The Mission Board on Vaccination in Europe

Consensus report

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Executive Summary

Vaccination is one of the greatest achievements in public health. A highly cost-effective intervention that saves millions of lives globally each year, vaccination significantly reduces mortality, morbidity, and functional decline associated with Vaccine-Preventable Diseases (VPDs). Immunisation policies and programmes contribute to the resilience of health systems and enhance both economic productivity and societal well-being.[1,2] Vaccination can also play a key role in addressing some of the leading health challenges of the 21st century – among them: antimicrobial resistance, demographic ageing (requiring a greater focus on healthy ageing policies, including adult vaccination), and the need to prepare for future pandemics.

These achievements, and the benefits that vaccination affords, cannot and should not be taken for granted. Declines in vaccine confidence, alongside inadequate data systems in many countries, increase the potential for new disease outbreaks. Climate change poses new threats from infectious diseases previously not found in Europe. These factors underline the need to strengthen immunisation systems and to reinforce the crucial contributions that they make to improving population health, health system sustainability, economic performance, societal fairness, and equity.[3] Expenditure in the area of immunisation should therefore be seen not as a cost, but an investment with broad value for governments and citizens.

The Mission Board on Vaccination in Europe (MBVE) is a multi-disciplinary, multi-stakeholder thought leadership group established in 2023 under the chairmanship of Professor Walter Ricciardi. It has adopted a 'mission approach' to the strengthening of immunisation systems across Europe. MBVE's recommendations, contained in this report, were developed through a series of roundtable meetings and multi-stakeholder working groups. The recommendations are set out in four **thematic chapters**:

1. Data and evidence for decision-making

There are critical gaps in the data and evidence currently available to decisions-makers, which need to be addressed in order to optimise vaccination policies and programmes. The chapter proposes steps to strengthen data collection and evidence generation mechanisms at national and European levels. In addition, MBVE recommends the development of a common European 'value framework' that would improve upon the current patchwork of national approaches to the evaluation of vaccines and vaccination programmes.

2. Beliefs, perceptions, and vaccine confidence

Continuous monitoring of confidence in vaccination among the public and Health Care Professionals (HCPs) is crucial to identify early-warning signals of risks to vaccine confidence, to trigger deeper investigations, and to develop tailored responses and policy actions where required. MBVE therefore proposes the development of an EU-wide vaccine confidence rapid alert and response system. Recommendations in this chapter also focus on the need for community engagement and citizen participation processes, as well as pre- and in-service training for HCPs on vaccination and communication skills.

3. Citizens' access to vaccines

MBVE examined citizens' access to vaccines in relation to the availability of vaccines, the accessibility of vaccination services, and vaccination equity. The chapter highlights a pressing need for policy action to: (i) enable faster population access to vaccination by improving the timeliness of decision-making; (ii) widen the provision of vaccination services beyond traditional health care settings – for example, in schools, workplaces and community pharmacies; and (iii) develop and implement strategies to improve access to vaccination for disadvantaged groups.

4. Convergence and alignment

Whilst recognising that decisions on vaccination programmes are a national competence, significant differences between (in particular) adult vaccination programmes cannot be justified on public health grounds, result in differing levels of health protection for citizens of different European countries, and may present risks to vaccine confidence. MBVE therefore recommends the development of a core calendar for adult vaccination as a step towards more aligned approaches to life course immunisation and as a key contribution to health ageing policies.

In addition, the chapter draws attention to important gaps in EU Member States' decision-making pathways on vaccination. Action to address those gaps is urgently needed to ensure optimal, and more aligned, decision-making processes across countries.

Equity is a central principle that has informed MBVE's approach across all chapters, in line with the UN 2030 Agenda for Sustainable Development, the goal of Universal Health Coverage (UHC), and the World Health Organization (WHO) definition of health equity as *'the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality'*.

Emphasis is also placed on the following cross-cutting themes:

- **Life course immunisation** – recognising the broad benefits of vaccination for people at all stages of life (children, adolescents and adults).
- **Intersectoral collaboration** – working with those outside the health sector to strengthen immunisation policies and their implementation (e.g., the education sector, employment, and social policy).
- **Strengthened and sustainable financing of immunisation systems** – it is crucial to recognise that immunisation is a highly cost-effective public health intervention that represents a strategic investment in population health and health system resilience, with substantial economic and societal benefits.
- **Immunisation system performance monitoring and assessment**: to examine the performance of vaccination programmes against key criteria / goals, to enable and facilitate cross-country learning, and to identify potential issues of concern and opportunities for improvement.

FIGURE 1: OVERVIEW OF MBVE RECOMMENDATIONS

Chapter 1: Data and evidence for decision-making

- **Rec. 1.1:** Enhance data collection and evidence generation to support the strengthening of vaccination policies, strategies, and the broader health care system.
- **Rec. 1.2:** Ensure an aligned approach to decision-making on vaccination through a common European value framework.

Chapter 2: Beliefs, perceptions, and vaccine confidence

- **Rec. 2.1:** Develop an EU vaccine confidence rapid alert and response system to enable timely risk analysis and policy action.
- **Rec. 2.2:** Strengthen community engagement on vaccination through national strategies, research, and exchanges of best practice.
- **Rec. 2.3:** Reinforce training on vaccination and communication skills for pre- and in-service health care professionals.

Chapter 3: Citizens' access to vaccines

- **Rec. 3.1:** Enhance the timeliness of evidence-based decision-making on vaccination to address inequities in vaccine availability.
- **Rec. 3.2:** Enhance the accessibility of vaccination services, in particular within schools, workplaces and community pharmacies, to support a life-course approach to immunisation.
- **Rec. 3.3:** Improve vaccination equity and uptake through national strategies that target disadvantaged groups, employ cross-sectoral collaboration, and leverage insights from best practice sharing.

Chapter 4: Convergence and alignment

- **Rec. 4.1:** Develop a more aligned approach to life course immunisation through a core calendar for adult vaccination.
- **Rec. 4.2:** Address key gaps in decision-making pathways on vaccination to enhance their consistency, inclusivity, transparency, and accountability.

Cross-cutting recommendations

- **Rec. 5.1:** Develop and implement national frameworks and processes to systematically monitor, assess, and publicly report on the performance of immunisation systems.
- **Rec. 5.2:** Strengthen, and ensure sustainable approaches to, the financing of immunisation systems as an investment in *inter alia* public health, health system sustainability, healthy ageing, and economic performance.

Introduction

1 A 'mission' for vaccination

The Mission Board on Vaccination in Europe (MBVE) is a multi-disciplinary, multi-stakeholder thought-leadership group. MBVE aims to support and contribute to the strengthening of immunisation systems in Europe, with a specific focus on decision-making related to vaccination policies and programmes.

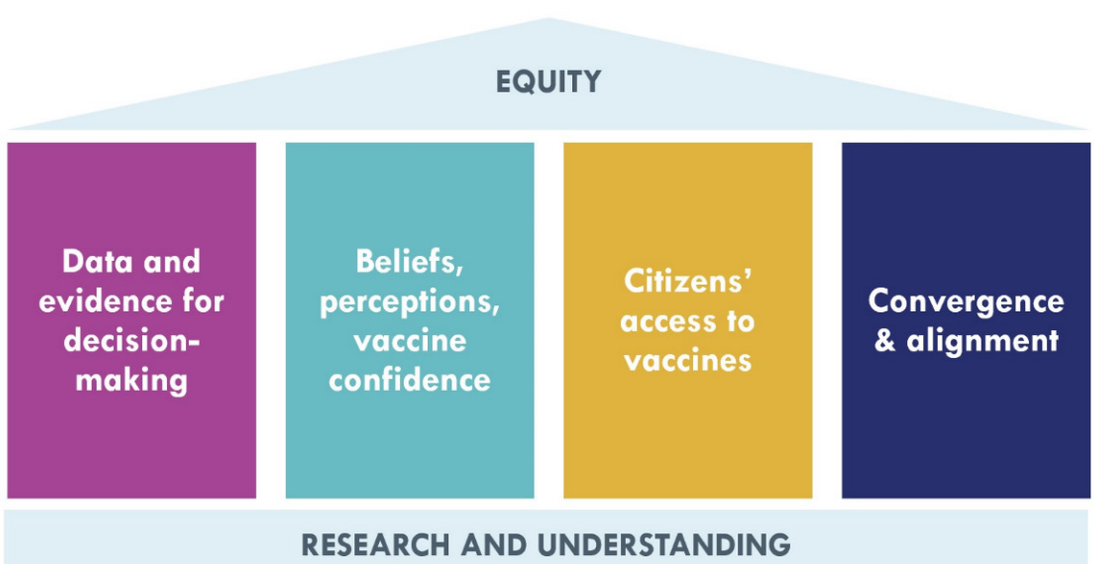
MBVE is founded upon a 'mission approach', which also underpins the European Union's Missions on cancer, climate change, and the renewal of oceans. Inspired by the Apollo project in the 1960s, which culminated in the moon landings, a 'mission approach' involves the identification of ambitious targets to address some of society's greatest challenges.

Maria Mazzucato's 2018 report on 'Mission-oriented Research and Innovation in the European Union' emphases that "Missions must be bold, activating innovation across sectors, across actors and across disciplines".[4] With this in mind, MBVE is composed of vaccinologists, public health experts, health economists, health care professionals (HCPs), civil society organisations, patient representatives, and industry.

The work is informed by a co-created 'mission temple' (see Figure 2 below), which seeks to make sense of the complex environment in which, and through which, decision-making on vaccination policies occurs. At the base of the temple is 'Research and understanding', which underpins all MBVE activities. The four pillars of the temple reflect key challenges, as well as opportunities, for the strengthening of immunisation systems in Europe.

The pinnacle of the temple captures the overarching principle of 'equity', which at the most basic level means fairness – from a health, as well as an economic and social perspective. Equity is also at the heart of the 2030 Agenda for Sustainable Development, including the objective Universal Health Coverage (UHC).

FIGURE 2: MBVE 'MISSION TEMPLE'



2 Policy context

In defining ambitious targets and policy recommendations for strengthening Europe's immunisation systems, MBVE also seeks to build upon a range of other important public health and vaccination policy agendas, which are outlined below.

European Immunization Agenda 2030

The *European Immunization Agenda 2030* (EIA2030)[5] is a flagship initiative within WHO Europe's European Programme of Work. The vision underpinning EIA2030 is "*a world where everyone, everywhere, at every age, fully benefits from vaccines for good health and wellbeing*". EIA2030 identifies three 'impact goals':

- Reduce mortality and morbidity caused by diseases preventable through vaccination;
- Increase equitable access to new and existing vaccines for everyone regardless of age, identity, and geographic location;
- Strengthen primary health care and thereby contribute to achieving UHC and sustainable development.

The MBVE recommendations, contained in this report, are also synergetic with several of the 'core principles' of EIA2030 – in particular that the implementation of EIA2030 should be:

- **Data-enabled** – to inform evidence-based decision-making, monitor progress, and 'foster transparency and accountability' (see MBVE recommendation 1.1);
- **Equity-based** – in particular to reach un- and under-vaccinated populations (see MBVE recommendation 3.3);
- **Innovation and research based** – through '*improved techniques to deliver vaccines and innovative ways of communicating about vaccines*' (see MBVE recommendations 2.2 and 3.2);
- **Partnership based** – strengthening 'collaboration across the health sector and … other sectors' (see cross-cutting theme 3 below).

Vaccination also plays a key role in the WHO's efforts to combat **anti-microbial resistance**,[6] and is an integral part of a **One Health** approach, which requires integrated strategies that 'balance and optimise the health of people, animals, and the environment'.[7]

EU action to strengthen cooperation against vaccine-preventable diseases

The EU treaties explicitly provide for EU action in matters of health protection. Article 6 of the Treaty on the Functioning of the European Union (TFEU) states that: *'The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States'* in relation to the *'protection and improvement of human health'*. Article 168 of the TFEU further mandates that: *'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'* and that the EU shall *'encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas'*.[8]

In 2018, the European Commission Communication[9] and EU Council Recommendation[10] on strengthened cooperation against vaccine-preventable diseases (VPDs) led to a range of EU actions (outlined in the Commission's 'implementation roadmap') focused on strengthening vaccination policies and programmes.[11] Following declines in vaccination coverage and new disease outbreaks in some European countries, a key aim was to strengthen vaccination uptake.

Important actions that resulted from the Communication and Council Recommendation included:

i. The EU Joint Action on Vaccination – the goal of which was to '*foster a sustainable cooperation between European countries and implement best practices in national vaccine policies in order to fight vaccine preventable diseases and improve population health*';[12]

ii. The creation of the European Vaccination Information Portal to ensure accurate information about vaccines is available;

iii. The establishment of the Coalition for Vaccination, composed of HCP and student associations, which aims to improve communication on vaccination;

iv. Measurement of vaccine confidence in Europe using a standardised methodology for the The State of Vaccine Confidence in the EU reports (developed by The Vaccines Confidence Project and funded by the European Commission). Three reports have been published: 2018, 2020, and 2022.

A voluntary collaboration between National Immunisation Technical Advisory Groups (NITAGs) was also initiated by the European Centre for Disease Prevention and Control (ECDC), with the aim of developing a *'system for the exchange of existing and new scientific evidence and the joint generation of up-to-date scientific evidence'*.

The COVID-19 pandemic subsequently triggered new forms of European cooperation – in particular EU procurement of vaccines as part of the EU Vaccines Strategy, as well as the creation of the European Health Emergency and Response Authority (HERA).

In December 2022, the Council of the EU adopted Conclusions on '*vaccination as one of the most effective tools for preventing disease and improving public health'*, which included a focus on both vaccine hesitancy and preparing for future challenges.[13]

Most recently, in January 2024, the European Commission proposed a Council Recommendation to support Member State efforts to prevent cancer through vaccination. The proposed Recommendation focuses on improving uptake of vaccination against Human Papilloma Virus (HPV) and Hepatitis B Virus (HBV).[14]

A 'value-based health care' approach to vaccination

The concept of Value-Based Health Care (VBHC) has gained prominence within Europe during the past decade, as countries have sought to improve the efficiency and effectiveness of their health care systems against a backdrop of constrained public finances.[15,16] However, many VBHC approaches are based upon a narrow definition of 'value' (health outcomes relative to cost), which cannot be easily reconciled with the broader goals of European, solidarity-based health care systems.[15]

In 2019, the European Commission's 'Expert Panel on effective ways of investing in Health' (EXPH) developed and proposed a broader, more inclusive definition which captures the broad range of objectives that underpin the design and functioning of European health systems.[17] The EXPH report identified four 'value-pillars' within a VBHC approach:

i. Appropriate care to achieve patients' personal goals – personal value;

ii. Achievement of best possible outcomes with available resources – technical value;

iii. Equitable resource distribution across all patient groups – allocative value;

iv. Contribution of health care to social participation and connectedness – societal value.

Guiding principles within this approach include access, equity, quality, and efficiency.

This EXPH definition is also in line with the perspective of a value-based health system proposed in 2020 by the WHO and the European Observatory on Health Systems and Policies. Within this approach, the central objective of health systems is to maximise social wellbeing – understood as the value created by the system as a whole, including health promotion and disease prevention.[18]

Initial attempts have been made to analyse how a VBHC approach, based on the EXPH definition, could be applied to vaccination policies and programmes.[3,19] The central conclusion is that action is needed in a range of areas – including research, decision-making, and public engagement. The recommendations contained in this report are in many cases closely aligned with the actions that would be needed for countries to implement a VBHC approach to vaccination.

3 Structure of MBVE consensus report & cross-cutting themes

The report is divided into four chapters, aligned with the four pillars of the 'mission temple'. Each chapter contains two to three recommendations for action (at European and national level) that have emerged from expert working groups (WGs) composed of MBVE members. An overview of the recommendations can be found in **Figure 2**. It will be apparent that, while most of the recommendations are contained within a specific thematic chapter, many of them are also closely linked and reflect a holistic approach to strengthening vaccination policies and programmes, with a particular focus on decision-making.

The process for the development of the recommendations included a 'conception phase' – in particular at the first MBVE roundtable in March 2023, which led to the definition of the MBVE mission temple. WGs were then convened to consider key challenges within the thematic domain of each WG, as well as potential recommendations. Draft recommendations were developed ahead of, and presented and discussed at, the second MBVE roundtable (June 2023), before being revised and elaborated in advance of the third roundtable (November2023) – the purpose of which was to finalise the consensus report as a whole.

Alongside the thematic chapters and associated recommendations, a number of cross-cutting themes also emerge from the report, and which should be emphasised here.

i. **Life course approach:** the WHO has outlined the core principles of a 'life-course approach' as one that takes *'a temporal and societal perspective on the health and well-being of individuals and generations, recognizing that all stages of a person's life are intricately intertwined with each other'*. Furthermore, it '*involves taking action early in the life-course, appropriately during life's transitions, and together as a whole society*'.[20]

   In line with EIA2030, vaccination strategies and programmes should embed life-course immunisation as a core principle. National Immunisation Technical Advisory Groups, which play a key role in the decision-making processes on vaccination, must be equipped with the appropriate expertise on vaccination across the life course – children, adolescent and adult vaccination.

   In support of a life-course approach: MBVE recommendation 3.2 calls for the inclusion of vaccination services in schools, workplaces and community pharmacies, while ensuring the safety of vaccine administration procedures; while MBVE recommendation 4.1 calls for the development of core calendar for adult immunisation as the basis for a more aligned EU-wide approach to vaccination across the life course.

ii. **Inter-sectoral collaboration:** the principle of collaboration across sectors is at the heart of a 'mission approach' and is especially vital in the case of vaccination. For example, strengthening data collection on economic and social impacts of vaccination (MBVE recommendation 1.1) requires collaboration with experts and agencies within those sectors. Expanding vaccination services outside of health care settings will require collaboration with employers and the education sector. Furthermore, action to address risks to vaccine confidence (see chapter 2) and improve vaccination uptake among disadvantaged groups (MBVE recommendation 3.3), will require collaboration with community leaders and community organisations.

iii. **Monitoring the performance of immunisation systems:** A further theme that emerges from several of MBVE's recommendations is the need to strengthen and expand vaccination-related monitoring. MBVE recommendation 5.1 thus focuses on steps that can be taken to enhance the monitoring of, and public reporting on, the performance of immunisation systems as a whole.

iv. **Sustainable immunisation financing:** addressing the challenges, and seizing the opportunities, identified by MBVE will require additional resources (financial, human, and technical) and sustainable investments are needed to strengthen immunisation systems across Europe. *Inter alia* that includes investing in enhanced data collection and evidence generation mechanisms, in new and innovative approaches to strengthening vaccine confidence, and in improving the availability and accessibility of vaccines and vaccination services. While decisions on immunisation financing are taken at national level, MBVE recommendation 4.2 also calls for action at European level to monitor and promote immunisation spending by EU Member States.

CHAPTER 1

Data and evidence for decision-making

Data and evidence are essential building blocks of public health policy and decision-making. In the case of immunisation systems, data and evidence are needed for a wide range of purposes, including to inform decisions on the introduction of new vaccines and vaccination programmes, for the surveillance of Vaccine-Preventable Diseases (VPDs), to monitor and analyse vaccination coverage and impact, and to assess vaccine confidence and uptake across different population groups.

That in turn requires a range of different data sources and evidence generation methods (quantitative and qualitative), including but not limited to:

- health data sources (e.g., surveillance systems);
- administrative databases (e.g., hospitalisations for VPDs and costs associated with care; vaccination coverage rates);
- survey data (e.g., relating to beliefs and perceptions about vaccines and to individual and contextual factors influencing behaviours[21]);
- epidemiological studies (e.g., on the burden of disease or Real World Evidence (RWE) on vaccine effectiveness);
- economic modelling (e.g., on the productivity impacts of vaccination programmes).

However, there are important gaps in the data and evidence currently available to policy-/decision-makers, which need to be addressed in order to optimise vaccination policies and programmes. Examples of these gaps include nationwide data and evidence on complications linked to several infections in population subgroups, as well as vaccination coverage rates (VCRs) among those groups.

As a key aim of national health authorities should be to achieve recommended VCRs (e.g., as recommended by the World Health Organization), robust data on vaccination coverage is essential to track whether those recommendations are being met.

Data and evidence gaps also pertain to several of the recommendations contained in this report, including: to assess the broader value of vaccines/vaccination programmes (chapter 1); monitoring, and developing policies that respond to, changes in vaccine confidence (chapter 2); measuring and assessing the quality and timeliness of citizens' access to vaccines (chapter 3); and monitoring the performance of immunisation programmes (cross-cutting recommendation).

In addition to the types of data and evidence that are available to decision-makers (and the need to address key gaps), MBVE has also examined the question of how data and evidence are used to support decision-making – in particular for the evaluation of vaccines and vaccination programmes.

A significant body of scientific literature has called attention to the fact that current (national) decision-making frameworks insufficiently capture the full 'value of vaccination'.[19,22,23,24] In high income countries, commonly used criteria for evaluation of vaccines include health gains to vaccinated individuals, savings in direct medical costs, and societal health gains (such as reductions in the transmission of VPDs and herd immunity). However, there are broader impacts and benefits of vaccination programmes that are generally not captured by current approaches. These concern (i) health systems strengthening, resilience, and security, (ii) social equity and ethics, and (iii) macro-economic gains.[25]

Inadequate consideration of those broader benefits will mean that European countries are likely to overlook opportunities to invest in vaccination programmes to improve health, economic and societal outcomes.

Furthermore, national approaches to the evaluation of vaccines / vaccination programmes already differ.[25,26] As new value concepts are gradually integrated into decision-making processes in some countries, these differences are likely to grow and impact on decisions about the content of immunisation programmes. That in turn creates risks with respect to diverging levels of health protection across European countries generally and within the EU in particular.

Recommendations

RECOMMENDATION 1.1

Enhance data collection and evidence generation to support the strengthening of vaccination policies, strategies, and the broader health care system.

Immunisation systems depend upon good quality data and evidence to inform and adapt vaccination policies and programmes. As the aims and scope of National Immunisation Programs (NIPs) expand, and as new challenges emerge, demands for new data and evidence also arise. That is the case, for example, with the shift towards life-course immunisation – requiring assessment and evaluation of the impact of vaccines and vaccination on healthy ageing as well as productivity.

Within the health sector, there is a need to strengthen and extend surveillance systems to ensure national representativeness and data completeness (e.g., on (sub)types of involved pathogen and characteristics of affected patients), monitoring of vaccination coverage and vaccine confidence, and the generation of timely RWE on vaccine safety, efficacy and the duration of protection.[27,28,29] For all these purposes, the use of electronic databases should also be prioritised.

In order to capture the broader value of vaccination within evaluation processes, there is also a need for additional data and evidence across a range of assessment criteria within and beyond the health sector. Data collection and evidence generation will accordingly require collaboration with agencies and experts in other sectors, such as economic and social policy.

In addition to strengthening the evidence base for decision-making on vaccination, improving data collection relating to immunisation policies and programmes can also support the work of other important actors in the field of public health, notably researchers.

To identify areas for strengthening data collection and evidence generation, it is first necessary to map what forms of data and evidence are currently available to Member State health authorities, as well as European agencies such as European Centre for Disease Prevention and Control (ECDC). The findings of the current EU-funded and EU-wide study to provide 'Guidance on methodologies to assess the performance of vaccination programmes' may provide an important starting point for such a mapping. The mapping will identify key gaps in data and evidence, as well as best practices (for example, Electronic Vaccination Registries in countries such as Denmark, Finland, Norway, and Sweden)[30] and can foster the development of intersectoral collaborations (at national and European level) to help address those gaps.

To support data collection and evidence generation on vaccination, and to contribute to health systems strengthening more broadly, there is a need for governments and the EU to invest in improving health data infrastructure.[31] The ECDC has a key role to play in Europe-wide data collection and dissemination. Expanding data collection and reporting on vaccination coverage rates (VCRs) for adolescent (e.g., HPV) and adult vaccines should be prioritised, as well as related data on disease burden.

The European Health Data Space has the potential to improve access to data for health policy-making, including on vaccination.[32] The EU can also play a vital role in facilitating cooperation between relevant national bodies

(such as National Immunisation Technical Advisory Groups - NITAGs) – for example, with a view to improved sharing of evidence to support decision-making on vaccination policies/programmes.[3,33]

In parallel, appropriate data governance frameworks should be implemented to enable privacy-protective data use that supports decision-making, including by removing 'barriers to effective cross-border cooperation in the processing of personal health data' and facilitating 'the compatibility or interoperability of health data governance frameworks'.[34,35]

RECOMMENDATION 1.2

Strengthen the alignment of national approaches to evidence-based decision-making on vaccination through a common European value framework.

To improve upon the current patchwork of national approaches to the evaluation of vaccines and vaccination programmes, and to avoid further fragmentation as new value concepts are introduced, it is vital to make progress towards a common (European) evaluation framework. This is needed to ensure that all countries take account of the opportunities afforded by vaccination programmes to invest in improved health, economic and societal outcomes, as well as to address the risk of further divergence between NIPs, which would result in differing levels of health protection across European countries.

With the adoption of the EU Regulation on Health Technology Assessment (HTA), which provides for joint clinical assessments of new vaccines from 2030, a more aligned (EU-wide) approach to the clinical assessment of new vaccines is already foreseen. The development of a common evaluation framework (hereafter 'value framework') should ensure complementarity with the joint clinical assessment process but focus on value dimensions that fall outside it. At the same time, it is vital to ensure that the HTA Regulation is well implemented in the case of vaccines and that methods, processes, and procedures are developed to take into account vaccines' unique characteristics.

The development of a common value framework requires the identification of priority value concepts, encompassing both well-established criteria and newer concepts that capture the broader value of vaccination. The common framework should also build upon existing national/international approaches to the evaluation of vaccines and vaccination programmes.

A geographically balanced, multi-disciplinary expert group should therefore be assembled to design and implement a process for the development of a draft value framework. That would include mapping existing assessment frameworks across EU Member States (and beyond). There is also a need for research to strengthen the evidence base across the different value dimensions – particularly macro-economic impacts, social ethics and equity. EU funding could facilitate research in this area.

The draft framework would then need to be tested and refined through processes of engagement and consultation with wider public health stakeholders – e.g., representatives of NITAGs and HTA bodies, ECDC, medical and public health professionals, patient and civil society organisations, and industry. The framework should also be accompanied by operational guidance to support its implementation by national authorities, including methods and tools for assessing vaccines and vaccinations against specific value criteria.

Progress in the adoption and use of the common value framework would need to be carefully monitored. That will require mechanisms to ensure transparency regarding the criteria used for, and rationales underpinning, NITAG/HTA body assessments and recommendations.

Summary of key actions per recommendation

Chapter 1: Data and evidence for decision-making

Recommendation 1.1. Enhance data collection and evidence generation to support the strengthening of vaccination policies and the broader health care system:

- Map data and evidence currently available to national health authorities and European agencies and establish intersectoral collaboration to fill data and evidence gaps;
- Invest in health data infrastructure at national and European level supported by appropriate data governance;
- Expand ECDC data collection and dissemination – especially on adolescent and adult vaccination.

Recommendation 1.2. Strengthen the alignment of national approaches to evidence-based decision-making on vaccination through a common European value framework:

- Identify priority value concepts through mapping of existing approaches to evaluation of vaccines and vaccination programmes;
- Establish a geographically balanced, multi-disciplinary expert group to design and implement a process for developing a common evaluation framework;
- Develop operational guidance to support implementation of the common value framework by national health authorities.

CHAPTER 2

Beliefs, perceptions, and vaccine confidence

While vaccination represents a substantial and undeniable success of public health, public reluctance to accept vaccines for themselves or their children can contribute to the reappearance and spread of Vaccine-Preventable Diseases (VPDs).

Vaccine confidence can be defined as *"the belief that vaccination – and by extension the providers and range of private sector and political entities behind it – serves the best health interests of the public and its constituents"*.[36] Vaccine confidence can be affected by a range of factors, including changes in policies or recommendations, the introduction of new vaccines, disease outbreaks or pandemics, or the spread of rumours and misinformation through the media, including social media.[37]

Vaccine confidence is extremely volatile.[38] This was highlighted during the COVID-19 pandemic, which saw important changes in confidence levels across the EU. While uncertainty and fear surrounding the disease created strong demand and trust in vaccination at the beginning of the pandemic, this confidence dropped as the pandemic was brought under control.[39]

Policymakers play a key role in developing and implementing policies and laws to support vaccination programmes within countries, including measures to promote vaccine confidence. Policy action to strengthen vaccine confidence is essential to ensure optimal vaccination coverage rates (VCRs), to protect the most vulnerable within societies, and to prevent and control VPDs (including in the case of future pandemics).

As declines in vaccine confidence represent a challenge across European countries, coordinated action at the local, national and European level is necessary. In a first instance, continuous monitoring of confidence in vaccination among the public and Health Care Professionals (HCPs) is needed to identify early-warning signals of confidence losses, and to provide a thorough understanding of beliefs and perceptions around vaccination across different population groups.

The 'State of Vaccine Confidence in the EU' reports (2018-2022) have shown that vaccine confidence varies by country, vaccine, and socio-demographic groups, with (for instance) important declines in confidence observed in the Balkans and Eastern Europe since the COVID-19 pandemic. In addition, the latest report highlighted a widening age "gap" in confidence between younger and older age groups, with younger adults (18-34) becoming less confident in vaccination.[39]

The information gathered through such monitoring can be used to develop targeted and effective strategies to restore and/or maintain confidence in vaccination, including communication and public engagement strategies or vaccination training for HCPs.[40,41,42] In particular, understanding and addressing the specific barriers to vaccine acceptance among populations where vaccine confidence is low or declining – or in relation to specific vaccines – is of crucial importance for the success of routine immunisation programmes.

Declines in vaccine coverage rates (partly caused by decreasing vaccine confidence) and new disease outbreaks were key factors behind the 2018 European Commission Communication and Council Recommendation on 'strengthened cooperation against vaccine-preventable diseases' – one outcome of which was the creation of the EU Joint Action on Vaccination. As the actions triggered by the Communication and Council Recommendation have now largely been implemented, it is important that EU action in this area is reviewed and renewed. That should include analysing the impact of the actions contained in the Commission's implementation roadmap[43],

as well as additional steps that might have been taken by Member States as follow up. Crucially, further actions should be envisaged to address current and future challenges related to vaccine confidence.

The EU has a vital role to play in supporting and enabling collaboration between health authorities and vaccine confidence experts across the EU. The EU can also provide joint infrastructures – such as monitoring, reporting and alert systems, which would be costly for individual Member States to implement on their own and which, if developed and implemented separately, might reduce opportunities for comparison and learning across countries, as well as opportunities to enhance preparedness for cross-border health threats.

In addition to this joint infrastructure:

- The EU should ensure funding for the urgent research that is needed to strengthen the knowledge base that underpins policy responses to vaccine confidence, including with respect to communication and community engagement strategies, and the training of HCPs (see recommendations 2.2 and 2.3 below).
- The European Centre for Disease Prevention and Control (ECDC) can further support efforts to focus attention on vaccine confidence challenges – in particular through the organisation of events as part of European Immunisation Week.
- Consideration should be given to the application of the Code of Practice on Disinformation (a self-regulatory tool outlining industry standards to combat online disinformation) to vaccine confidence – for example through the development of expert guidance on the optimal implementation of the Code.

The December 2022 Council Conclusions on vaccination also invited the European Commission *inter alia* to '*provide Member States, upon request with non-binding tailormade recommendations and guidelines on how to tackle vaccine hesitancy taking into account national specificities*'.[13]

Recommendations

RECOMMENDATION 2.1

Develop an EU vaccine confidence rapid alert and response system to enable timely risk analysis and policy action.

Continuous and real-time monitoring of vaccine confidence in the EU is essential to allow the timely detection of changes in confidence levels across the region and facilitate coordinated actions to respond to emerging challenges.[44] Continuous monitoring of vaccine confidence is also essential to detect where issues might arise and enable rapid response systems to be put in place to restore confidence and prevent negative impacts on coverage levels.[45]

The added value of creating an EU-wide surveillance system is also made evident by the cross-border nature of vaccine confidence challenges. Disinformation and rumours do not stop at borders, and can spread rapidly from one country to another, threatening vaccination programmes across the EU.[46] A standardised surveillance and alert system would enable the instant comparison of confidence levels across the region, identifying trends and areas of concern and facilitating the exchange of knowledge and lessons learnt between countries. As vaccine confidence levels have been shown to predict vaccine uptake rates,[47] a surveillance and alert system is essential to prevent long-lasting, negative impacts on vaccine coverage levels and consequences for the control of infectious diseases in the EU.

A comprehensive EU Vaccine Confidence Rapid Alert and Response System would not only enable the detection of changes in vaccine confidence across EU Member States, identifying specific populations or regions with low or decreasing confidence, it would also enable timely and targeted responses to address emerging challenges.

The EU Vaccine Confidence Rapid Alert and Response System should have a multi-dimensional approach encompassing the following key components:

- **Surveillance**: Establish a centralised surveillance system to continuously monitor vaccine confidence levels in Member States at national and regional levels using a standardised and comparable tool. This system can utilise data from large-scale surveys, social media, public health agencies, and other relevant sources to detect early warning signs of declining vaccine confidence.

- **Risk assessment**: Develop a risk assessment framework focusing on the potential for declines in vaccine coverage (e.g., low-, medium-, or high-risk countries/regions) due to changes in confidence levels or the spread of rumours or misinformation, including via social media. This framework will provide real-time insights and trends, allowing policymakers and public health officials to identify areas of concern promptly – for example with the use of an interactive display system.

- **Rapid Response Mechanism**: Establish a platform for Member States to share best practices and lessons learnt on effectively addressing vaccine confidence issues, with the organisation of regular expert meetings. The platform can propose different responses based on risk levels, such as additional local and in-depth qualitative studies to explore concerns and issues in regions assessed as medium-risk. Countries flagged as high-risk could receive targeted support with developing interventions, such as tailored risk communication strategies or capacity-building initiatives for HCPs.

The EU Vaccine Confidence Rapid Alert and Response System would need to be regularly updated, to ensure identified risk levels are accurate and reflect potentially evolving challenges to vaccine confidence. When developing the system, attention should be paid to existing or past EU initiatives. For example, tools such as the Eurobarometer or the 2018-2022 EU State of Vaccine Confidence Reports can be used as a baseline for the development of survey tools that can rapidly and effectively be deployed across the EU to measure vaccine confidence levels.

The EU Vaccine Confidence Rapid Alert and Response System should also be linked with vaccine coverage surveillance systems to track changes in vaccine uptake and establish the effectiveness of strategies and policies implemented in different contexts.

RECOMMENDATION 2.2

Strengthen community engagement on vaccination through national strategies, research and exchange of best practice.

While the importance of effective communication on vaccines and vaccination is increasingly recognised, improved communication (and information provision) alone is not sufficient to enhance vaccine confidence across populations. Building trust is also essential. Trust is shaped by a variety of factors, including the extent to which individual citizens and communities trust governments, HCPs, and other experts. Within certain groups – e.g., the economically deprived, ethnic minorities and migrants – trust may be shaped by past experiences and interactions with public institutions (experiences that may entail exclusion and/or discrimination).[48]

These complex factors require strategies that go beyond informing communities about the risks and benefits of vaccination via communication efforts. They should also focus on long-term trust building initiatives that enable citizens to directly engage with, and participate in, decision-making related to vaccination policies, as well as in the design and planning of communication strategies.

National and regional health authorities should therefore develop and implement community engagement strategies, informed by behavioural and cultural insights (BCI) and best practices in citizen participation

processes, with the objective of strengthening trust in vaccines, providers and policy-makers. These strategies should include a particular focus on groups that may be at risk of under-vaccination.

Community engagement on vaccination can include the creation of fora for discussion with citizens (e.g., in order to identify appropriate responses to specific vaccination-related challenges) and more broadly seeking the input of the public on the development and implementation of vaccination policies and programmes, communication strategies, and directions for vaccine-related research. For example, in France, community engagement on declining VCRs contributed to the decision to introduce mandatory vaccinations.[49]

Community engagement should be adapted to the needs of different groups/communities, taking into account prevalent concerns, perceptions and experiences among those groups. Feedback mechanisms should be established in order to support monitoring and continuous learning by health authorities and policy makers, including with respect to common beliefs and concerns about vaccination, as well as to identify and track rumours and sources of disinformation.[50] Feedback mechanisms of this kind can also enable community engagement plans and information materials to be updated and revised in the light of identified issues and challenges.

Given the complexity of vaccine confidence in general, and community engagement on vaccination more specifically, there is clearly a need for expert guidance for governments regarding the development and implementation of community engagement strategies. The European Union can provide valuable support for the development of such guidance through funding for research and other relevant projects, and more broadly by facilitating the exchange of best practices via the Expert Group on Vaccination and Vaccine Confidence and the 'best practice portal' of the Expert Group on Public Health.

For the development of guidance in this area, attention should be paid to what the health sector can learn from other policy areas in which deliberative and participatory approaches have been tested and implemented. The OECD Public Governance Directorate, for example, has developed Guidelines for Citizen Participation Processes, which highlights the importance of inter alia: identifying the problem to be solved and the moment for participation; identifying relevant groups of people to be involved; and defining the participation method.

RECOMMENDATION 2.3

Ensure training on vaccination and communication skills for pre- and in-service health care professionals.

HCPs play a pivotal role in the success of vaccination efforts, as they are widely regarded, and trusted, as experts that can provide accurate information and guidance to patients and communities.[51,52,53] Primary care doctors, paediatricians, gynaecologists, pulmonologists, nurses and pharmacists (among others) all have an important role to play in communicating with patients and the public about vaccination, encouraging them to get vaccinated, and addressing concerns.

However, while vaccine confidence among HCPs is generally high, HCPs face multiple pressures and demands and may not always feel confident in discussing vaccination with their patients. In particular, they may consider that they lack the necessary information to advise patients about vaccines.[54]

HCPs also need to be equipped to provide reassurance and guidance to potentially vaccine hesitant individuals, including parents.[55] This is not simply a question of having access to accurate information, but also of understanding what to communicate and how to communicate it.

There is therefore a pressing need to support HCPs in strengthening their knowledge and confidence to communicate on vaccines and VPDs, including with respect to the purpose, benefits, and safety of vaccines. In particular, there is currently insufficient training on vaccination and communication skills within the education

curriculum of HCPs.[54,56] In addition, training should also be provided (at regular intervals) to practicing HCPs in relevant specialisms.

EDUCATIONAL CURRICULA

- The educational curriculum of HCPs should aim to provide a firm knowledge base on vaccines/vaccination and strengthen communication skills in order to ensure that, post-qualification, HCPs are sufficiently confident and able to communicate effectively with patients on the subject of vaccination.

- Vaccination training should begin early in the educational pathway, ensuring that students are exposed to this knowledge from the beginning of their professional development. This training should emphasise that vaccination is a key public health intervention that protects people against communicable diseases across the life course, supports herd immunity, and delivers broader health system, economic and societal benefits.

- Building upon the EU JAV curriculum on vaccinology for health care providers and students, topics such as vaccine rationale development and quality, immunisation policies and schedules, active listening, or communication should be included. To achieve this, it is important to collaborate with educational institutions and student associations.

IN-SERVICE TRAINING

- In-service training should focus on refreshing and updating practicing HCPs on recent developments, including as regards new threats, new vaccines that may have become available, changes in policies, as well the latest scientific literature on vaccination. Here national professional organisations play a pivotal role in facilitating continuous professional development to stay up-to-date with best practices and address knowledge and practice gaps.

- The WHO-ASPHER (Association of Schools of Public Health in the European Region) Roadmap to Professionalization curriculum recommends that professional organisations drive forward professional knowledge sharing and deliver high-quality competency-based training, education and assessment on an ongoing basis.

- Providing accreditation points contributing to continuous education requirements for HCPs can constitute an important incentive for taking part in vaccination and communication trainings.

At the European level, an important role can be played by civil society organisations with support from the EU. The Coalition for Vaccination, for example, comprises European associations of HCPs as well as student associations, with the aim to '*support delivering accurate information to the public, combating myths around vaccines and vaccination, and exchanging best practices on vaccination*'. This important initiative should be supported through sustainable resourcing from the EU, which is essential to ensure impact within countries.

Important EU-funded projects in this area include: (i) Protect Europe (led by the European Cancer Organisation), which will provide Member States with guidance on communication on HPV vaccination between clinicians and young people and their parents/caregivers; (ii) Educating Vaccination Competence (EDUVAC), which focuses vaccination learning programs for health care students; and (iii) the EU Joint Action PERCH (Partnership to Contrast HPV), which includes a focus on improving 'knowledge and abilities' on HPV vaccination among HCPs.

Summary of key actions per recommendation

Chapter 2: Beliefs, perceptions, and vaccine confidence

Recommendation 2.1. Develop an EU vaccine confidence rapid alert and response system to enable timely risk analysis and policy action:

- Establish a centralised surveillance system to continuously monitor vaccine confidence levels in EU Member States using a standardised and comparable tool;
- Develop a risk assessment framework to assess the potential for declines in vaccine coverage due to changes in confidence levels or the spread of rumours/misinformation;
- Establish a platform for Member States to share best practices and lessons learnt on how to effectively address vaccine confidence issues, with regular expert meetings.

Recommendation 2.2. Strengthen community engagement on vaccination through national strategies, research and exchange of best practice:

- Community engagement strategies should be developed by national and regional health authorities, informed by behavioural and cultural insights as well as best practices in citizen participation processes;
- Tailor engagement strategies to the needs of specific groups/communities, taking into account prevalent concerns, perceptions, and experiences among those groups;
- The EU should support (e.g., through funding and best practice sharing) the development of expert guidance on the design and implementation of community engagement strategies.

Recommendation 2.3. Ensure training on vaccination and communication skills for pre- and in-service health care professionals:

- Integrate vaccination training early in the educational pathway of HCPs;
- Build on the EU JAV curriculum on vaccinology for health care providers and students, and include topics such as vaccine rationale, immunisation policies and schedules, active listening, and communication;
- Implement in-service training to refresh and update practicing HCPs on recent developments – including new disease threats, new vaccines, policy changes, and the latest scientific literature.

CHAPTER 3

Citizens' Access to Vaccines

Access to preventative health care is a major health determinant and accordingly recognised as a fundamental right, including by the European Charter of Fundamental Rights. This means that people should be able to access preventative health services regardless of their background, income level, or any other impediment. Vaccination is a highly cost-effective preventative health measure that saves millions of lives globally each year, protects people against a wide range of infectious diseases, and substantially reduces the burden of disease. In spite of these benefits, however, a range of obstacles continue to have negative impacts on citizens' ability to access vaccines.

The Mission Board on Vaccination has approached to the question of citizens' access to vaccines based on a definition of 'access' with three dimensions:

DIMENSION 1: AVAILABILITY

Whether a vaccine is available to the population or specific sub-groups that may be at particular risk from specific Vaccine-Preventable Diseases (VPDs). Availability is principally determined by whether or not a vaccine is included in the National Immunisation Programme (NIP), whether adequate public funding is provided to ensure implementation of the vaccination programme, and whether public procurement practices enable vaccines to be made available in good time. In some countries, vaccines may also be made available to individuals on a commercial basis (i.e. without reimbursement). Finally, vaccine manufacturing capacity, relative to global demand, is an important determinant of vaccine availability.

DIMENSION 2: ACCESSIBILITY

The accessibility of vaccines concerns the ease with which people are able to reach and benefit from vaccination services. People may encounter barriers (e.g., related to the location and convenience of vaccination services) that reduce the accessibility of vaccination.

DIMENSION 3: EQUITY

Health equity is defined by the World Health Organization (WHO) as "*the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality*". An equity perspective needs to be applied both to dimension 1 (i.e. whether certain vaccines are available in some countries but not others) and dimension 2 (i.e. whether there are differences in the accessibility of vaccination between different population groups). In the latter case, particular attention should be paid to disadvantaged groups.

Regarding availability, this chapter emphasises the need to strengthen the timeliness of decision-making relating to NIPs. Chapter 4 will go on to recommend convergence between the adult immunisation calendars of EU Member States. In both cases, the recommendations of the Mission Board aim to address inequity in the availability of vaccines across countries, and thereby address the gaps that exist in levels of health protection available to EU citizens (children, adolescents, and adults), no matter the country in which they grow, live, and work.

Turning to the accessibility of vaccination services: it is necessary to ensure that such services are provided 'where people are' – that is to say, at or close to where people live, study, and work (e.g., schools, workplaces, and community pharmacies), which requires action based upon a robust life-course immunisation approach.

There is also an urgent need for strategies to improve vaccination equity within countries by tackling accessibility barriers that disproportionately affect disadvantaged groups. Enhancing the accessibility of vaccination services therefore demands inter-sectoral collaboration – i.e. with employers and education, whilst also ensuring that vaccination is appropriately integrated with the wider health system.

Affordability considerations also impinge on citizens' access to vaccines. To make progress on the recommendations outlined in this chapter, it is essential that national and regional health authorities make sustainable investments in immunisation programmes (see recommendation 5.2).

Recommendations

RECOMMENDATION 3.1

Enhance the timeliness of evidence-based decision-making on vaccination programmes to address inequities in vaccine availability.

In too many European countries, decisions on whether to include a vaccine in the NIP are unnecessarily prolonged.[26,57,58] Several studies have highlighted the substantial variation that exists in 'time to population access' (hereafter TTPA) – defined as the time between a vaccine receiving marketing authorisation and a final decision on its inclusion in the NIP with public funding. In one recent analysis, Laigle *et al*. found that in seven EU Member States, median TTPA is less than two years, in ten countries it is between two and six years, and in a further nine countries (a third of EU Member States) median TTPA is *more than six years*.

Taking into account epidemiological features and patterns across Europe, such variation in the timeliness of decision-making is not acceptable and will result in inequitable access to vaccines between the citizens of different EU Member States, which in practice means differing levels of health protection. It is therefore imperative to strengthen national decision-making procedures and practices with the aim of enhancing the timeliness of decision-making on vaccination programmes.

Ensuring timely assessment of vaccines requires that National Immunisation Technical Advisory Groups (NITAGs) and Health Technology Assessment (HTA) bodies have sufficient resources, expertise, and capacity to undertake the evaluation of all paediatric, adolescent, and adult vaccines in a timely manner.

With this in mind, and as stipulated by the WHO European Immunisation Agenda 2030 (EIA2030), countries should *'Review the composition, terms of reference and capacity of NITAGs to develop evidence-based recommendations for immunisation across the life course'*.[5] In addition, NITAGs and HTA bodies should:

- Ensure mechanisms are in place to conduct horizon scanning for vaccines expected to be licensed in the near future. This can help to ensure that NITAGs and HTA bodies are well prepared for the assessment of new vaccines and immunisation agents, and thereby avoid unnecessary delays.

- Assess the expected outcomes of vaccination based on the health needs of the population, mainly through the clinical, epidemiological, and socio-economic burden of VPDs. Accessibility procedures for the population/individuals should also be assessed (in line with recommendation 3.2 below).

At EU level, cooperation between NITAGs (with respect to evidence generation, for example) can reduce capacity pressures on individual NITAGs and thereby contribute to more timely and efficient decision-making. The implementation of the EU Regulation on HTA is particularly important in this respect as it will lead to joint clinical assessments and joint scientific consultations for vaccines. The Regulation is also an opportunity for capacity building, strengthening of evidence-based decision-making across EU Member States, and faster vaccine availability for EU citizens. It is therefore vital to ensure that the Regulation is well implemented and takes into account vaccines' specific characteristics.

A 180-day timeframe for decision-making is already provided for in EU legislation.[59] However, based on the analysis outlined above, the majority of EU countries currently exceed that timeframe.[26] Thus, in parallel with the implementation of the EU Regulation on HTA, it is important that steps are taken to transparently monitor the speed of decision-making on the inclusion of vaccines in NIPs using a standardised methodology.

RECOMMENDATION 3.2

Enhance the accessibility of vaccination services, in particular within schools, workplaces, and community pharmacies, to support a life-course approach to immunisation.

A life-course immunisation strategy aims to adapt to the epidemiological threats and exposures, and support quality of life and healthy ageing by reducing morbidity and mortality at all ages. Strategic Priority 4 of EIA2030 aims to ensure that all people benefit from recommended immunisations throughout the life-course.[4] Furthermore, it emphasises the importance of integrating tailored immunisation services with other essential services within and outside the health care system. Hence, fostering coordination and collaboration across all health programmes becomes imperative for effective immunisation initiatives.[60]

National health authorities should promote collaboration with other public policy areas (or sectors) to ensure that the administration of vaccines can happen in non-health care settings, while safeguarding the safety and effectiveness of administration procedures. Workplace vaccination, in particular, should be seen as a key component of a broader intersectoral approach to health and well-being, in which employers offer a range of health promoting and preventative services. Through the occupational health structures already in place (including legally required health and safety measures in the workplace), it is possible to expand these structures to encompass other health-related interventions, notably vaccination.

From an EU perspective, the increasing geographic, cross-border mobility of citizens for employment purposes underscores the need to expand vaccination services within the workplace. Moreover, considering the potential for the workplace to act as a point of transmission of VPDs, there is a strong case for incorporating adult vaccination for certain diseases within EU legislation on health and safety in the workplace.[61]

National health authorities and legislatures can enhance the role of occupational health services by broadening the range of vaccinations offered in the workplace, as well as by encouraging and enabling 'active promotion' (e.g., informing employees of the benefits of vaccination and providing vaccination services free of charge).[62] At the same time, it is vital that appropriate digital tools are available and used, and can thereby support the strengthening of data collection on vaccination programmes and policies.[63]

National health authorities should also examine possibilities for increasing the administration of vaccines in school settings. Several studies conducted in recent years documented how vaccination strategies in schools, for example against Human Papilloma Virus (HPV), contributed to increased vaccination coverage and helped to tackle vaccine hesitancy.[64,65,66] In addition to enhancing the accessibility of vaccination, the expansion of vaccination services in schools and workplaces can create opportunities to enhance education on the benefits of vaccination, as well as vaccine literacy, among key groups (such as children and parents).[67] For instance, interventions to improve vaccine literacy in workplace settings can lead to greater awareness about the benefits of vaccination for employees' family members.

Community pharmacies can also play an important role in strengthening the accessibility of vaccination services (particularly for adults) as they provide an additional setting for vaccine administration. This may require expanding the scope of practice of pharmacists (in some cases, building on experiences during COVID-19) and could also include pharmacist-led vaccination programmes.[68] In some countries, vaccination in community pharmacies has been shown to significantly improve vaccination coverage rates, while lowering the cost of treatment, as well as minimising inappropriate antibiotic therapies.[69]

The development and implementation of models for administering vaccines in pharmacies (by pharmacists) requires appropriate legal and organisational frameworks at the national level, as well as arrangements for the financing of such services and the integration of vaccination training within pharmacists' educational curricula.

This recommendation also links to other recommendations and chapters in this report. For example, vaccination in schools and community pharmacies can support efforts to strengthen vaccination equity (MBVE recommendation 3.3). Schools, workplaces, and community pharmacies, alongside travel clinics, sports centres, and community associations, are also settings in which active promotion of vaccination should be implemented – for instance, by recommending that people get vaccinated, asking about their vaccination status, and by providing leaflets and other information materials. Ensuring appropriate communication on vaccination in these settings can also support efforts to promote vaccine confidence (see chapter 2).

In each of the settings, 'fallback' options should be available, so that if for any reason a person does not (or is unable to) receive a vaccination at the time originally envisaged, alternative arrangements can easily be made to 'catch up' and thus ensure that the vaccination is not missed altogether.

RECOMMENDATION 3.3

Improve vaccination equity and uptake through national strategies that target disadvantaged groups, employ cross-sectoral collaboration, and leverage insights from best practice sharing.

In Europe, vaccination inequity is strongly associated with lower vaccine uptake and under-vaccination within disadvantaged population groups. These include minority ethnic groups, those living in economic deprivation, religious communities, migrants, those who live in remote areas, and other hard-to-reach populations (e.g., the homeless), as well as people with severe mental illness and learning disabilities. In addition to vaccine hesitancy (addressed in chapter 2), there are a range of other barriers which mean that the accessibility of vaccination services is reduced for these groups. They include: structural barriers (e.g., proximity to/accessibility of appropriate health care services); administrative barriers (such as documentation requirements); and cultural and linguistic barriers. To address these barriers to access, tailored and context-specific solutions are required.[70]

National and regional health authorities should develop and implement 'vaccination equity strategies' that actively identify and dismantle barriers to vaccination accessibility among disadvantaged groups.[11] The strategies should leverage cross-sectoral collaboration, including education, employment, and other social policies. They should aim to ensure that disadvantaged groups have access to vaccination sites, including for those living in remote areas, as well as during non-standard hours to accommodate diverse schedules. Mobile vaccination units should be considered as a means to reach the very elderly, refugee communities, and other groups living in remote areas.

National and regional strategies on vaccination equity should ensure that vaccination uptake is monitored and disaggregated into population sub-groups, including disadvantaged communities. The strategies should also be informed by WHO Europe's guidance on *Tailoring Immunisation Programmes*, as well as the outcomes of the EU-funded RIVER-EU (Reducing Inequalities in Vaccine uptake in the European Region – Engaging Underserved communities) project, which will include the development of evidence-based guidelines to support 'equitable access to vaccination across Europe'.[71,72]

Vaccination equity strategies should be closely aligned, or integrated, with broader approaches to community engagement on vaccination (see MBVE recommendation 2.2). As language barriers can significantly impede vaccination accessibility, communication campaigns must prioritise culturally sensitive, translated materials that resonate with disadvantaged communities. Community and civil society organisations should be consulted on the development of the strategies and involved in their implementation – providing additional resources, capacity, and knowledge about population groups at risk of under-vaccination.

The EU can support the development of vaccination equity strategies by facilitating the exchange of knowledge and best practices via the EU Expert Group on Public Health, as well as the dissemination of those practices via other EU funded projects and activities that aim to increase awareness of VPDs and strengthen vaccination coverage. In this context, and informed by the findings of RIVER-EU in particular, consideration should be given to the creation of multilingual resources that would support efforts to improve access to vaccination among disadvantaged groups. Vaccination equity should also form part of the agenda of the European Parliament's Subcommittee on Public Health.

Summary of key actions per recommendation

Chapter 3: Citizens' access to vaccines

Recommendation 3.1. Enhance the timeliness of evidence-based decision-making on vaccination programmes to address inequities in vaccine availability:

- In line with EIA2030, national health ministries should '*Review the composition, terms of reference and capacity of NITAGs to develop evidence-based recommendations for immunisation across the life course*';
- Within the EU, continue to facilitate cooperation between NITAGs in order to reduce capacity pressures and avoid duplication of efforts;
- Implement horizon scanning for vaccines expected to be licensed in the near future and thereby help to ensure NITAGs are better prepared for the assessment of new vaccines in a timely manner.

Recommendation 3.2. Enhance the accessibility of vaccination services, in particular within schools, workplaces, and community pharmacies, to support a life-course approach to immunisation:

- National health authorities should promote collaboration with other public policy areas (notably education and employment) to expand vaccination services beyond health care settings while safeguarding the safety and effectiveness of vaccine administration procedures;
- Ensure that appropriate legal / organisational frameworks and financial mechanisms are in place to enable vaccination within community pharmacies, and integrate vaccination training into pharmacists' educational curricula;
- Examine the feasibility of integrating adult vaccination for certain diseases within EU policies and legislation on health and safety in the workplace.

Recommendation 3.3. Improve vaccination equity and uptake through national strategies that target disadvantaged groups, employ cross-sectoral collaboration, and leverage insights from best practice sharing:

- Monitor vaccination uptake and disaggregate by population sub-group, including disadvantaged communities, and link this to broader monitoring on the performance of immunisation programmes;
- Leverage cross-sectoral collaboration – including education, employment, and other social policies – to ensure that disadvantaged groups have access to vaccination services, including those living in remote areas;
- Consult community and civil society organisations on the development of vaccination equity strategies and involve them in the implementation of those strategies.

CHAPTER 4

Convergence and alignment

As responsibility for the organisation and delivery of health services rests at national level, European countries differ with respect to their decision-making processes on vaccination, as well as the outcomes of those processes (including vaccination programmes). Such differences do not necessarily constitute a public health concern. However, if the differences between National Immunisation Programmes (NIPs) give rise to substantially different levels of health protection across countries, it is relevant to consider whether NIPs should be adapted so as to ensure greater alignment and equity.

Similarly, variation in decision-making processes on vaccination often reflect broader differences between national health systems. It is to be expected, however, that certain processes should form part of the decision-making pathway for vaccination in all European countries. Should they not do so, policy action may be warranted in order to address identified gaps.

Life course immunisation is a strategic priority of the World Health Organization (WHO) European Immunisation Agenda 2030 (EIA2030)[5] and can also make an important contribution to healthy ageing policies.[13,73] Within the European Union, however, there are notable differences between national approaches to adult immunisation.[74] An analysis of adult vaccination coverage in the EU, conducted by Federation of European Academies of Medicine (FEAM), highlights variation with respect to vaccine components, target groups, and the regulatory framework of implementation.[74] Consequently, the protection of adult EU citizens against Vaccine-Preventable Diseases (VPDs) varies according to the country in which they live and/or work. As these differences cannot be explained on public health grounds[3,19], they may also present risks to vaccine confidence.

The first recommendation of this chapter therefore focuses on the need for a more aligned approach to vaccination throughout life, in particular through the development of a core calendar for adult immunisation.

The second recommendation focuses on the decision-making pathways that underpin NIPs.[11] Several academic studies have drawn attention to the heterogeneity of national pathways for decision-making on vaccination,[75,76] as well as country-specific opportunities to enhance their design and functioning.[26] In its 2018 Communication on strengthened cooperation against VPDs, the European Commission clearly identified a need for action in this area – in particular to '*strengthen the efficiency and consistency of decision making on vaccines/vaccination policies*'.[9] This chapter will also emphasise the need for action to enhance the *consistency, inclusiveness, transparency* and *accountability* of decision-making. It thereby complements recommendation 3.1, which focused on the need for greater *timeliness* within the decision-making process.

Recommendations

RECOMMENDATION 4.1

Develop a more aligned approach to life course immunisation through a core calendar for adult vaccination.

In order to ensure greater equity in levels of health protection against VPDs, to reduce the burden and transmission of those diseases, and as a contribution to healthy ageing, there is a pressing need for a more aligned approach to life course immunisation across the EU. As the alignment of adult vaccination programmes is currently far behind that of pediatric vaccination programmes, initial priority should be given to the development of a core calendar for adult vaccination.

A core calendar for adult vaccination would contribute significantly to a more aligned approach to life course immunisation within the EU (as well as other European states that wished to participate), while providing space for individual countries to go further – i.e. by expanding their adult vaccination programmes in line with principle of national competence on health. It would also provide a foundation for additional steps in aligning national approaches to vaccination throughout life (e.g., future action could focus on alignment with respect to new pediatric vaccines).

The case for greater alignment in the area of adult immunisation is underpinned by the multiple benefits that vaccination affords to the adult population, including: reduced mortality and morbidity associated with VPDs; improved health outcomes for people with Non-Communicable Diseases (NCDs); and prevention against disability and age-related dysfunction.[77] For instance, influenza vaccination was recently shown to provide a significant positive cardiovascular protection. Similarly, vaccines specifically targeting pneumococcal disease and herpes zoster have been associated with off-target protective effects on both cardio- and neuro-vascular diseases.[74] As outlined in chapter 1, there are also broader benefits to health systems, society, and the economy associated with vaccination programmes, including reduced antibiotic usage, reduced pressure on health services that would otherwise be needed to treat VPDs, and – especially in the case of adult immunisation, economic benefits.[67]

Given that the EU treaties specifically mandate EU-level action to support national efforts to combat VPDs, MBVE proposes that the EU NITAG Network should be mandated to initiate work on the development of a core calendar for adult immunisation. The European Centre for Disease Prevention and Control (ECDC) could also play a key role through the provision of scientific, advisory, and coordination support.[78]

The core calendar for adult immunisation should reflect the health needs of, and epidemiology of VPDs within, the adult population. It would also need to be kept under regular review to take account of the evolving epidemiological situation in Europe (e.g., with respect to the prevalence of seasonal VPDs and potential impacts of climate change) as well as the development of new vaccines.

The implementation of the core calendar for adult immunisation would also need to be underpinned by political commitment at the national level, including through immunisation financing arrangements that support and enable the expansion of adult vaccination programmes. There would be a need for communication with Health Care Professionals (HCPs) and target populations with the aim of ensuring that the purpose and benefits of adult vaccination programmes are clearly understood. The potential for expanding vaccination in workplaces and community pharmacies (see MBVE recommendation 3.2) should also be considered in this context.

The development of an aligned approach to life course immunisation could also facilitate the adoption of a standardised EU digital vaccination record. That in turn would support EU-wide data collection on vaccination, while enabling citizens to keep track of their vaccination status even when moving between European countries to live/work.

RECOMMENDATION 4.2

Address key gaps in decision-making pathways on vaccination to enhance their consistency, inclusivity, transparency, and accountability.

The decision-making pathways underpinning NIPs centre on the assessments and recommendations carried out by NITAGs and Health Technology Assessment (HTA) bodies, as well as a final policy decision (often by the Ministry of Health). A number of related processes should also be considered indispensable to ensure the optimal functioning of these pathways. They include: horizon scanning, the adoption of formal decision-analysis frameworks to support NITAG/HTA body assessments and recommendations, consultation with wider stakeholders, and transparency.

A recent mapping and analysis of decision-making pathways within EU Member States and the UK identified numerous gaps across those countries.[26] For instance, at the time of the research (2018-19), it was found that:

- Only 7 of 27 NITAGs had adopted a formal decision-analysis framework;
- Only 2 made use of a recognised tool (such as GRADE) for assessing the quality of evidence;
- Only 14 countries published the rationale for decisions on whether to include a vaccine in the NIP.[26,79]

While recognising that the organisation and delivery of health services is a national competence, action is necessary to address these and other gaps within decision-making pathways on vaccination. One effect of such action would be to reduce the heterogeneity of decision-making processes, and thereby contribute to greater alignment and convergence.[11]

With this objective in mind, MBVE has identified the following four principles that should underpin decision-making pathways on vaccination in all European countries (a further principle, timeliness, was considered in Chapter 3):

- **Consistency**: there should be a consistent approach to the assessment of vaccines across the life-course. A consistently applied decision-analysis framework is critical in this respect.
- **Inclusiveness:** relevant stakeholders should have the opportunity to submit information and analyses relating to the work being undertaken by NITAGs and HTA bodies.
- **Transparency** of decision-making processes and outcomes – in particular, NITAG / HTA body recommendations, and final policy decisions should be made publicly available in accessible formats.
- **Accountability:** decisions regarding NIPs should be fully implemented, their implementation should be appropriately monitored, and formal mechanisms should be provided in order to raise issues and concerns relating to implementation.

National health authorities should assess the conformity of their respective decision-making pathways with these principles. NITAGs and HTA bodies, in particular, should examine whether and how the transparency of their processes can be enhanced. At the EU level, sharing of best practices (e.g., through the EU NITAG Network) can also facilitate cross-country learning.[80]

Sustainable financing of immunisation systems is also essential to ensure high quality decision-making processes across countries, as well as full implementation of the decisions that are taken in relation to vaccination policies and programmes (see MBVE recommendation 5.2).

Summary of key actions per recommendation

Chapter 4: Convergence and alignment

Recommendation 4.1. Develop a more aligned approach to life course immunisation through a core calendar for adult vaccination:

- Mandate the EU NITAG Network to initiate work on the development of a core calendar for adult immunisation, supported by ECDC;
- Communicate effectively with HCPs and target populations to ensure that the purpose and benefits of adult vaccination programmes are clearly understood;
- Regularly review the core calendar to take account of the evolving epidemiological situation in Europe as well as the development of new vaccines.

Recommendation 4.2. Address key gaps in decision-making pathways on vaccination to enhance their consistency, inclusivity, transparency, and accountability:

- National health authorities should assess the conformity of their respective decision-making pathways with the principles of consistency, inclusiveness, transparency, and accountability;
- NITAGs and HTA bodies should examine how to enhance the transparency of decision-making processes on vaccination;
- Within the EU, share best practices on decision-making processes/practices (e.g., via the EU NITAG Network) to facilitate cross-country learning.

Cross-cutting recommendations

RECOMMENDATION 5.1

Develop and implement national frameworks and processes to systematically monitor, assess, and publicly report on the performance of immunisation systems.

The vital role of monitoring and surveillance systems as a tool to inform vaccination policies and programmes has been highlighted several times in the preceding chapters, including in relation to:

- Ensuring appropriate data are available to support decision-making on vaccination (chapter 1);
- The development of an EU rapid alert and response system on vaccine confidence (chapter 2);
- Citizens access to vaccines – monitoring the timeliness of decision-making on vaccination programmes and vaccination equity (chapter 3).

In addition to these purposes, data gathered through monitoring and surveillance systems should *also* be used to monitor and assess the overall performance of immunisation systems.

Performance monitoring can be used to:

- Analyse and assess the effectiveness of existing vaccination policies and programmes;
- Identify potential issues of concern which may need to be addressed through new or different policies/interventions;
- Enable public reporting on, and thereby enhance accountability for, immunisation system performance[81].

The first step is for national health authorities to develop a conceptual framework to monitor and assess the performance of immunisation policies and programmes. The performance assessment framework should clarify the main goals of the immunisation system and identify indicators that can be used to assess performance in relation to those goals.[82]

In line with the themes addressed in this report, key criteria/domains for performance monitoring and assessment include:

- Prevention and control of Vaccine-Preventable Diseases (VPDs) across the life-course – vaccination coverage rates (which can be disaggregated according to geographic, socioeconomic, gender, and other factors), incidence of VPDs, hospitalisations due to VPDs;
- Vaccine confidence – survey data on public perceptions towards vaccination;
- Access and equity – timeliness of decision-making; provision and use of vaccination services beyond health care settings; and vaccination uptake among disadvantaged groups;
- Immunisation financing – total budget allocated to vaccination programmes and spending on broader immunisation-related activities (e.g., measures to strengthen vaccine confidence and improve vaccination equity).

The performance of immunisation systems can be assessed against targets or benchmarks, longitudinally (i.e. by analysing change and improvement over time), or through international comparisons based on standardised indicators and data collection methods. From a European perspective, international comparisons can also be used to assess divergence in levels of health protection across EU Member States, as well as to identify and learn from best practices.

To support the design and implementation of national performance monitoring and assessment processes, a geographically balanced expert group should be tasked with the development of a model performance assessment framework (including key criteria or domains for assessment, as well as potential indicators or targets associated with those criteria), which can be used and adapted by national health authorities in accordance with country specificities.

The model framework should build upon the outcomes of the ongoing EU-funded study on 'Guidance on methodologies to assess the performance of vaccination programmes'. Consideration should also be given to the potential for expanding EU-level monitoring on the performance of immunisation programmes (and propose how this can be done) – for example as part of the State of Health in the EU cycle.

The expert group should provide guidance on, and where possible identify best practices relating to, the implementation of performance monitoring/assessment processes, as well as mechanisms for public reporting on vaccination policies and programmes.

RECOMMENDATION 5.2

Strengthen, and ensure sustainable approaches to, the financing of immunisation systems as an investment in *inter alia* public health, health system sustainability, healthy ageing, and economic performance.

Vaccination is a highly cost-effective preventative health intervention, which delivers broad benefits for people, health systems, and the economy. Investments in the strengthening of immunisation systems – in line with the recommendations in this report – have the potential to enhance vaccination coverage, uptake and equity, reduce the burden of VPDs, and thereby contribute to the resilience and sustainability of health systems.

Full implementation of MBVE's recommendations will require a strengthening of the resources available to immunisation systems, as well as mechanisms to ensure that those investments are sustained. Prior to the COVID-19 pandemic, most EU Member-States spent less than 0.5% of their health care budget on immunisation.[83,84] The pandemic inevitably led to an increase in immunisation-related expenditure, however this was focused on vaccination against COVID-19.

Health systems are now facing heightened resource pressures and constraints.[85] As the experience of post-2008 'fiscal consolidation' measures clearly demonstrated,[86] greater pressure on resources (in that case, public finances in general) creates a risk of short-sighted cuts to prevention spending (including immunisation) despite the harmful and counter-productive impacts that such measures may have in the longer-term. To ensure the sustainability of immunisation financing arrangements, mechanisms should be created to protect prevention spending from short-term pressures on health spending, recognising that such cuts would be likely to lead to greater pressure on health care resources in future.

The EU can play an important role in this area by promoting sustainable approaches to immunisation spending. For instance, as part of the European Semester process for economic and social policy coordination, the European Commission should take steps to monitor immunisation budgets and promote sustainable immunisation expenditure via its country-specific reports, recommendations, and policy guidance.

Immunisation budgets should also be determined on a multi-year basis. This would enable secure planning of vaccination programmes and related activities, whilst also reducing the risk of reductions in immunisation

spending at times of heightened resource pressure. In addition, immunisation spending should be premised upon a life-course approach and provide flexibility to introduce new vaccination programmes in response to new challenges and as new vaccines become available.

Summary of key actions per recommendation

Cross-cutting recommendations

Recommendation 5.1. Develop and implement national frameworks and processes to systematically monitor, assess, and publicly report on the performance of immunisation systems:

- To support the development of national performance assessment frameworks, a geographically balanced expert group should be tasked with producing a model framework, including key criteria for assessment and potential indicators, which national health authorities can use and adapt;
- The expert group should also seem to identify best practices for public reporting on the performance of vaccination policies and programmes;
- Consideration should be given to expanding EU-level monitoring on the performance of immunisation programmes, including by means of international comparisons based on standardised indicators.

Recommendation 5.2. Strengthen, and ensure sustainable approaches to, the financing of immunisation systems as an investment in *inter alia* public health, health system sustainability, healthy ageing, and economic performance:

- Implement mechanisms to protect prevention, including immunisation, spending from short-term cost-containment measures, recognising that cuts would likely lead to greater pressure on health care resources in future;
- Monitor prevention spending, including immunisation budgets, within the EU's European Semester process, and promote such spending as an investment in population health, healthy ageing, and the resilience of health systems.

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