Data-informed decision-making

Driving life-course immunisation in National Immunisation Programs (NIPs)

A policy paper

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LCI Coalition for Life Course Immunisation

SE health policy.

CLCI works towards a vision where everyone, regardless of age or life stage, can be vaccinated and shielded from vaccine-preventable diseases (VPDs).

Comprehensive life course immunisation (LCI) is critical for protecting the health of individuals and communities across Europe. The complexity of today's health landscape and persistent vaccine access and uptake inequities call for a more systematic, data-driven approach to policymaking.

Furthermore, harnessing the potential of data in vaccination decision-making requires a coordinated effort across various sectors.

CLCI recommendations

1. **Support NITAGs to utilise multi-dimensional data that tells the right story.** Utilising clinical trial, real-world and conceptual data can address knowledge gaps and inform sustainable decision-making. This requires investment in both developing the data sets and upskilling the NITAGs.
2. **Standardise and harmonise diverse data sets to ensure interoperability.** Platforms like the European Health Data Space (EHDS) can support European data harmonisation, ensuring robust data security and privacy policies.
3. **Utilise modern technologies to expand systematic testing and surveillance** to predict and identify emerging health threats, define vaccination goals and evaluate annual vaccine uptake.
4. **Further open communication channels to share data and build public trust.** Sharing data between government, healthcare, and industry supports decision-making, and open communication with the public can increase confidence in recommendations.

Addressing these calls to action will strengthen our collective capability to protect individual and community health across Europe. This future, underpinned by data-driven decisions, promises healthier lives and stronger communities. It is a future that CLCI is committed to realising.

1. Support NITAGs to utilise multi-dimensional data that tells the right story.

Vaccine licensure is globally well-regulated, whereas NITAG decisions are not. NITAGs give vaccination, and sometimes vaccine, recommendations, which may be implemented in comprehensive national immunisation programs (NIPs). Vaccination recommendations only become available after a review of current scientific medical

data (e.g., the burden of disease), sometimes including financial aspects (healthcare budget), cooperation between the many local stakeholders (politicians, vaccine manufacturers, vaccinators, etc.), cultural, religious and expected public acceptance.[1]

Almost all countries have written legal modalities for vaccine licensure, clear-cut market authorisation pathways, and formalised WHO-type NITAGs.[1] However, NITAG standard operating procedures, resourcing, and members' expertise and experience vary.[2]

There has been a paradigm shift from eminence-based decision-making guided by expert opinion and insight to an evidence-based model with the advent of technologies enabling the aggregation and analysis of diverse data sets.[3] The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach is a transparent framework for developing and presenting evidence summaries and provides a systematic approach to making clinical practice recommendations. It is the most widely adopted tool for grading the quality of evidence and making recommendations, with over 100 organisations officially endorsing GRADE worldwide.[4]

First, the authors decide on the clinical question, target population, and the most critical outcomes. The authors then rate the quality of evidence based on the research methodology's ability to remove or control for confounding and bias. For example, data from randomised controlled trials (RCTs) are of high quality, and observational studies are of low quality according to the GRADE ranking.

This approach has some shortcomings:

1. While RCTs are the golden standard for evidence quality, the findings are often less generalisable to the real world due to the study's strict inclusion/exclusion criteria (lack of external study validity).[5]
2. The GRADE approach only makes recommendations where there is sufficient evidence to draw upon. However, the absence of evidence does not necessarily translate to evidence of absence, as disease burdens may be around even in the absence of appropriate surveillance.[3]
3. GRADE can only use data from the past; however, as the COVID-19 pandemic exemplified, there may be an unmet medical need today, and it may take years of disease, complications and deaths before sufficiently strong GRADE evidence has become available to make the right decision.[3]
4. RCTs may be biased, indicating higher vaccine efficacy than real, resulting in wrong decisions. For example, some event-driven RCTs were repeatedly GRADED as incidence-driven, resulting in wrong assessments.
5. RCTs are not always the optimal study design. For example, conceptual modelling and real-world data are more valid and appropriate in health economic assessments.
6. GRADE neglects to use expert insights for local and historical knowledge, losing vital nuance in disease presentation and prevention opportunities.

Ultimately, the process (GRADING) should not be the only and dominant contributor to public health decisions as the process is less relevant than achieving specific goals. NITAG recommendations should be goal-driven, implemented with clear responsibilities and accountabilities and with regular evaluation and adjustments as appropriate based on vaccine uptake and burden of disease data.

We need more than one data source to help us understand how complex systems behave. Healthcare and population health are adaptive, dynamic and unpredictable systems, with multiple interdependencies and various factors influencing outcomes. Analysis of clinical trial, real-world and conceptual data are required to understand the nuances of health behaviours and interventions.[6] Big data analytics can help researchers and decision-makers utilise and understand large volumes of variable datasets by applying modern technologies such as artificial intelligence (AI) algorithms and machine learning.[7] Basing recommendations and decisions on large volumes of diverse data sets can help address gaps, bias or confounding presented by any single data collection methodology. Thus providing a more nuanced, in-depth understanding of the disease and the best approach for cost-effective prevention.

Greater investment is required to ensure high-quality capture of the necessary health data. Data should not only illustrate the burden of disease, but it should also evidence recommendations and immunisation uptake, geographically localised prevalence rates, vaccination rates, side-effects and complications from the vaccination and adverse consequences of the disease.[8]

2. Standardise diverse data sets to ensure interoperability.

Bringing together multiple data sources presents challenges of standardisation and interoperability of systems to ensure data quality and comparability. The European Health Data Space (EHDS)[9] can be a crucial tool in harmonising data from different member states, collected via various methods and sources and presented across different formats and systems.

EHDS provides a solid legal framework for using health data for research, innovation, public health, policy-making and regulatory purposes. Under strict conditions, researchers, innovators, public institutions or industry will have access to high-quality health data crucial to developing vaccines. The availability of large-scale health data within the EHDS can support the generation of robust evidence on vaccine effectiveness and safety. Researchers can analyse data across different populations, age groups, and geographical regions to assess the real-world data of vaccines, identify potential subgroups that may benefit most from vaccination, and detect rare adverse events. Also, EHDS will provide the exchange of information on vaccination plans between Member States or verification of vaccination certificates. This can provide insights into VPDs, vaccine coverage rates, adverse events, and other relevant factors.

The European Commission launched the EHDS on 3 May 2022. It is a crucial pillar of a strong European Health Union and is the first specific data space to emerge from the European data strategy.

A collaborative and multidisciplinary approach involving various stakeholders, Europe and its member states supports evidence-based disease prevention and control strategies. This collaborative effort will foster synergies between vaccination and related policies, encompassing crisis preparedness, e-health, research and development, and the pharmaceutical industry. It will thus contribute to the effectiveness and efficiency of national health systems and improve health security within Europe and beyond while respecting country-specificities and the competencies of EU national and regional authorities.

As data collection capabilities grow, so does the need for trust between all stakeholders. Trust, transparency, and open dialogue from various stakeholders – data scientists, healthcare professionals, policymakers, patient groups and the general public - are crucial for this to work. Enhanced data collection, surveillance systems, collaboration, and stakeholder engagement are vital to building public trust and confidence in decision-making. NITAGs, with their expertise and multi-disciplinary composition, can help bridge gaps between different stakeholders, promote transparency, and encourage open dialogue to build trust and support for data-driven policies. However, data privacy and security pose a challenge, particularly to public trust and vaccine acceptance, which calls for a delicate balance between data access and privacy protection.

3. Utilise modern technologies to expand systematic testing and surveillance.

Proof of concept data is well-accepted in determining efficacy and safety in licensing and needs to be better accepted in determining disease burden and vaccination needs in NIP planning.[3] NITAG decision-making and recommendations are based on historical evidence of disease burden rather than on conceptual data illuminating what future burdens we could encounter.

Life course immunisation (LCI) requires various evidence and conceptual models to inform decision-making. LCI looks at vaccination value and impact through a broader lens, encompassing future risks and threats, vertical transmission (parent to child) and long-term consequences.

AI offers the potential for better surveillance, planning and rapid mobilisation of resources in crises like the COVID-19 pandemic. The applications of AI are vast, from predicting hospital admissions and staff absences to supporting patient-centred care. However, its potential to enhance health outcomes and patient experiences depends on overcoming technical, legal, and implementation challenges, such as understanding the

local context, cultural relevance, and transferability of AI models across different healthcare systems.

Spotlight: Global.health for dynamic decision-making

Global.health has set a 100 Day Mission to provide decision-makers, researchers, and the public with timely and accurate data during the early phase of an outbreak when the chance for containment is highest.

Researchers from institutions around the world created the open-source platform to access real-time, anonymised health data on infectious disease outbreaks, including COVID-19. With over 100 million verified case records from 130+ countries, it is a comprehensive repository of COVID-19 line-list data.

Funded by Google, Oxford Martin School and Rockefeller Foundation.

4. Further open communication channels to share data and build public trust.

Governments, NITAGs and Ministries of Health need more transparent communication with industry. Although it would be helpful to have more information sharing, this often does not occur because it is seen as inappropriate influencing.[3] The WHO sets R&D targets for funders and developers through target product profile (TPP), which outlines the desired 'profile' or characteristics of a target product aimed at a particular disease or disease. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics.[10] Governments and industry should be sharing TPPs for current and future threats.

Facilitating the secure and responsible sharing of health data across European countries can contribute to a deeper understanding of vaccine effectiveness, safety profiles, and real-world outcomes. Effective structures and frameworks with strict data ownership and security protocols could support data sharing between public and private institutions. This bi-directional communication can support collaboration on critical data required for development, monitoring and evaluation. A more coordinated approach could improve vaccine impact through broader coverage and strategic use of certain vaccines, including adjuvanted vaccines.[3]

The wide-scale use of large data sets, which are relatively easy to access, has resulted in more data-informed and, therefore, better decisions. However, the public is now swamped with massive amounts of information often communicated and understood inaccurately, as is the quality of different data. This overload has given rise to 'fake news' associated with vaccine hesitancy; both are significant, ongoing vaccine challenges.

*'The situation today is an infodemic, which gives rise to **the good:** More data usually means more informed decisions; **the bad:** We are lost in data, and high-quality analysis and interpretation are needed, **and the ugly:** fake news is always with us.*

Professor Joe Schmitt, CLCI board member

We need to be better communicators of complex concepts and data. When COVID emerged, journalists reporting on the developments did not fully understand certain concepts and terminology and unintendedly propagated misunderstanding, which fuelled distrust. For example, the media reported daily disease incidences. However, few countries calculated and communicated scientifically valid incidences with a denominator (persons-tested) that reflected the variation in people getting tested daily based on the ever-changing testing recommendations. Media coverage also focused on the COVID-19 vaccine reducing transmission, which to date is almost impossible for respiratory virus vaccines. These can only "control" respiratory tract infection, i.e. reduce morbidity and mortality.[11]

Lack of clarity can fuel misunderstanding and distrust towards national vaccination campaigns. Contextual factors influencing NITAG recommendations are also poorly communicated to the public, who do not understand why one country recommends a vaccine when another does not.

5. Conclusion

CLCI envisions a future where everyone, regardless of age or life stage, can be protected from VPDs through comprehensive NIPs. This future, underpinned by data-driven decisions, promises healthier lives and stronger communities. The CLCI recognises the need to standardise and harmonise diverse data sets through platforms like the EHDS, enhance surveillance systems, and promote open communication between governments, NITAGs, industry, and the public. Future-proofed decision-making requires the upskilling of NITAGs to utilise modern technologies like AI and conceptual data from modelling studies in developing recommendations. While big data can lead to data overload, confusion and misinformation amongst the public and healthcare professionals, these can be overcome through multidisciplinary stakeholder collaboration, transparency, open dialogue and clear accountability.

We call on stakeholders in the European vaccination space to follow the CLCI recommendations to realise a future where a systematic, data-driven approach to vaccination recommendations protects individual and community health, fostering healthier lives and stronger communities.

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