitical contexts

International collaborations may be a suitable approach in specific geographical contexts, as developed in the Caribbean [44] and under discussion for small Pacific Island countries and areas. Models may also need to be adapted for large countries with highly devolved health systems, where key decisions may be made at a state level.

5.4.2. Expanding remits

As NITAGs become established within countries, they have the potential to play a wider range of roles. They can foster local research by identifying key local evidence gaps and can also provide opportunities for capacity building, especially for young scientists, for example through involvement in working groups. There is also the potential for NITAGs to advise more broadly on integration of vaccination activities into national disease control programmes and into more integrated primary health care services.

As an independent trusted voice, they can provide authoritative comment on vaccine-related issues among general populations. Well-established NITAGs can therefore consider how to develop effective community and media engagement strategies.

Depending on national and regional context, there is also potential for NITAGs to play a more active oversight role for national immunization programmes. In the South-East Asia Region, for example, national immunization programmes share annual action plans with NITAGs, which review and advise on national progress towards regional immunization goals. In turn, NITAGs report annually to the RITAG on progress in implementing RITAG recommendations and priority requirements to achieve immunization goals, promoting harmonization of roles and identifying development needs.

6. Conclusions

It takes time for NITAGs to establish their niche in national immunization systems, to develop effective working relationships and practices, and to demonstrate their value to decision-makers. Many NITAGs have been established within the past decade and are at different levels of maturity. Hence, although there is still a need to create NITAGs (or NITAG-equivalent structures) in countries that lack them, a major focus for the future needs to be on development of NITAG capacities so they can perform their essential role more effectively.

COVID-19 is providing an important test of how well NITAGs are embedded in national immunization decision-making systems. Rollout of COVID-19 vaccines will require careful analysis, providing an opportunity to consolidate the position of NITAGs as a key element in the national vaccine decision making process. COVID-19 may therefore also create an opportunity to strengthen NITAGs and their secretariat support so that they are better able to advise on COVID-19 and all other aspects of national immunization strategy and practice.

Mature NITAGs also cannot afford to stand still. The financial sustainability of many is not assured and budgets need to be continuously justified. Many are expanding their roles, for example considering ethical issues as well as scientific evidence. Community engagement and improving and sustaining vaccine uptake may be additional areas where NITAGs need to play a more prominent role, requiring a widening of expertise. Mature NITAGs can also explore use of new technologies or approaches, and have a critical role to play in supporting the development of less mature NITAGs, for instance through the Global NITAG Network.

At their best, NITAGs are a national asset, ensuring that health expenditure on immunization has the greatest population benefit. They support more effective functioning of national immunization programmes, and in doing so will help to increase coverage, equity of coverage and the achievement of national immunization targets to reach and sustain disease elimination. They can be an influential voice for immunization, promoting public trust in vaccination.

The Decade of Vaccines saw great advances in the establishment and strengthening of NITAGs around the world. With data and evidence and country ownership as core principles of the Immunization Agenda 2030, the next decade needs to witness a consolidation of their role and ability to guide national policies and their establishment and well-functioning as a key element of national immunization systems.

To achieve high genuine impact, NITAGs' importance needs to be recognized at the national level, and they need to be integrated into national decision-making structures. NITAGs need to be able to demonstrate impact and use this to advocate for further investment and to promote their role in national health systems. Global and regional partners must continue to support the development of NITAG capacities, promoting good practices and exchanges between NITAG, while countries need to demonstrate their commitment to evidence-informed decision-making by providing long-term sustainable resources.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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