BACKGROUND DOCUMENT

AIB Technical Meeting

Strategies for introducing and implementing vaccines for adults into National Immunization Programs in Europe: Exemplary Approaches and Key Insights

Prague, Czech Republic
18 – 19 April 2024

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Purpose of the background document
This pre-meeting background document contains a list of, AIB secretariat selected, abstracts/references from a PubMed Medline and grey literature search on the adult immunization related topic(s) of the technical meeting. The references are ranged by publication year (*most recent first, search from earliest dates available to March 2024*) and for each year in alphabetical order of the first author's name.
This document should guide you in the preparation of the meeting, it should not be considered as a complete literature review, but hopefully it will give an overview of what has been published on the topic(s) of the technical meeting. Inclusion of references in this document does not indicate that the AIB secretariat agrees with the content or correctness of the content.

Introduction

Meeting objectives

Provide updated information for the introduction and implementation of vaccines for adults into national immunization programs in European countries now and in the coming years.

- **Decision-making objectives**:
  - Explore and understand the evolving criteria influencing national decision-making processes for the introduction of vaccines for adults
  - Identify pivotal factors facilitating effective decision-making in different European countries
- **Implementation objectives: planning and managing**
  - Investigate the current status and evolution of vaccination programs for adults in EU
  - Analyze the implementation procedures of vaccines for adults, including setting goals and targets, defining the scope of application, identifying target populations, selecting introduction strategies, and managing the planning, scheduling, coordination, and associated costs
- **Monitoring and Evaluation objectives**:
  - Gain valuable insights from monitoring, evaluation, and impact assessment examples across European adult vaccination programs
  - Utilize lessons learned from real-world scenarios to enhance the efficiency and impact of adult vaccination introductions

Intended impact and target audience

In light of the increasing implementation of adult vaccines within lifelong vaccination initiatives across several EU countries, the AIB aims to convene to explore the latest strategies and valuable insights regarding the implementation of adult vaccines into National Immunization Programs. Through this meeting, the AIB seeks to gather diverse perspectives from various contexts, adult vaccines, and disciplines.

More information about the adult immunization board:
www.adultimmunizationboard.org

Part 1 Short agenda: AIB Technical Meeting

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	2.4 The UK decision on RSV vaccination in adults in the national immunization program	Harish Nair (Online)
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	2.6 On the Belgian decision on Herpes Zoster vaccination in the national immunization program	Isabel Leroux-Roels
Session 3: Implementation: planning and managing vaccine introduction	3.1 Implementation science: What is it and why should we care for implementing, adopting and maintaining vaccination practices	Michel Wensing

	3.2 The evolution and current status of Vaccination Programs for Adults in Europe	Helena Maltezou
	3.3 Control, Elimination and eradication goals for communicable diseases (focus on prevention targets of different adult vaccination programs)	Laila Khawar
	3.4 Scientific approaches toward improving cervical cancer elimination strategies	Laia Bruni
	3.5 How and why to set goals: lessons learned from the seasonal Influenza vaccination strategy	Kanta Subbarao
	3.6 Assessing and improving the accuracy of target population estimates for immunization coverage	Carolina Danovaro
	3.7 Target population of COVID-19 adult vaccination in Europe: evolution and current status	Hanna Nohynek
	3.8 Leveraging lessons learned from the COVID-19 vaccine rollout to improve the introduction and implementation of vaccines for adults and ensure their sustainability and resilience	Rebecca Forman
	3.9 Introduction of Respiratory Syncytial Virus Vaccines in Older Adults and Pregnant Women in the US (focus on organizational aspects)	Michael Melgar
	3.10 Introduction of pertussis vaccination for pregnant women in Denmark (focus on organizational aspects)	Ida Aase Glode Helmut
	3.11 Equipping healthcare professionals and students: The role of training for implementing adult vaccines	Kamel Senouci
	3.12 Communicating with the public about vaccines: Implementation considerations	Jacob Dag Berild
	3.13 The impact of pharmacist involvement on immunization uptake in Europe	Marleen Haems
Session 4: Monitoring – impact assessment	4.1 From insights to implementation: using behavioral and cultural insights to increase vaccine uptake	Tiina Likki

	4.2 Adult vaccination program as part of the life-time vaccination in Spain - its cost/investment	Laura Sánchez Cambronero
	4.3 Monitoring Influenza/COVID-19 Vaccine Effectiveness in Europe – I-MOVE/VEBIS	Esther Kissling
	4.4 Safety Monitoring of COVID-19 and other vaccines for adults in the EU	Jean-Michel Dogné

Part 2 Article References by session

Meeting title definitions

Adult immunization	Adult immunization refers to the administration of vaccines (active immunization) or antibodies (passive immunization) to individuals who are 18 years of age or older in order to protect them against various infectious diseases, before or after exposure. *Source: AIB secretariat*
Introduction	The act of introducing something: such as the act of bringing something into practice or use for the first time. *Source: Cambridge dictionary* Introducing a vaccine refers to a (sub)national recommendation and inclusion of a vaccine in immunization programs. *Source: AIB secretariat*
Implementation	The process of moving an idea from concept to reality. It refers to a building process rather than a design process. *Source: Cambridge dictionary* Implementing a vaccine involves the detailed process of defining targets, distribution, ensuring access, managing logistics, monitoring coverages, to achieve widespread vaccination. *Source: AIB Secretariat*
Implementation science	Implementation science is the scientific study of the methods to promote the uptake of research findings into routine healthcare in clinical, organisational, or policy contexts. *Source: Wensing M. Implementation science in healthcare: Introduction and perspective. Z Evid Fortbild Qual Gesundhwes. 2015;109(2):97-102. doi:10.1016/j.zefq.2015.02.014*

Session 1: Opening, Introduction and Objectives

Session 1: Opening, Introduction and Objectives	1.1 Welcome and Introduction of Adult Immunization Board (AIB)	Greet Hendrickx
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1.1 Welcome and Introduction of Adult Immunization Board (AIB)

Potential questions/outcomes: *What is the mission and objectives of the AIB? What is the operating procedure of the AIB? What is an AIB technical and country meeting? Who are the AIB advisors? How is the AIB funded?*

Related articles:
Source: Proposed by AIB secretariat

1.1.1 Pattyn J, Del Riccio M, Bechini A, Hendrickx G, Boccalini S, Van Damme P, Bonanni P. ***The Adult Immunization Board (AIB): A new platform to provide multidisciplinary guidelines for the implementation and optimization of adult immunization in Europe****. Vaccine. 2024 Jan 1;42(1)*

1.1.2 Pattyn J, Bonanni P; Adult Immunization Board working group. ***Assessing the health burden of vaccine-preventable infections in European adults: challenges and opportunities translated into action.*** *Euro Surveill. 2023 Nov;28(48):2300791.*

Abstract: **Background** - Accurate information on the health burden of vaccine-preventable infections (VPIs) is needed to support evidence-informed vaccine policy recommendations and programs. The first technical meeting of the Adult Immunization Board (AIB) was dedicated to the assessment of health burden evidence of VPIs in European adults. **Methods** - The AIB technical meeting, held in Antwerp, Belgium, in April 2023, convened international experts on health burden of VPIs. Presentations by subject-matter experts and group discussions were held based on pre-defined meeting objectives, covering multiple topics on the availability and use of health burden evidence of adult VPIs in Europe. **Results** - Both opportunities and challenges were identified. Key points discussed included (1) the need for further harmonization of Burden of Disease (BoD) methodologies for cross-study and cross-country comparison, (2) the recognition that health burden studies require significant resources and high-quality data, and therefore improved infectious disease surveillance and collaborative efforts in Europe, (3) the important geographical differences and inequalities found at all levels of adult immunization in Europe that are to be considered when interpreting BoD results, and (4) the importance of tailored communication of VPI health burden data to each stakeholder for an effective translation into vaccine policy decisions. **Conclusion** - Several European initiatives promote health BoD harmonized methodologies and/or capacity building collaborations that are to be further built upon. Although VPI health burden data is available and is a key component in the evidence-based decision-making processes behind immunization strategies, data gaps remain, particularly for certain diseases and at-risk populations.

1.1.3 ***Adult Immunization Board website****:*
https://www.adultimmunizationboard.org

All meeting materials (background document + slides + conclusions) are published on the AIB website. Summary meeting reports are published in peer-reviewed journals.

1.2 Introduction of the meeting definitions, framework and expected outcomes

Potential questions/outcomes: What does it mean introduction/implementation of vaccines? What do we understand if we talk about adult immunization? What can we learn from different approaches and key insights concerning the introduction, implementation, and evaluation of (new) vaccines for adults into existing national immunization programs and health systems in Europe? What are the expected outcomes of this technical meeting?

Related articles:
Source: Proposed by AIB secretariat

1.2.1 ***WHO. Essential Programme on Immunization. Introducing new vaccines***

To assist national policy-makers with decisions on whether a vaccine should be added to a national immunization programme and guidance on how to introduce a new vaccine, WHO has developed a general vaccine introduction document which includes information on planning and budgeting, monitoring implementation, evaluating impact, calculating vaccine supplies and managing the cold chain. Several vaccine and product-specific guidelines have been developed to facilitate introduction and WHO vaccine position papers are available for all new vaccines. Tools to conduct post-introduction evaluations as well as to support cold chain assessments to prepare countries for the increased space that will be required by the addition of new vaccines are also available. WHO, UNICEF and their partners recommended that national programme managers attempt to consolidate existing plans for immunization objectives into a single comprehensive multi-year plan (cMYP), including an evaluation of the costs and financing of that plan.

1.2.2 WHO Europe: ***Introducing new vaccines into national routine immunization programmes.***

Abstract: The decision of whether to add a new vaccine into a national immunization schedule is influenced by multiple factors, including affordability and relative cost-effectiveness, disease burden, availability and price of vaccines, and safety and suitability of available vaccine products for national programmes. Once the decision is made to add a new vaccine, several steps are needed to ensure its successful introduction and sustainable use. WHO/Europe supports Member States through the entire process of decision-making, introduction and management of new and underutilized vaccines and post-introduction monitoring. It facilitates the sharing of knowledge and good practice through meetings and workshops held across the Region and provides guidance and technical support to countries in collecting evidence and making informed decisions about whether, when and how to introduce new antigens. It helps educate medical professionals and academics about the new vaccine to ensure their support and acceptance, and with training of vaccinators. Post-introduction evaluations are also supported to assess the impact of new vaccines on disease burden and develop lessons learnt for future vaccine introductions.

1.2.3 WHO Europe. ***A field guide to qualitative research for new vaccine introduction: step-by-step instructions to help immunization programmes understand their target audiences before communicating about the introduction of a new vaccine***

Expanding a national routine immunization schedule to include a new vaccine is a positive step forward in reducing a country's burden of disease. This field guide is intended for staff of any national immunization programme planning to introduce a new vaccine. It guides the reader through a simple and step-wise process, building the skills needed to design and conduct qualitative formative research with key target groups, analyse the findings and utilize the outcomes by developing targeted communication activities.

1.2.4 WHO. ***New vaccine introduction: checklist for planning communication and advocacy: World Health Organization vaccine safety supporting document.*** *2017*

Overview Vaccine-safety-related events, and how we respond to them, can affect public trust in vaccines and health authorities. These events may or may not be linked to vaccines and include: adverse events following immunization (AEFIs), vaccination programme changes, or events that lead to increased negative public debate on the topic of immunization. The guidance in this library was developed based on lessons learned in countries, as well as scientific evidence and research in the fields of psychology, social and behavioural science, and communication. It is intended to help stakeholders prepare for and avert possible crises, as well as to minimize the negative impacts of any event that has the potential to erode trust. This document proposes a simple step-wise process for planning communication and advocacy for a new vaccine introduction. It includes suggested activities for four key stakeholder groups: health care workers influencers media public. Planning a detailed communication and advocacy strategy will help you: ensure stakeholder groups have a consistent knowledge of the facts and messages avoid or limit misperceptions; be prepared for vaccine safety events; facilitate high uptake of the new vaccine; build resilience against vaccine safety scares. Use the document for guidance and inspiration when introducing a new vaccine. Use it early in the process, as communication needs to be planned and initiated well in advance of the introduction date.

1.2.5 WHO, 2014. ***Principles and considerations for adding a vaccine to a national immunization programme*****.**

Abstract: This is a general guidance document that can be used as a reference for making decisions about and planning the introduction of a vaccine into a national immunization programme. It draws from the experiences of many countries that have introduced new vaccines. This document is an update of the 2005 WHO Vaccine Introduction Guidelines and it brings together the recommendations and guidance from many recent guidelines, tools and other documents on specific aspects of immunization and on specific vaccines. It provides updated information relevant to many vaccines that are being introduced into national immunization programmes now and in the coming years, including pneumococcal conjugate, rotavirus, meningococcal A, rubella, human papillomavirus (HPV), Japanese encephalitis, and inactivated polio vaccines. For more detailed information about a specific vaccine or aspect of immunization, decision-makers and planners should

consult vaccine-specific introduction guidelines and other tools developed by WHO, UNICEF and other partners. This document provides links to many of these guidelines and tools. Drawing upon recent research findings, this document also places new emphasis on the potential impact of vaccine introduction on the immunization programme and the overall health system. Suggestions are provided throughout the document on ways to minimize possible negative effects of introducing a vaccine on the immunization programme and health system, as well as ways to maximize the opportunities that a vaccine introduction can provide to strengthen these systems.

1.2.6 WHO. PanAmerican Health Organization (PAHO). 2010. ***Introduction and Implementation of New Vaccines: Field Guide***

Abstract: New, safe, and effective vaccines are licensed and introduced to the international market every year. Moreover, advances in biotechnology contribute to the improvement of current vaccines through new formulations of the vaccines in use. Although they are available, these vaccines have not yet become part of the official immunization schedule in many countries. Political authorities must often make decisions about public health interventions without the technical facts that would guarantee that their decisions are the most appropriate, in terms of cost-benefit, therefore ensuring the interventions' sustainability. Before a new vaccine is added to an immunization program, its feasibility and sustainability should be evaluated based on previously established technical criteria in order to determine whether it is actually a public health investment priority. This field guide has been adapted from the WHO report Vaccine Introduction Guidelines: Adding a Vaccine to a National Immunization Programme: Decision and Implementation.

Session 2: Deciding on the introduction of vaccines for adults: what are criteria for inclusion in a national vaccination program?

Session 2: Deciding on the introduction of vaccines for adults: what are the criteria for inclusion in a national vaccination program?	2.1 National decision-making for the introduction of new vaccines: a global systematic review, 2010-2020	Morgane Donadel Abigail Shefer
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2.1 National decision-making for the introduction of new vaccines: a global systematic review, 2010-2020

Potential questions/outcomes: *What are the evolving criteria influencing national decision-making processes for the introduction of vaccines for adults? What are the factors facilitating effective decision-making in different European countries?*

Related articles:
Source: Proposed by AIB secretariat

2.1.1 Henaff L, Zavadska D, Melgar M, Fihman J, Steffen C, Hombach J. ***The role of NITAGs in government decisions on vaccine use: insights from the Fifth Global NITAG Network meeting.*** *Lancet Infect Dis. 2024 Feb 16:S1473-3099(24)00078-1. doi: 10.1016/S1473-3099(24)00078-1. Epub ahead of print. PMID: 38373425.*

Abstract: not available

Key points discussed (relevant for the meeting:

- the introduction and use of a vaccine in a public health programme require a strategic decision resulting in a longterm commitment
- Governments rely on the expertise of independent technical expert panels such as National Immunization Technical Advisory Groups (NITAGs) to inform their decisions
- Evidence-based, independent, transparent, and timely recommendations made by NITAGs are instrumental to the success of both current and future immunization programmes
- Much welcomed progress in vaccine development and the increasing availability of new or improved vaccines pose a challenge for countries and NITAGs in terms of how to prioritise vaccine interventions and target populations while accounting for the limited financial and programmatic capacities.
- A survey conducted among Global NITAG Network representatives revealed the varying degrees of NITAG involvement in such decisions and emphasised the need to incorporate additional dimensions to the decision-making process. These included considerations relating to supply, political will, sustainability, demand, and opportunity cost, as part of an overarching approach to national strategic planning. Using tools such as multicriteria decision analysis could help to address these complexities.

2.1.2 Guillaume D, Meyer D, Waheed DE, Schlieff M, Muralidharan K, Chou VB, Limaye R. ***Factors influencing the prioritization of vaccines by policymakers in low- and middle-income countries: a scoping review.*** *Health Policy Plan. 2023 Mar 16;38(3):363-376. doi: 10.1093/heapol/czac092. PMID: 36315461.*

Abstract: Vaccination decision making in low- and middle-income countries (LMICs) has become increasingly complex, particularly in the context of numerous competing health challenges. LMICs have to make difficult choices on which vaccines to prioritize for introduction while considering a wide range of factors such as disease burden, vaccine impact, vaccine characteristics, financing and health care infrastructures, whilst adapting to each country's specific contexts. Our scoping review reviewed the factors that influence decision-making among policymakers for the introduction of new vaccines in LMICs. We identified the specific data points that are factored into the decision-making process for new vaccine introduction, whilst also documenting whether there have been any changes in decision-making criteria in new vaccine introduction over the last two

decades. A comprehensive database search was conducted using a search strategy consisting of key terms and Medical Subject Headings (MeSH) phrases related to policy, decision-making, vaccine introduction, immunization programmes and LMICs. Articles were screened following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. A total of 843 articles were identified, with 34 articles retained after abstract screening, full-text screening and grading with the mixed methods appraisal tool (MMAT). The Burchett framework for new vaccine introduction was used to identify indicators for vaccine-decision making and guided data extraction. Articles in our study represented a diverse range of perspectives and methodologies. Across articles, the importance of the disease, which included disease burden, costs of disease and political prioritization, coupled with economic factors related to vaccine price, affordability and financing were the most common criteria considered for new vaccine introduction. Our review identified two additional criteria in the decision-making process for vaccine introduction that were not included in the Burchett framework: **communication and sociocultural considerations.** Data from this review can support informed decision-making for vaccine introduction amongst policymakers and stakeholders in LMICs.

*2.1.3 Donadel M, Panero MS, Ametewee L, Shefer AM. **National decision-making for the introduction of new vaccines: A systematic review**, 2010-2020. Vaccine. 2021 Apr 1;39(14):1897-1909. doi: 10.1016/j.vaccine.2021.02.059. Epub 2021 Mar 6. PMID: 33750592; PMCID: PMC10370349.*

Abstract: **Background:** Competing priorities make using a transparent and evidence-based approach important when deciding to recommend new vaccines. We conducted a literature review to document the processes and frameworks for national decision-making on new vaccine introductions and explored which key features have evolved since 2010. **Methods**: we searched literature published on policymaking related to vaccine introduction from March 2010 to August 2020 in six databases. We screened articles for eligibility with the following exclusion criteria: non-human or hypothetical vaccines, the sole focus on economic evaluation or decision to adopt rather than policy decision-making. We employed nine broad categories of criteria from the 2012 review for categorization and abstracted data on the country, income level, vaccine, and other relevant criteria
Results: of the 3808 unique references screened, 116 met eligibility criteria and were classified as: a) framework of vaccine adoption decision-making (27), b) studies that analyse empirical data on or examples of vaccine adoption decision-making (45), c) theoretical and empirical articles that provide insights into the vaccine policymaking process (44 + 17 already included in the previous categories). Commonly reported criteria for decision-making were the burden of disease; vaccine efficacy/effectiveness, safety; impact on health and non-health outcomes; economic evaluation and cost-effectiveness of alternative interventions. Programmatic and acceptability aspects were not as often considered. Most (50; 82%) of the 61 articles describing the process of vaccine introduction policymaking highlighted the role of country, regional, or global evidence-informed recommendations and a robust national governance as enabling factors for vaccine adoption. **Conclusions:** The literature on vaccine adoption decision-making has expanded since 2010. We found that policymakers and expert advisory committee members (e.g., National Immunization Technical Advisory

Highlights

- Interest in strengthening evidence-based policymaking for vaccines has increased.
- Burden of disease, vaccine efficacy and safety, impact are used for decision-making.
- Programmatic, acceptability and equity aspects are not as often considered.
- Policymakers and advisory groups value interventions based on economic evaluations.
- Evidence-based recommendation, national governance are enablers for vaccine adoption.

Group [NITAG]) increasingly value interventions based on economic evaluations. The results of this review could guide discussions on evidence-informed immunization decision-making among country, sub-regional, and regional stakeholders.

*2.1.4 Houweling H, Verweij M, Ruitenberg EJ; **National Immunisation Programme Review Committee of the Health Council of the Netherlands. Criteria for inclusion of vaccinations in public programmes**. Vaccine. 2010 Apr 9;28(17):2924-31. doi: 10.1016/j.vaccine.2010.02.021.*

Abstract: As more and more new vaccines are developed and brought to the market, governments have to make decisions about which vaccinations to include in public programmes. This paper describes the experience in the Netherlands in developing a framework for assessing whether a vaccination should be included in the National Immunization Programme (NIP). Bearing in mind the public nature, the factors that determine a vaccine's suitability for inclusion in a communal vaccination programme have been translated into seven selection criteria, grouped under five thematic headings: **seriousness and extent of the disease burden, effectiveness and safety of the vaccination, acceptability of the vaccination, efficiency of the vaccination, and priority of the vaccination**. The seven criteria and the explanation of them provide a framework for the systematic examination of arguments for and against the inclusion and prioritisation of particular vaccinations. As an illustration, the vaccinations currently provided in the Netherlands through public programmes as well as 23 'candidate' vaccinations are assessed against the seven criteria. The proposed assessment framework including the selection criteria can take full account of the values and specificities as they may differ between situations and countries; **the transparency of the approach may help to clarify which elements of the assessment are pivotal in specific situations.** Using the criteria furthers a trustworthy, transparent and accountable process of decision-making about inclusion of new vaccinations in public vaccination programmes and may help to retain public confidence.

2.2 Vaccine delivery costing to support decision making

Potential questions/outcomes: *Why is it important to include vaccine delivery cost in economic evaluations on new vaccine introductions? How important are they to estimate the total cost of vaccine introduction? Which methodologies are used in new vaccine cost projection studies? How can future research and guidance better address the methodology of sampling, data collection, and analysis to support accurate vaccine-delivery cost projections?*

Related articles:

Source: Proposed by AIB secretariat

*2.2.1 Levin A, Yeung KHT, Hutubessy R. **Systematic review of cost projections of new vaccine introduction**. Vaccine. 2024;42(5):1042-1050. doi:10.1016/j.vaccine.2024.01.024*

Abstract: **Background**: A recent review of guidance documents on vaccine delivery costing revealed current guidance on cost projections for new vaccine introduction has gaps on methods of sampling, data collection and analysis. In preparation for updating the respective guidance, this systematic review was undertaken to qualitatively assess *methodologies used in new vaccine cost*

projection studies. This will inform researchers and stakeholders about the methods of new vaccine introduction cost projections for strategic directions in countries where cost data are not available. **Methods**: We systematically searched four search engines (PubMed, Cochrane Open Access, Mendeley and Google Scholar) for articles on cost projections for new vaccines published between 1999 and 15 June 2022. We developed inclusion and exclusion criteria for the selection of articles and analyzed the results using a PRISMA 2020 flow diagram. **Results**: Out of 1,108 articles identified, 171 met the criteria for inclusion in the study. Half of the articles were from high-income countries (50%), and most cost projections were part of cost-effectiveness analysis (84%). The most common source of cost data was secondary national information (43%), followed by author's assumptions (17%), secondary international information (14%), and primary data collection (7%). 19% of studies didn't include costs to deliver vaccines in their cost estimation. Among studies that included secondary vaccine delivery costs, approximately half only calculated vaccine administration costs (50%), while 35% included incremental system costs and 15% utilized ingredients data. Two thirds of the studies were conducted to inform policymakers of the cost-effectiveness or cost-benefit of introducing the vaccine. **Conclusions**: Half of the economic evaluations on new vaccine introductions only included partial vaccine delivery costs. Thus, total costs of vaccine introduction were often being underestimated in economic evaluations. This suggests that guidelines on economic evaluations and journals should recommend that authors include more extensive vaccine delivery costs in their studies.

2.2.2 Levin A, Boonstoppel L, Brenzel L, Griffiths U, Hutubessy R, Jit M, Mogasale V, Pallas S, Resch S, Suharlim C, Yeung KHT. ***WHO-led consensus statement on vaccine delivery costing: process, methods, and findings****. BMC Med. 2022 Mar 8;20(1):88. doi: 10.1186/s12916-022-02278-4.*

Abstract: Background: Differences in definitions and methodological approaches have hindered comparison and synthesis of economic evaluation results across multiple health domains, including immunization. At the request of the World Health Organization's (WHO) Immunization and Vaccines-related Implementation Research Advisory Committee (IVIR-AC), WHO convened an ad hoc Vaccine Delivery Costing Working Group, comprising experts from eight organizations working in immunization costing, to address a lack of standardization and gaps in definitions and methodological guidance. The aim of the Working Group was to develop a consensus statement harmonizing terminology and principles and to formulate recommendations for vaccine delivery costing for decision making. This paper discusses the process, findings of the review, and recommendations in the Consensus Statement. **Methods**: The Working Group conducted several interviews, teleconferences, and one in-person meeting to identify groups working in vaccine delivery costing as well as existing guidance documents and costing tools, focusing on those for low- and middle-income country settings. They then reviewed the costing aims, perspectives, terms, methods, and principles in these documents. Consensus statement principles were drafted to align with the Global Health Cost Consortium costing guide as an agreed normative reference, and consensus definitions were drafted to reflect the predominant view across the documents reviewed. **Results**: The Working Group identified four major workstreams on vaccine delivery costing as well as nine guidance documents and eleven costing tools for immunization costing. They found that some terms and principles were commonly defined while others were specific to individual workstreams. Based on these findings and extensive consultation, recommendations to harmonize differences in terminology and principles were made. **Conclusions**: Use of standardized principles and definitions outlined in the Consensus Statement within the immunization delivery costing community of practice can facilitate interpretation of economic evidence by global, regional, and

national decision makers. Improving methodological alignment and clarity in program costing of health services such as immunization is important to support evidence-based policies and optimal resource allocation. On the other hand, this review and Consensus Statement development process revealed the limitations of our ability to harmonize given that study designs will vary depending upon the policy question that is being addressed and the country context.

*2.2.3 Erondu NA, Ferland L, Haile BH, Abimbola T. **A systematic review of vaccine preventable disease surveillance cost studies**. Vaccine. 2019 Apr 17;37(17):2311-2321. doi: 10.1016/j.vaccine.2019.02.026.*

Abstract: Background: Planning and monitoring vaccine introduction and effectiveness relies on strong vaccine-preventable disease (VPD) surveillance. In low and middle-income countries (LMICs) especially, cost is a commonly reported barrier to VPD surveillance system maintenance and performance; however, it is rarely calculated or assessed. This review describes and compares studies on the availability of cost information for VPD surveillance systems in LMICs to facilitate the design of future cost studies of VPD surveillance. **Methods:** PubMed, Web of Science, and EconLit were used to identify peer-reviewed articles and Google was searched for relevant grey literature. Studies selected described characteristics and results of VPD surveillance systems cost studies performed in LMICs. Studies were categorized according to the type of VPD surveillance system, study aim, the annual cost of the system, and per capita costs. **Results:** Eleven studies were identified that assessed the cost of VPD surveillance systems. The studies assessed systems from six low-income countries, two low-middle-income countries, and three middle-income countries. The majority of the studies (n = 7) were conducted in sub-Saharan Africa and fifteen distinct VPD surveillance systems were assessed across the studies. Most studies aimed to estimate incremental costs of additional surveillance components and presented VPD surveillance system costs as mean annual costs per resource category, health structure level, and by VPD surveillance activity. Staff time/personnel cost represents the largest cost driver, ranging from 21% to 61% of total VPD surveillance system costs across nine studies identifying a cost driver. **Conclusions:** This review provides a starting point to guide LMICs to invest and advocate for more robust VPD surveillance systems. Critical gaps were identified including limited information on the cost of laboratory surveillance, challenges with costing shared resources, and missing data on capital costs. Appropriate guidance is needed to guide LMICs conducting studies on VPD surveillance system costs.

*2.2.4 Blau J, Hoestlandt C, D Clark A, Baxter L, Felix Garcia AG, Mounaud B, Mosina L. **Strengthening national decision-making on immunization by building capacity for economic evaluation: Implementing ProVac in Europe**. Vaccine. 2015 May 7;33 Suppl 1:A34-9. doi: 10.1016/j.vaccine.2014.12.073. PMID: 25919171.*

Abstract: Background: For many years, low- and middle-income countries have made efforts to strengthen national decision-making on immunization. The Pan American Health Organization (PAHO) ProVac Initiative was established to help expedite the use of evidence-based decision-making around new vaccine introduction. This initiative provides training in user-friendly cost-effectiveness models and supports the development of country-led economic evaluations. Due to the success of the ProVac Initiative in the Americas, and following requests from countries from outside the Americas, the Bill & Melinda Gates Foundation funded a two-year pilot effort to expand the initiative to other world regions. Called the ProVac International Working Group (IWG), this endeavor took place in 2012 and 2013. It was coordinated by PAHO and carried out in collaboration with several international partners, including the Agence de Médecine Préventive (AMP), London

School of Hygiene & Tropical Medicine (LSHTM), Program for Appropriate Technology in Health, Sabin Vaccine Institute, United States Centers for Disease Control and Prevention, and the World Health Organization (WHO). In the WHO European Region, technical support was provided by AMP, in close collaboration with the WHO Regional Office for Europe and other ProVac IWG partners. **Methods:** In 2012, AMP, the WHO Regional Office for Europe, and other partners held a training workshop in Dubrovnik, Croatia, for 31 participants from four countries of the WHO European Region. The aim was to train health professionals in standard methods of economic evaluation and to assess regional demand for economic studies to support decision-making on immunization. AMP and the other organizations also supported four national cost-effectiveness studies in the WHO European Region. The assistance included country visits and support over a period of six months, the establishment of multidisciplinary teams of experts, ongoing training on the TRIVAC decision-support model for new-vaccine economic analysis, review of local evidence, recommending key data inputs, and support in presenting results to national decision makers. **Results:** National cost-effectiveness studies were conducted in four countries: Albania (rotavirus vaccine [RV]), Azerbaijan (pneumococcal conjugate vaccine [PCV]), Croatia (PCV), and Georgia (PCV). All four countries improved their estimates of the burden of disease preventable by the new vaccines. National advisory bodies and ministries of health obtained economic evidence that helped Albania and Croatia to make decisions on introducing the new vaccines. Azerbaijan and Georgia used economic evidence to confirm previously made preliminary decisions to introduce PCV and make corresponding financial commitments. The study helped Albania to obtain access to affordable prices for rotavirus vaccines through participation in the UNICEF procurement mechanism for middle-income countries. Croatia was able to define the PCV price that would make its introduction cost-effective and can use this figure as a basis for price negotiations. **Discussion:** Despite some challenges due to competing national priorities, tight budgets for immunization, and lack of available national data, the ProVac IWG helped to build capacity of national health professionals, support decision-making for the introduction of new vaccines, and promote utilization of economic evidence for making decisions on immunization. This type of strong collaboration among international partners and countries should be scaled up, given that many other countries in the WHO European Region have expressed interest in receiving assistance from the ProVac IWG.

2.2.5 Hutubessy R, Henao AM, Namgyal P, Moorthy V, Hombach J. ***Results from evaluations of models and cost-effectiveness tools to support introduction decisions for new vaccines need critical appraisal.*** *BMC Med. 2011 May 12;9:55. doi: 10.1186/1741-7015-9-55. PMID: 21569407; PMCID: PMC3117725.*

Abstract: The World Health Organization (WHO) recommends that the cost-effectiveness (CE) of introducing new vaccines be considered before such a programme is implemented. However, in low- and middle-income countries (LMICs), it is often challenging to perform and interpret the results of model-based economic appraisals of vaccines that benefit from locally relevant data. As a result, WHO embarked on a series of consultations to assess economic analytical tools to support vaccine introduction decisions for pneumococcal, rotavirus and human papillomavirus vaccines. The objectives of these assessments are to provide decision makers with a menu of existing CE tools for vaccines and their characteristics rather than to endorse the use of a single tool. The outcome will provide policy makers in LMICs with information about the feasibility of applying these models to inform their own decision making. We argue that if models and CE analyses are used to inform decisions, they ought to be critically appraised beforehand, including a transparent evaluation of their structure, assumptions and data sources (in isolation or in comparison to similar tools), so that decision makers can use them while being fully aware of their robustness and limitations.

2.3 Role of the National Immunisation Technical Advisory Groups in the decision-making process on vaccine recommendations

2.3.1 Martinelli D, Quattrone F, Fortunato F, Di Maggio E, Filia A, Rota MC, Lopalco PL, Prato R. **Role of the National Immunisation Technical Advisory Groups in 13 European countries in the decision-making process on vaccine recommendations**. Euro Surveill. 2023 Oct;28(43):2300131.

Abstract - In Europe, National Immunisation Technical Advisory Groups (NITAGs) were established in most countries to promote evidence-informed decision-making in introducing new or improved vaccines or changing recommendations for existing ones. Still, the role, activities and outcomes of NITAGs have not been optimally implemented across Europe. Within the European Joint Action on Vaccination (EU-JAV), we conducted a survey to collect information on decision-making process including the main criteria for the introduction of new vaccines or changes to recommendations on their use. Between December 2021 and January 2022, 13 of the 28 European countries invited participated in an online survey. The criteria ranked as most relevant were disease burden and availability of financial resources. Only one country specified that the NITAG recommendations were binding for the government or the health authority. Vaccinations more often reported for introduction or recommendation changes were those against herpes zoster, influenza, human papillomavirus infection, pneumococcal and meningococcal disease. The planned changes will mainly address children and adolescents (2-18 years) and adults (≥ 45-65 years). Our findings show potential overlaps in the activities of NITAGs between countries; and therefore, collaboration between NITAGs may lead to optimisation of the workload and better use of resources.

2.4 The UK decision on RSV vaccination in the national immunization program

Potential questions/outcomes: *What will be the main criteria for assessing the potential introduction of RSV vaccination for older adults and pregnant women in Sweden/UK? What data will be taken into consideration? Are there already plans for the proposed implementation program? What preparation is planned to be done before implementing a new vaccine: including research, education, price negotiation, supply, logistics?*

Related articles:

Source: Proposed by AIB secretariat

2.4.1 ***The Journal of Infectious Diseases. Volume 229, Issue Supplement 1, 15 March 2024 Preparing Europe for Introduction of Immunization Against RSV: Bridging the Evidence and Policy Gap. .***

Abstract: Not available

2.4.2 UK Parliament. House of Lords Library. ***Adding new vaccinations to the NHS national immunisation programme.*** *January 2024.*

Summary: The NHS national immunisation programme in England offers vaccinations against a range of illnesses. The Joint Committee on Vaccination and Immunisation recommends additions to the programme. The House of Commons Health and Social Care Committee has noted that the pace of adopting new vaccines can be affected by several factors, including product availability. The government's

new vaccination strategy seeks to address some of these concerns, as well as focusing on increasing vaccine uptake.

*2.4.3 Independent report: **Respiratory syncytial virus (RSV) immunisation programme for infants and older adults: JCVI full statement**, 11 September 2023*

Introduction: The Joint Committee on Vaccination and Immunisation (JCVI) is an expert scientific advisory committee which advises the UK government on matters relating to vaccination and immunisation. JCVI has been monitoring products in development for the prevention of respiratory syncytial virus (RSV) disease for several years. Since January 2023, JCVI has been actively reviewing the latest evidence on immunisation products in the late stages of development or which are newly licensed which could protect both newborns or infants and older adults against RSV infection and disease. A series of meetings of the JCVI RSV subcommittee have taken place in 2023. JCVI has reviewed evidence from manufacturers on the efficacy, safety and duration of protection of these immunisation products alongside clinical and epidemiological data on the burden of RSV in infants and older adults. JCVI has also considered programme delivery including ensuring high uptake in different population groups and clinical settings. Modelling of the impact and cost effectiveness of potential immunisation strategies by the London School of Hygiene and Tropical Medicine (LSHTM) has been used to inform JCVI's advice, along with second opinion modelling by other expert academic groups. Cost effectiveness is a key factor in JCVI's considerations to ensure that the finite resources of the health service are used to maximise the health of the population. JCVI recognises that there is a significant burden of RSV illness in the UK population and unmet public health need which has a considerable impact on NHS services during the winter months. Following the 7 June 2023 meeting, JCVI issued a short statement of its advice on a RSV immunisation programme. JCVI advised that a RSV immunisation programme that is cost effective should be developed for both infants and older adults. This comprehensive statement provides details on the evidence considered and the key discussions and conclusions of the committee.

*2.4.4 Atkins KE, Hodgson D. **Vaccination of Older Adults Against Respiratory Syncytial Virus: The Final Pieces of the Puzzle**. Clin Infect Dis. 2023;77(3):490-491. doi:10.1093/cid/ciad162*

Abstract: not available

*2.4.5 Martinón-Torres F, Navarro-Alonso JA, Garcés-Sánchez M, Soriano-Arandes A. **The Path Towards Effective Respiratory Syncytial Virus Immunization Policies: Recommended Actions.** Arch Bronconeumol. 2023 Sep;59(9):581-588. English, Spanish. doi: 10.1016/j.arbres.2023.06.006.*

Abstract: The respiratory syncytial virus (RSV) causes a substantial burden worldwide. After over six decades of research, there is finally a licensed immunization option that can protect the broad infant population, and other will follow soon. RSV immunization should be in place from season 2023/2024 onwards. Doing so requires thoughtful but swift steps. This paper reflects the view of four immunization experts on the efforts being made across the globe to accommodate the new immunization options and provides recommendations organized around five priorities: (I) documenting the burden of RSV in specific populations; (II) expanding RSV diagnostic capacity in clinical practice; (III) strengthening RSV surveillance; (IV) planning for the new preventive options; (V) achieving immunization targets. Overall, Spain has been a notable example of converting RSV

prevention into a national desideratum and has pioneered the inclusion of RSV in some of the regional immunization calendars for infants facing their first RSV season.

2.4.6 ***WHO. SAGE Working Group on Respiratory Syncytial Virus (RSV) Immunization Products (established December 2023)***

Abstract: not available

2.4.7 Redondo E, Rivero-Calle I, Mascarós E, et al. ***Respiratory Syncytial Virus Vaccination Recommendations for Adults Aged 60 Years and Older: The NeumoExperts Prevention Group Position Paper****. Arch Bronconeumol. 2024;60(3):161-170. doi:10.1016/j.arbres.2024.01.004*

Abstract: Respiratory syncytial virus (RSV) is a major cause of respiratory tract infections in adults, particularly older adults and those with underlying medical conditions. Vaccination has emerged as a potential key strategy to prevent RSV-related morbidity and mortality. This Neumoexperts Prevention (NEP) Group scientific paper aims to provide an evidence-based positioning and RSV vaccination recommendations for adult patients. We review the current literature on RSV burden and vaccine development and availability, emphasising the importance of vaccination in the adult population. According to our interpretation of the data, RSV vaccines should be part of the adult immunisation programme, and an age-based strategy should be preferred over targeting high-risk groups. The effectiveness and efficiency of this practice will depend on the duration of protection and the need for annual or more spaced doses. Our recommendations should help healthcare professionals formulate guidelines and implement effective vaccination programmes for adult patients at risk of RSV infection now that specific vaccines are available.

2.4.8 Zeevat F, Luttjeboer J, Paulissen JHJ, et al. ***Exploratory Analysis of the Economically Justifiable Price of a Hypothetical RSV Vaccine for Older Adults in the Netherlands and the United Kingdom****. J Infect Dis. 2022;226(Suppl 1):S102-S109. doi:10.1093/infdis/jiab118*

Abstract: Background: In older adults, the burden of respiratory syncytial virus (RSV) resembles that of influenza and may even be considered worse due to the lack of preventive interventions. This study was performed to identify the available literature on RSV infection in older adults, and to provide updated exploratory results of the cost-effectiveness of a hypothetical RSV vaccine in the Netherlands and the United Kingdom. **Methods**: A literature search was performed in Medline and EMBASE on 11 November 2019, which served as input for a static decision-tree model that was used to estimate the EJP, for an RSV vaccine applying different willingness-to-pay (WTP) thresholds. WTP thresholds applied were €20 000 and €50 000 per quality-adjusted life-year for the Netherlands, and £20 000 and £30 000 per quality-adjusted life-year for the United Kingdom. Analyses were—in line with country-specific guidelines—conducted from a societal perspective for the Netherlands and a third-party payer perspective for the United Kingdom. The robustness of the cost-effectiveness results was tested in sensitivity analysis. **Result**: After screening the literature, 3 studies for the Netherlands and 6 for the United Kingdom remained to populate the country-specific models. In the base case analysis for the Netherlands (mean RSV incidence, 3.32%), justifiable vaccine prices of €16.38 and €50.03 were found, based on applying the lower and higher WTP thresholds, respectively. Similarly, for the United Kingdom (mean incidence, 7.13%), vaccine prices of £72.29 and £109.74 were found, respectively. **Conclusion**: RSV vaccination may well be cost-effective in both the Netherlands

and the United Kingdom, depending on the exact RSV incidence, vaccine effectiveness and price. However, sensitivity analysis showed that the results were robust based on varying the different parameter estimates and assumptions. With RSV vaccines reaching the final stages of development, a strong need exists for cost-effectiveness studies to understand economically justifiable pricing of the vaccine.

2.5 The German decision on Pneumococcal vaccination in adults in the national immunization program

Potential questions/outcomes: *What were the criteria for the inclusion of PCV and recent changes in PCV programs (e.g. schedules, vaccines) in Germany? What was the impact (e.g. coverage)? What can we expect in the future with potential newer PCV vaccines coming on the market, such as PCV21 (V116, of Merck) and PCV24 (GSK)?*

Related articles:

Source: Proposed by AIB secretariat

*2.5.1 Nakashima K, Fukushima W. **Strategies for pneumococcal vaccination in older adults in the coming era**. Hum Vaccin Immunother. 2024 Dec 31;20(1):2328963. Epub 2024 Mar 22. PMID: 38517265.*

Abstract - Pneumonia, predominantly caused by Streptococcus pneumoniae, remains a leading cause of global mortality. The 23-valent Pneumococcal polysaccharide vaccine (PPSV23) and conjugate vaccines (PCVs) are vital measures to fight against it. This paper discussed the changes in pneumococcal vaccination strategies, particularly for older adults, as vaccine effectiveness and epidemiological patterns shift. While PPSV23 maintains effectiveness against invasive pneumococcal disease (IPD), its effectiveness against pneumococcal pneumonia is declining. Conversely, PCV13 consistently demonstrates effectiveness against both IPD and pneumonia. Consequently, the US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommends using PCVs, notably PCV20 and PCV15, over PPSV23. Japanese studies indicate a change in the efficacy/effectiveness of PPSV23 following PCV introduction in children, likely owing to serotype replacement and herd immunity. Additionally, recent data reveals a plateau in the reduction of PCV13 and PPSV23-covered serotypes, posing a challenge to current strategies. This paper indicates a paradigm shift in pneumonia management, acknowledging its chronic nature and potential to exacerbate other diseases. The future of pneumococcal vaccination lies in broader serotype coverage through PCVs, adapting to serotype changes driven by childhood vaccination programs. Furthermore, continuous research and vaccine development are crucial in this evolving field.

*2.5.2 Arya S, Norton N, Kaushik P, Brandtmüller A, Tsoumani E. **Recent changes to adult national immunization programs for pneumococcal vaccination in Europe and how they impact coverage: A systematic review of published and grey literature**. Hum Vaccin Immunother. 2023 Dec 15;19(3):2279394. doi: 10.1080/21645515.2023.2279394.*

Abstract: Despite widespread use of pneumococcal vaccines throughout Europe, the burden of pneumococcal disease (PD) in adults is considerable. To mitigate this burden, National Immunization Technical Advisory Groups (NITAGs) and Health Technology Assessment (HTA) agencies assess the value of different vaccine schedules for protecting against PD. The aim of this review was to assess the evidence and rationales used by NITAGs/HTA agencies, when considering recent

changes to National Immunization Programs (NIPs) for adults, and how identified changes affected vaccine coverage rates (VCRs). A systematic review was conducted of published literature from PubMed® and Embase®, and gray literature from HTA/NITAG websites from the last 5 y, covering 31 European countries. Evidence related to NIP recommendations, epidemiology (invasive PD, pneumonia), health economic assessments and VCRs were collected and synthesized. Eighty-four records providing data for 26 countries were identified. Of these, eight described explicit changes to NIPs for adults in seven countries. Despite data gaps, some trends were observed; first, there appears to be a convergence of NIP recommendations in many countries toward sequential vaccination, with a pneumococcal conjugate vaccine (PCV), followed by pneumococcal polysaccharide vaccine 23. Second, reducing economic or healthcare burden were common rationales for implementing changes. Third, most health economic analyses assessing higher-valency PCVs for adults found its inclusion in NIPs cost-effective. Finally, higher coverage rates were seen in most cases where countries had expanded their NIPs to cover at-risk populations. The findings can encourage agencies to improve surveillance systems and work to reach the NIP's target populations more effectively.

2.5.3 Kobayashi M, Cohen AL, Poehling KA. ***The Present and Future of the Adult Pneumococcal Vaccine Program in the United States.*** *NEJM Evid. 2023;2(11):EVIDra2300221. doi:10.1056/EVIDra2300221*

Abstract: Streptococcus pneumoniae (pneumococcus) is a common cause of bacterial respiratory infections, such as pneumonia, sinusitis, and acute otitis media, and it also causes invasive diseases (i.e., infection in a normally sterile site), such as meningitis and bacteremia, leading to substantial morbidity and mortality. Before the coronavirus disease 2019 (Covid-19) pandemic, it is estimated that ≥100,000 pneumococcal pneumonia hospitalizations, ≥30,000 invasive pneumococcal disease cases, and 3000 invasive pneumococcocal disease deaths occurred among U.S. adults in a year. Resurgence of non-SARS-CoV-2 respiratory virus infections was reported in the United States in late 2022, and preliminary invasive pneumococcocal disease incidence in late 2022 exceeded the pre–Covid-19 baseline incidence in children and young adults (Centers for Disease Control and Prevention Active Bacterial Core surveillance, unpublished data). Effective pneumococcal vaccines are available and have been used in many countries. Although children have been the focus of pneumococcal vaccination programs globally, pneumococcal vaccines have also been recommended for adults in the United States for more than 40 years. The Advisory Committee on Immunization Practices updated their adult pneumococcal vaccine recommendations in October 2022, the fifth time since 2012 (Table 1), with the goal of increasing population-level protection against pneumococcal disease as well as reducing disparities in pneumococcal disease burden among those at increased risk. What have we learned from the U.S. adult pneumococcal vaccine program, what are the remaining gaps, and how can we address these gaps in considering future U.S. pneumococcal vaccine recommendations?

2.5.4 Noharet-Koenig R, Lasota K, Faivre P, Langevin E. ***Evolution of Pneumococcal Vaccine Recommendations and Criteria for Decision Making in 5 Western European Countries and the United States.*** *MDM Policy Pract. 2023;8(1):23814683231174432.*

Abstract: Objectives: Pneumococcal vaccine recommendations have become increasingly complex. This study aims to understand how national immunization technical advisory groups (NITAGs) and health technology assessment (HTA) agencies of 5 European countries and the United States formed their pneumococcal vaccine recommendations, by providing reviewed evidence and key drivers for new

recommendations. **Methods:** Centers for Disease Control and Prevention, European Centre for Disease Prevention and Control, and National Health Authorities Web sites were screened to capture the evolution of pneumococcal recommendations. A narrative review was conducted on NITAGs and HTA bodies' Web sites. Assessments of pneumococcal vaccines published from 2009 to 2022 were included. **Results:** Thirty-four records were identified including 21 assessments for risk groups, 17 for elderly, and 12 for children. Burden of disease and vaccine characteristics were almost systematically reviewed during assessments. All 6 countries recommended the use of higher-valent pneumococcal vaccine (PCV; i.e., PCV10 and PCV13) in childhood vaccination programs, given their broader serotype coverage and their comparable profile to PCV7. PCV13 was progressively added to the vaccine schedule (in addition to polysaccharide vaccine) in at least the high-risk group, given the high burden in this population and expected additional benefits of PCV13. For the elderly, unlike the United States, European countries issued negative recommendation for PCV13 routine use because of substantial herd effects from childhood vaccination program making PCV13 likely not cost-effective. **Conclusions:** This research provides an overview of decision-making processes for higher-valent PCVs recommendations and could be of interest to anticipate the place of next generation of PCVs in the vaccination landscape. **Highlights:** By describing evidence-based criteria for decision making, this study emphasizes the framework analysis of NITAGs and HTA bodies when assessing pneumococcal vaccines and demonstrates that variation exists between countries and also according to population evaluated. While the burden of disease and immunogenicity/efficacy data were almost systematically reviewed by national stakeholders, economic assessments were reported to a lesser extent but played a major role in the limited use of PCV13 in the adult population.

2.5.5 Bonnave, C., Mertens, D., Peetermans, W. et al. ***Adult vaccination for pneumococcal disease: a comparison of the national guidelines in Europe****. Eur J Clin Microbiol Infect Dis 38, 785–791 (2019). https://doi.org/10.1007/s10096-019-03485-3*

Abstract: Pneumococcal disease constitutes a major global health problem. Adults aged over 50 years and younger adults with specific chronic health conditions are at risk for invasive pneumococcal disease, associated with substantial morbidity and mortality. In Europe, two vaccine types are used in adults for pneumococcal immunization: pneumococcal polysaccharide vaccine (PPV23) and pneumococcal conjugate vaccine (PCV13). To provide an overview and to compare the national guidelines for pneumococcal immunization for adults in Europe. In November 2016, national guidelines on pneumococcal vaccination for adults of 31 European countries were obtained by Google search, the website of European Centre for Disease Prevention and Control, and contacting public health officials. In our analysis, we distinguished between age-based and risk-based guidelines. In October 2017, we used the same method to retrieve guideline updates. We observed great variability regarding age, risk groups, vaccine type, and use of boosters. In age-based guidelines, vaccination is mostly recommended in adults aged over 65 years using PPV23. Boosters are generally not recommended. An upper age limit for vaccination is reported in three countries. In the immunocompromised population, vaccination with both vaccines and administration of a booster is mostly recommended. In the population with chronic health conditions, there is more heterogeneity according vaccine type, sequence, and administration of boosters. Asplenia is the only comorbidity for which all countries recommend vaccination. The great variability in European pneumococcal vaccination guidelines warrants European unification of the guidelines for better control of pneumococcal disease.

2.6 The Belgian decision on Herpes Zoster vaccination in the national immunization program

Potential questions/outcomes: *What were the main criteria for not including Herpes Zoster vaccination in the national immunization program in Belgium? What data were taken into consideration? What is the current status and the future perspectives for herpes zoster and other vaccines for adults?*

Related articles:
Source: Proposed by AIB secretariat

*2.6.1 Federal Public Service Health, Food Chain Safety and Environment. **Report of the Superior Health Council no. 9684: Vaccination against Herpes Zoster**. 2022.*

Introduction: The varicella zoster virus (VZV) is responsible for two distinct clinical syndromes. Primary VZV-infection induces varicella (chickenpox), an infectious skin disease that typically affects children. There are several (monovalent and combined) vaccine formulations against primary VZV-infection available on the Belgian market. For the guidelines on preventing primary VZV-infections in children, we refer to advisory report No. 9212 of the Superior Health Council (SHC). VZV can reactivate after several decades and cause herpes zoster (HZ, shingles). This localised or generalised, painful skin eruption mainly affects older adults. Around one third of the population will experience HZ in the course of their lives. Postherpetic neuralgia (PHN) is a complication of HZ that can cause chronic pain for several months or even years also with increasing incidence in the older population. In Belgium, a live attenuated vaccine Zostavax® (MSD) and a non-live adjuvanted recombinant subunit vaccine against HZ, Shingrix® (GSK) are registered. This report sets out the recommendations vaccination against HZ and PHN and is an update of the previous report SHC 9209. 1 The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued. Superior Health Council www.shc-belgium.be – 2 – II **Conclusions**: Findings from clinical and post-marketing studies on the adjuvanted recombinant subunit vaccine against HZ (Shingrix) indicate that: - ZOE-50 study (NEJM 2015) with a VE of 96 % after a 4 year period. Results were confirmed among old persons aged over 70 years, (ZOE-70 study), even in an old frail population. - Robust immunologic responses were found in immunocompromised patients along with an acceptable safety profile. - Recombinant HZ subunit vaccine reduces also the risk of PHN (VE of 89-91%). - Results were confirmed in real-world studies showing VE between 70-86 %. - Results of VE are higher for recombinant HZ subunit vaccines compared to lived attenuated HZ vaccine. - Intermediate results of long-term follow-up studies are showing that VE remains high (over 90 %) after 7 years of follow-up. - Vaccination against HZ is safe. Injection site reactions and mild to moderate systemic reactions were the most reported side effects. Serious adverse events were similar between the vaccination and the control group. **Recommendation**: The SHC recommends vaccination against Herpes Zoster with a non-live adjuvanted recombinant HZ subunit vaccine (2 dose regimen) for: - Immunocompetent adults aged ≥ 60 years. - Immunocompromised patients, including those under immunosuppressive therapy aged ≥ 16 years and also patients under treatment with anti-JAK therapy (SHC 9158 – chapter 5). Co-administration with the seasonal influenza vaccine or pneumococcal vaccine (PPV23 or PCV13) or dTpa is safe. The SHC is aware of the high cost of the vaccine at this moment and suggests to take into account cost-effectiveness studies and the results of the ongoing Health Technology Assessment of the Shingrix vaccine by KCE (results expected later this year).

*2.6.2 Belgian Health Care Knowledge Center. **EVALUATION OF SHINGRIX VACCINE AGAINST HERPES ZOSTER**. Report. 2022.*

Abstract: not available.

*2.6.3 Pieters Z, Ogunjimi B, Beutels P, Bilcke J. **Cost-Effectiveness Analysis of Herpes Zoster Vaccination in 50- to 85-Year-Old Immunocompetent Belgian Cohorts: A Comparison between No Vaccination, the Adjuvanted Subunit Vaccine, and Live-Attenuated Vaccine**. Pharmacoeconomics. 2022 Apr;40(4):461-476. doi: 10.1007/s40273-021-01099-2.*

Abstract: **Background**: A new adjuvanted subunit vaccine (HZ/su), with higher vaccine efficacy than live-attenuated vaccine (ZVL), has been licensed in Europe since March 2018. Therefore, Belgian decision-makers might need to re-assess their recommendations for vaccination against herpes zoster (HZ). **Methods**: We conducted a cost-effectiveness analysis, using a Markov decision tree, of vaccinating 50- to 85-year-old immunocompetent Belgian cohorts with no vaccination, HZ/su, ZVL, and ZVL with booster after 10 years. Due to the uncertainty in vaccine waning of HZ/su vaccine beyond 4 years, we used a logarithmic and 1-minus-exponential function to model respectively a long and short duration of protection. We used a lifetime horizon and implemented the health care payer perspective throughout the analysis. **Results**: HZ/su had the greatest impact in avoiding health and economic burden. However, it would never become cost-effective at a willingness-to-pay threshold of €40,000 per quality-adjusted life year (QALY) gained at its market price set by the manufacturer in the USA. Depending on the waning function assumed for HZ/su, the price per dose needs to drop 60% or 83% such that vaccination with HZ/su, assuming respectively a long or short duration of protection, would become cost-effective in 50- and 80-year-old individuals. At €40,000 per QALY gained, ZVL or ZVL with booster was never found cost-effective compared with HZ/su, even if only administration cost was considered. **Conclusion**: HZ/su is cost-effective in the 50-year-old age cohort at the unofficial Belgian threshold of €40,000 per QALY gained, if its price drops to €55.40 per dose. This result is, however, very sensitive to the assumed duration of protection of the vaccine, and the assumed severity and QALY loss associated with HZ and post-herpetic neuralgia (PHN).

- 2.6.3.1 Giannelos N, Nishimwe ML, Lecrenier N. **Comment on "Cost-Effectiveness Analysis of Herpes Zoster Vaccination in 50- to 85-Year-Old Immunocompetent Belgian Cohorts: A Comparison between No Vaccination, the Adjuvanted Subunit Vaccine, and Live-Attenuated Vaccine"**. Pharmacoeconomics. 2022;40(10):1011-1012. doi:10.1007/s40273-022-01184-0
- 2.6.3.2 Bilcke J, Beutels P. **Authors' Reply to Comment on "Cost-Effectiveness Analysis of Herpes Zoster Vaccination in 50- to 85-Year-Old Immunocompetent Belgian Cohorts: A Comparison Between No Vaccination, the Adjuvanted Subunit Vaccine, and Live-Attenuated Vaccine"**. Pharmacoeconomics. 2022;40(10):1013-1014. doi:10.1007/s40273-022-01186-y

*2.6.4 Bilcke J, Marais C, Ogunjimi B, Willem L, Hens N, Beutels P. **Cost-effectiveness of vaccination against herpes zoster in adults aged over 60 years in Belgium**. Vaccine. 2012;30(3):675-684. doi:10.1016/j.vaccine.2011.10.036*

Abstract: Aim: To assess the cost-effectiveness of vaccinating all or subgroups of adults aged 60 to 85 years against herpes zoster. Methods: A deterministic compartmental static model was developed (in freeware R), in which cohorts can acquire herpes zoster according to their age in years. Surveys and database analyses were conducted to obtain as much as possible Belgian age-specific estimates for input parameters. Direct costs and Quality-Adjusted Life-Year (QALY) losses were estimated as a function of standardised Severity Of Illness (SOI) scores (i.e. as a function of the duration and severity of herpes zoster disease). Results: Uncertainty about the average SOI score for a person with herpes zoster, the duration of protection from the vaccine, and the population that can benefit from the vaccine, exerts a major impact on the results: under assumptions least in favour of vaccination, vaccination is not cost-effective (i.e. incremental cost per QALY gained >€48,000 for all ages considered) at the expected vaccine price of €90 per dose. At the same price, but under assumptions most in favour of vaccination, vaccination is found to be cost-effective (i.e. incremental cost per QALY gained <€5500 for all ages considered). Vaccination of age cohort 60 seems more cost-effective than vaccination of any older age cohort in Belgium. Discussion: If the vaccine price per dose drops to €45, HZ vaccination of adults aged 60-64 years is likely to be cost-effective in Belgium, even under assumptions least in favour of vaccination. Unlike previous studies, our analysis acknowledged major methodological and model uncertainties simultaneously and presented outcomes for 26 different target ages at which vaccination can be considered (ages 60-85).

Session 3: Implementation: planning and managing vaccine introduction

Session 3: Implementation: planning and managing vaccine introduction	3.1 Implementation science: What is it and why should we care for implementing, adopting and maintaining vaccination practices	Michel Wensing
	3.2 The evolution and current status of Vaccination Programs for Adults in Europe	Helena Maltezou
	3.3 Control, Elimination and eradication goals for communicable diseases (focus on prevention targets of different adult vaccination programs)	Laila Khawar
	3.4 Scientific approaches toward improving cervical cancer elimination strategies	Laia Bruni
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	3.7 Target population of COVID-19 adult vaccination in Europe: evolution and current status	Hanna Nohynek
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	3.10 Introduction of pertussis vaccination for pregnant women in Denmark (focus on organizational aspects)	Ida Aase Glode Helmut
	3.11 Equipping healthcare professionals and students: The role of training for implementing adult vaccines	Kamel Senouci
	3.12 Communicating with the public about vaccines: Implementation considerations	Jacob Dag Berild
	3.13 The impact of pharmacist involvement on immunization uptake in Europe	Marleen Haems

3.1 Implementation science: What is it and why should we care for implementing, adopting and maintaining vaccination practices

Potential questions/outcomes:

What is implementation science? Why is it important for the proper introduction and implementation of vaccines? As the adult vaccination choices get more crowded, what are our implementation strategies and key challenges? How can the principles of implementation science be used to overcome barriers identified related to vaccine delivery?

Related articles:
Source: Proposed by AIB secretariat

3.1.1 Adamu AA, Ndwandwe D, Jalo RI, Wiysonge CS. ***Positioning implementation science in national immunization programmes to improve coverage equity and advance progress toward Immunization Agenda 2030: An urgent global health imperative.*** *Hum Vaccin Immunother. 2024 Dec 31;20(1):2331872.*

Abstract - Despite the availability of effective vaccines for preventing common childhood infectious diseases, there is still significant disparities in access and utilization across many low- and middle-income countries (LMIC). The factors that drive these disparities are often multilevel, originating from individuals, health

facilities, health systems and communities, and also multifaceted. Implementation science has emerged as a field to help address "know-do" gaps in health systems, and can play a significant role in strengthening immunization systems to understand and solve implementation barriers that limit access and uptake within their contexts. This article presents a reflexive perspective on how to position implementation research in immunization programmes to improve coverage equity. Furthermore, key points of synergy between implementation research and vaccination are highlighted, and some potential practice changes that can be applied within specific contexts were proposed. Using a human rights lens, it was concluded that the cost that is associated with implementation failure in immunization programmes is significant and unjust, and future directions for implementation research to optimize its application in practice settings have been recommended.

*3.1.2 Zimmerman S, Gaugler JE, Nkimbeng M. **COVID-19 Vaccination and Implementation Science: How One Can Benefit the Other**. J Am Med Dir Assoc. 2021 Nov;22(11):2223-2224. doi: 10.1016/j.jamda.2021.09.018.*

Abstract: (…)

Implementation science provides a framework to understand the uptake of research evidence into routine practice, with the ultimate goal of improving the quality and effectiveness of health services. Employing this lens underscores why COVID-19 vaccination has been challenging in long-term care and sheds light on the broader context of striving to change any care practice.

Implementation science lays bare the complexity of "diffusion of innovations"—in this case, the innovation being COVID-19 vaccination. The extent to which any new care practice is adopted relates to numerous considerations, all of which have been evident in the effort to vaccinate persons providing and receiving long-term care.

- The innovation itself, including its perceived benefits and risks; for COVID-19, the perceived risks have largely centered around safety, efficacy, and length of testing;
- Communication and influence, such as the extent to which potential adopters are similar to current adopters; in the case of COVID-19 vaccination, potential adopters tend to have lower education and income than adopters, suggesting a mismatch in communication and influence between the two;
- The outer context, a relevant example being less acceptance of vaccination among those holding certain political beliefs or of certain cultural backgrounds;
- System antecedents for the innovation; toward this end, decentralized decision making is known to promote adoption, but nursing homes tend to be centralized organizations;
- Linkages, such that if developers are linked to users early on, adoption is more likely—which of course was not the case in vaccine development;
- System readiness for the innovation, which is promoted by tension for change (certainly true of COVID-19) and also existing practices, policies, and resources; in many ways, efforts related to seasonal influenza vaccination in long-term care have promoted system readiness;
- The adopter himself or herself, such as the desire of long-term care staff to protect their patients and residents;
- System assimilation, which includes structural changes relating to the innovation, with a recent example being mandates for vaccination; and

- The implementation process, such as whether frontline workers are involved in decision making, which is not typical of a centralized organization.

To simplify this complexity, some researchers have consolidated these areas into 5 domains (ie, the Consolidated Framework for Implementation Research): intervention characteristics, outer setting, inner setting, the process of implementation, and the characteristics of the individuals involved. (…)

*3.1.3 Bauer MS, Kirchner J. **Implementation science: What is it and why should I care?**. Psychiatry Res. 2020;283:112376. doi:10.1016/j.psychres.2019.04.025*

Abstract: Centuries of experience make it clear that establishing the effectiveness of a clinical innovation is not sufficient to guarantee its uptake into routine use. The relatively new field of implementation science has developed to enhance the uptake of evidence-based practices and thereby increase their public health impact. Implementation science shares many characteristics, and the rigorous approach, of clinical research. However, it is distinct in that it attends to factors in addition to the effectiveness of the clinical innovation itself, to include identifying and addressing barriers and facilitators to the uptake of evidence-based clinical innovations. This article reviews the definition, history, and scope of implementation science, and places the field within the broader enterprise of biomedical research. It also provides an overview of this Special Issue of Psychiatry Research, which introduces the principles and methods of implementation science to mental health researchers.

*3.1.4 Kirchner Joann E, Waltz Thomas J, Powell Byron J, Smith Jeffrey L, Proctor Enola K. Implementation Strategies. In: RC B, GA C, EK. P, editor. **Dissemination and Implementation Research: Translating Science into Practice**. 2nd ed. Oxford Univrsity Press; 2018. p. 245–66.*

Extract: Persistent gaps in the quality of healthcare provided in routine care settings have led to the development and prioritization of implementation science. Core to this rapidly growing science is the recognition that evidence-based innovations must be complemented by evidence-based implementation strategies. Throughout, this chapter uses the term "innovation" inclusively. In a clinical setting this may be a new clinical intervention. In a public health setting it may be a prevention program, or in a community setting a new model of service. In recognition of the need to build an evidence base for implementation, the identification, development, refinement, and testing of implementation strategies has been prioritized. (…) We define implementation strategies as methods to enhance the adoption, implementation, sustainment, and scale-up of an innovation.

*3.1.5 Wensing M. **Implementation science in healthcare: Introduction and perspective**. Z Evid Fortbild Qual Gesundhwes. 2015;109(2):97-102. doi:10.1016/j.zefq.2015.02.014*

Abstract: Implementation science is the scientific study of the methods to promote the uptake of research findings into routine healthcare in clinical, organisational, or policy contexts. The presence of gaps between knowledge and practice is well documented and a range of strategies is available to overcome these gaps. To optimize their impact, it is recommended that implementation strategies are tailored to the target population, setting and goals for improvement. Themes for future research in the field are: implementation of personalized medicine, the economics of implementation, knowledge implementation in various health professions, patient involvement in implementation, and a better understanding of the determinants of implementation. Addressing these challenges requires

dedicated training programs, research funding, and networks for effective collaboration with stakeholders in healthcare.

3.1.6 Arora NK, Lal AA, Hombach JM, et al. ***The need for targeted implementation research to improve coverage of basic vaccines and introduction of new vaccines. Vaccine****. 2013;31 Suppl 2:B129-B136. doi:10.1016/j.vaccine.2013.01.058*

Abstract: The Decade of Vaccines Collaboration (DoVC) Research and Development (R&D) Working Group identified implementation research as an important step toward achieving high vaccine coverage and the uptake of desirable new vaccines. The R&D Working Group noted that implementation research is highly complex and requires participation of stakeholders from diverse backgrounds to ensure effective planning, execution, interpretation, and adoption of research outcomes. Unlike other scientific disciplines, implementation research is highly contextual and depends on social, cultural, geographic, and economic factors to make the findings useful for local, national, and regional applications. This paper presents the broad framework for implementation research in support of immunization and sets out a series of research questions developed through a Delphi process (during a DoVC-supported workshop in Sitges, Spain) and a literature review.

3.1.7 Eccles Martin P, Mittman Brian S. ***Welcome to Implementation Science*** *2006. https://doi.org/10.1186/1748-5908-1-1*

Abstract: Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care. This relatively new field includes the study of influences on healthcare professional and organisational behaviour.

3.2 *The current status & evolution of Vaccination Programs for Adults in Europe*

Potential questions/outcomes: *What is the status and evolution of adult vaccination programs in Europe What are the differences among European countries in terms of vaccines, doses, and target population? Are there vaccines for adults that are mandatory in EU countries?*

Related articles:
Source: Proposed by AIB secretariat

3.2.1 European Vaccination Information Portal. ***Vaccination schedules in the EU/EEA. ECDC Vaccine Scheduler.***

Extract: Each EU/EEA country is responsible for its own national public health policy, including its national immunisation programme and vaccination schedule. Information on the national vaccination schedules in EU/EEA countries can be found in the ECDC Vaccine Scheduler (https://vaccine-schedule.ecdc.europa.eu).
There are some differences in the way countries organise their vaccination schedules, which are similar but not identical in different EU/EEA countries. These may include the age and population to be vaccinated (for example, all children of a certain age or only those in a risk group), the exact type of vaccine (e.g. some ingredients may differ), the number and timing of doses, and whether a vaccine is given alone or in combination with others. Factors driving such differences may include the disease's burden, prevalence of the disease and trends in different

countries, the resources and structures of healthcare systems, political and cultural factors, as well as the resilience of the vaccination programme.

3.2.2 Jones CH, Jenkins MP, Adam Williams B, Welch VL, True JM. ***Exploring the future adult vaccine landscape-crowded schedules and new dynamics. NPJ Vaccines****. 2024;9(1):27. Published 2024 Feb 9.* **Disclaimer: please note that all authors of this paper are affiliated with Pfizer Inc.**

Abstract: Amidst the backdrop of the COVID-19 pandemic, vaccine innovation has garnered significant attention, but this field was already on the cusp of a groundbreaking renaissance. Propelling these advancements are scientific and technological breakthroughs, alongside a growing understanding of the societal and economic boons vaccines offer, particularly for non-pediatric populations like adults and the immunocompromised. In a departure from previous decades where vaccine launches could be seamlessly integrated into existing processes, **we anticipate potentially than 100 novel, risk-adjusted product launches over the next 10 years in the adult vaccine market, primarily addressing new indications.** However, this segment is infamous for its challenges: **low uptake, funding shortfalls, and operational hurdles** linked to delivery and administration. To unlock the societal benefits of this burgeoning expansion, we need to adopt a fresh perspective to steer through the dynamics sparked by the rapid growth of the global adult vaccine market. This article aims to provide that fresh perspective, offering a detailed analysis of the anticipated number of adult vaccine approvals by category and exploring how our understanding of barriers to adult vaccine uptake might evolve. We incorporated pertinent insights from external stakeholder interviews, spotlighting shifting preferences, perceptions, priorities, and decision-making criteria. Consequently, this article aspires to serve as a pivotal starting point for industry participants, equipping them with the knowledge to skillfully navigate the anticipated surge in both volume and complexity.

3.2.3 Young S, Goldin S, Dumolard L, et al. ***National vaccination policies for health workers - A cross-sectional global overview****. Vaccine. 2024;42(4):757-769. doi:10.1016/j.vaccine.2023.04.083*

Abstract: Background: Immunization is essential for safeguarding health workers from vaccine-preventable diseases (VPDs) that they may encounter at work; however, information about the prevalence and scope of national policies that protect health workers through vaccination is limited. Understanding the global landscape of health worker immunization programmes can help direct resources, assist decision-making and foster partnerships as nations consider strategies for increasing vaccination uptake among health workers. **Methods:** A one-time supplementary survey was distributed to World Health Organization (WHO) Member States using the WHO/United Nations Children's Fund (UNICEF) Joint Reporting Form on Immunization (JRF). Respondents described their 2020 national vaccination policies for health workers - detailing VPD policies and characterising technical and funding support, monitoring and evaluation activities and provisions for vaccinating health workers in emergencies. **Results:** A total of 53 % (103/194) Member States responded and described health worker policies: 51 had a national policy for vaccinating health workers; 10 reported plans to introduce a national policy within 5 years; 20 had subnational/institutional policies; 22 had no policy for vaccinating health workers. Most national policies were integrated with occupational health and safety policies (67 %) and included public and private providers (82 %). Hepatitis B, seasonal influenza and measles were most frequently included in policies. Countries both with and without national vaccination policies reported monitoring and reporting vaccine uptake (43 countries), promoting vaccination (53 countries) and assessing vaccine demand, uptake or reasons for undervaccination (25 countries) among health workers. Mechanisms for introducing a vaccine for

health workers in an emergency existed in 62 countries. **Conclusion:** National policies for vaccinating health workers were complex and context specific with regional and income-level variations. Opportunities exist for developing and strengthening national health worker immunization programmes. Existing health worker immunization programmes might provide a foothold on which broader health worker vaccination policies can be built and strengthened.

*3.2.4 Maltezou HC, Effraimidou E, Cassimos DC, et al. **Vaccination programs for pregnant women in Europe, 2021**. Vaccine. 2021;39(41):6137-6143. doi:10.1016/j.vaccine.2021.08.074*

Abstract: Vaccination during pregnancy is increasingly adopted worldwide in order to protect the mother and her offspring. We studied the current vaccination programs specifically for pregnant women in 42 European countries. Vaccination programs for pregnant women are in place in 37 countries, as follows: influenza (36 countries), pertussis (28), hepatitis B (12), tetanus (10), pneumococcal disease (10), meningococcal disease (10), rabies (8), tick-borne encephalitis (6), hepatitis A (5), poliomyelitis (4), diphtheria (3), Haemophilus influenzae (2), and human papilloma virus (1). **Recommendations for vaccination against influenza and pertussis concern almost exclusively pregnant women regardless of high-risk conditions**, however differences between vaccination recommendations are noted in terms of timing. Vaccinations against hepatitis B, hepatitis A, pneumococcal disease, meningococcal disease, poliomyelitis, H. influenzae, rabies, and tick-born encephalitis mainly concern pregnant women at high-risk for exposure or serious illness and post-exposure vaccinations. Overall, five European countries have no vaccination recommendations specifically for pregnant women. In conclusion, there are significant differences in vaccination programs for pregnant women in Europe. Vaccination programs for pregnant women should expand in order to protect maternal and infant health. A consensus-based vaccination program is needed.

*3.2.5 Cassimos DC, Effraimidou E, Medic S, Konstantinidis T, Theodoridou M, Maltezou HC. **Vaccination Programs for Adults in Europe, 2019**. Vaccines (Basel). 2020;8(1):34. Published 2020 Jan 20. doi:10.3390/vaccines8010034*

Background: While all European countries implement vaccination programs for children, there are gaps in terms of vaccination programs for adults. **Methods:** We studied the 2019 vaccination policies for adults in 42 European countries. **Results:** Vaccination programs for adults were in place in all countries. However, there were considerable differences between countries in terms of number of vaccinations, target populations and frame of implementation (recommended or mandatory vaccinations). In particular the following vaccination policies were in place: influenza (42 countries), tetanus (31), diphtheria (30), pneumococcus (29), hepatitis B (20), pertussis (18), measles (14), human papilloma virus (14), meningococcus tetravalent A,C,W,Y (14), rubella (13), hepatitis A (11), mumps (11), poliomyelitis (10), herpes zoster (9), varicella (8), tick-born encephalitis (8), meningococcus B (6), rabies (6), Haemophilus influenzae type b (5), tuberculosis (3), typhoid fever (3), meningococcus C (2), and yellow fever (1). Seventeen countries implement mandatory vaccinations, mainly against diphtheria, tetanus and hepatitis B. **Conclusions:** There are significant differences in vaccination programs for adults in Europe. Routine vaccination programs for adults need to be strengthened. A consensus-based vaccination program is needed.

*3.2.6 Maltezou HC, Poland GA. **Immunization of healthcare personnel in Europe: Time to move forward with a common program**. Vaccine. 2020;38(16):3187-3190. doi:10.1016/j.vaccine.2020.02.090*

Abstract: not available

*3.2.7 Sheikh S, Biundo E, Courcier S, Damm O, Launay O, Maes E, Marcos C, Matthews S, Meijer C, Poscia A, Postma M, Saka O, Szucs T, Begg N. **A report on the status of vaccination in Europe**. Vaccine. 2018 Aug 9;36(33):4979-4992. doi: 10.1016/j.vaccine.2018.06.044.*

Abstract: Vaccine policy, decision processes and outcomes vary widely across Europe. The objective was to map these factors across 16 European countries by assessing (A) national vaccination strategy and implementation, (B) attributes of healthcare vaccination systems, and (C) outcomes of universal mass vaccination (UMV) as a measure of how successful the vaccination policy is. A. Eleven countries use standardised assessment frameworks to inform vaccine recommendations. Only Sweden horizon scans new technologies, uses standard assessments, systematic literature and health economic reviews, and publishes its decision rationale. Time from European marketing authorisation to UMV implementation varies despite these standard frameworks. Paediatric UMV recommendations (generally government-funded) are relatively comparable, however only influenza vaccine is widely recommended for adults. B. Fourteen countries aim to report annually on national vaccine coverage rates (VCRs), as well as have target VCRs per vaccine across different age groups. Ten countries use either electronic immunisation records or a centralised registry for childhood vaccinations, and seven for other age group vaccinations. C. National VCRs for infant (primary diphtheria tetanus pertussis (DTP)), adolescent (human papillomavirus (HPV)) and older adult (seasonal influenza) UMV programmes found ranges of: 89.1% to 98.2% for DTP-containing vaccines, 5% to 85.9% for HPV vaccination, and 4.3% to 71.6% for influenza vaccine. Regarding reported disease incidence, a wide range was found across countries for measles, mumps and rubella (in children), and hepatitis B and invasive pneumococcal disease (in all ages). These findings reflect an individual approach to vaccination by country. High VCRs can be achieved, particularly for paediatric vaccinations, despite different approaches, targets and reporting systems; these are not replicated in vaccines for other age groups in the same country. Additional measures to improve VCRs across all age groups are needed and could benefit from greater harmonisation in target setting, vaccination data collection and sharing across EU countries.

3.3 Control, Elimination and eradication goals for communicable diseases (focus on prevention targets of different adult vaccination programs in Europe)

Potential questions/outcomes: *What are the current control, elimination and/or eradication goals for adult vaccine-preventable diseases in Europe? What are the major challenges in Europe in setting and achieving these control, elimination, and eradication goals for communicable diseases. What is the added value of having well-defined goals and how can we do better in the future?*

Related articles:
Source: Proposed by AIB secretariat

*3.3.1 Khawar L, Donovan B, Peeling RW, Guy RJ, McGregor S. **Elimination and eradication goals for communicable diseases: a systematic review.** Bull World Health Organ. 2023 Oct 1;101(10):649-665. doi: 10.2471/BLT.23.289676.*

Abstract: **Objective** To consolidate recent information on elimination and eradication goals for infectious diseases and clarify the definitions and associated terminology for different goals. **Methods** We conducted a systematic search of the

World Health Organization's Institutional Repository for Information Sharing (WHO IRIS) and a customized systematic Google advanced search for documents published between 2008 and 2022 on elimination or eradication strategies for infectious conditions authored by WHO or other leading health organizations. We extracted information on names of infectious conditions, the elimination and eradication goals and timelines, definitions of goals, non-standardized terminology, targets and assessment processes. **Findings** We identified nine goals for 27 infectious conditions, ranging from disease control to eradication. In comparison with the hierarchy of disease control, as defined at the Dahlem Workshop in 1997, six goals related to disease control with varying levels of advancement, two related to elimination and one to eradication. Goals progressed along a disease-control continuum, such as end of disease epidemic to pre-elimination to elimination as a public health problem or threat. We identified the use of non-standardized terminology with certain goals, including virtual elimination, elimination of disease epidemics, public health threat and public health concern. **Conclusion** As we approach the 2030 target date to achieve many of the goals related to disease control and for other infections to become candidates for elimination in the future, clarity of definitions and objectives is important for public health professionals and policy-makers to avoid misperceptions and miscommunication.

3.3.2 Dr Hans Henri P. Kluge, WHO Regional Director for Europe. ***Statement: Control, elimination, eradication: three actions we need to take on three different public health emergencies in the European Region in the coming months****. 2022.*

Extract: Control, elimination, eradication. Three actions that underpin my remarks today, on three different public health emergencies of international concern, each requiring its own distinct response strategy and aims. First, control – specifically in the context of COVID-19. (…) Our recently launched COVID-19 autumn and winter strategy is comprehensive, spelling out what needs to be done by countries to control both SARS-CoV-2 and other respiratory viruses. (…) That's why this week we've launched 2 comprehensive policy briefs – one outlining the policy objectives and steps needed for the control and eventual elimination of monkeypox, the other specifically on the use of monkeypox vaccines. (…) All countries – whether they currently have cases or not – need to implement a set of combined interventions towards this end. (…) The third action for today is eradication – this, in the context of polio, a disease that crippled many children in our region in the past. As we look forward to celebrating the 20th year of polio-free status in the European Region we are reminded that the momentous progress made towards global eradication is very fragile. This is a wake-up call for us all. It is our shared responsibility to eradicate polio globally. Everyone who is not vaccinated, or whose children have missed their scheduled vaccinations, should seek vaccination as soon as possible. Polio vaccines are proven to be very effective and very safe. Polio, monkeypox, COVID-19 – all of these have demonstrated repeatedly that a disease threat anywhere can quickly become a disease threat everywhere – a lesson we would indeed be foolish to ignore, all the more in the world of today.

3.4 How and why to set goals: Scientific approaches toward improving cervical cancer elimination strategies

Potential questions/outcomes: *Exploration of Cervical Cancer Elimination Strategies. Lessons learned from strategically optimal deployment of vaccination to accelerate elimination of HPV and cervical cancer (vaccination in both males and females, extension of vaccination catch-up, and high coverage HPV vaccination in multiple population segments). Did the Cervical Cancer elimination strategy change*

over time? If yes, how? What can be learned from the global cervical cancer elimination initiative experiences that can be used for other (adult) VPD goals?

Related articles:
Source: Proposed by AIB secretariat

3.4.1 Lehtinen M, Bruni L, Elfström M, Gray P, Logel M, Mariz FC, Baussano I, Vänskä S, Franco EL, Dillner J. ***Scientific approaches toward improving cervical cancer elimination strategies.*** *Int J Cancer. 2024 Jan 9. doi: 10.1002/ijc.34839.*

Abstract: *At the 2023 EUROGIN workshop scientific basis for strategies to accelerate the elimination of cervical cancer and its causative agent, human papillomavirus (HPV) were reviewed. Although some countries have reached key performance indicators toward elimination (>90% of girls HPV vaccinated and >70% of women HPV screened), most are yet to reach these targets, implying a need for improved strategies.* ***Gender-neutral vaccination, even with moderate vaccination coverage was highlighted as a strategy to achieve elimination more rapidly. It is more resilient against major disturbances in vaccination delivery, such as what happened during the coronavirus pandemic.*** *Further, an analysis of ethical/legal issues indicated that female-restricted vaccination is problematic. Extended catch-up of vaccination with concomitant screening, and outreach to vulnerable groups were highlighted. Although birth cohorts with high coverage of HPV vaccination at school are protected against HPV, and HPVs have a very low reproductive rate in women above age 35, adult women below age 30 have inadequate direct protection. In addition to herd protection from gender-neutral vaccination, this group can be protected by offering* ***concomitant catch-up HPV vaccination and HPV screening****. Furthermore, hepatitis B vaccination experiences indicate that elimination cannot be achieved without prioritizing vulnerable/migrant populations. The long-lasting durability of vaccination-induced antibody responses suggests prolonged protection with HPV vaccines when adequately administrated. Finally, cost-effectiveness modelling suggests that high-coverage HPV vaccination in multiple population segments will be resource-saving due to reduced need for screening. In summary, the workshop found that strategically optimal deployment of vaccination will accelerate elimination of HPV and cervical cancer.*

3.4.2 WHO. World Health Organization. ***Cervical Cancer Elimination Initiative****.* **2024.**

Achieving elimination: To eliminate cervical cancer, all countries must reach and maintain an incidence rate of below 4 per 100 000 women. Achieving that goal rests on three key pillars and their corresponding targets:

- vaccination: 90% of girls fully vaccinated with the HPV vaccine by the age of 15;
- screening: 70% of women screened using a high-performance test by the age of 35, and again by the age of 45;
- treatment: 90% of women with pre-cancer treated and 90% of women with invasive cancer managed.

Each country should meet the 90–70–90 targets by 2030 to get on the path to eliminate cervical cancer within the next century.

3.4.3 Arbyn M, Gultekin M, Morice P, et al. ***The European response to the WHO call to eliminate cervical cancer as a public health problem****. Int J Cancer. 2021;148(2):277-284. doi:10.1002/ijc.33189*

Abstract: The age-standardised incidence of cervical cancer in Europe varies widely by country (between 3 and 25/100000 women-years) in 2018. Human papillomavirus (HPV) vaccine coverage is low in countries with the highest incidence and screening performance is heterogeneous among European countries. A broad group of delegates of scientific professional societies and cancer organisations endorse the principles of the WHO call to eliminate cervical cancer as a public health problem, also in Europe. All European nations should, by 2030, reach at least 90% HPV vaccine coverage among girls by the age of 15 years and also boys, if cost-effective; they should introduce organised population-based HPV-based screening and achieve 70% of screening coverage in the target age group, providing also HPV testing on self-samples for nonscreened or underscreened women; and to manage 90% of screen-positive women. To guide member states, a group of scientific professional societies and cancer organisations engage to assist in the rollout of a series of concerted evidence-based actions. European health authorities are requested to mandate a group of experts to develop the third edition of European Guidelines for Quality Assurance of Cervical Cancer prevention based on integrated HPV vaccination and screening and to monitor the progress towards the elimination goal. The occurrence of the COVID-19 pandemic, having interrupted prevention activities temporarily, should not deviate stakeholders from this ambition. In the immediate postepidemic phase, health professionals should focus on high-risk women and adhere to cost-effective policies including self-sampling.

3.5 How and why to set goals: lessons learned from the seasonal Influenza vaccination strategy

Potential questions/outcomes: *Why and how was the 75% threshold for the elderly defined? What are the lessons learned from setting this target and what are the main reasons the target is not reached in several countries? What can be done better when setting goals and what can be learned from the seasonal influenza vaccination strategy that can be used for other (adult) VPD goals?*

Related articles:
Source: Proposed by AIB secretariat

3.5.1 ECDC; Technical report; ***Seasonal influenza vaccination recommendations and coverage rates in EU/EEA Member States****. 2023*

Extract: In 2009, the Recommendation by the Council of the European Union set an objective for EU Member States to achieve a 75% vaccination coverage rate (VCR) with the seasonal influenza vaccine by the 2014/15 influenza season in key target groups, such as older individuals, and those at risk of more severe disease. The recommendation also encouraged Member States to improve VCRs among healthcare workers. The main objective of the ECDC-funded network 'Vaccine European New Integrated Collaboration Effort' (VENICE) that ran between 2006 and 2017 was to strengthen best practices related to vaccination and support the dissemination of knowledge in vaccination programmes. Several studies were undertaken by the VENICE network on the description of influenza vaccination policies and the monitoring of influenza vaccination coverage.

3.5.2 Palache A, Billingsley JK, MacLaren K, Morgan L, Rockman S, Barbosa P; ***IFPMA Influenza Vaccine Supply (IFPMA IVS) task force. Lessons learned from the COVID-19 pandemic for improved influenza control.*** *Vaccine. 2023 Sep 15;41(40):5877-5883. doi: 10.1016/j.vaccine.2023.08.028.*

Abstract: The World Health Organization noted that COVID-19 vaccination programmes could be leveraged to deliver influenza vaccination. In 2008, the

International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Influenza Vaccine Supply International Task Force (IVS) developed a survey method using the number of influenza vaccine doses distributed globally to estimate vaccination coverage rates. Seven hundred and ninety-seven million doses were distributed in 2021, representing a 205% increase over the 262 million doses distributed in 2004, exceeding the number of doses distributed during and after the 2009-2010 influenza pandemic. The most obvious explanation for the global increase is the enabling of critical elements of the vaccine ecosystem by decision-makers during the COVID-19 pandemic to reinforce implementation of influenza vaccination programs. Most of the improvements in performance of influenza programs during the COVID-19 pandemic can be classified in four categories: **1) promoting vaccination using tailored approaches for specific populations; 2) improving convenient access to influenza vaccines in COVID-safe settings; 3) improving reimbursement of seasonal influenza vaccination for priority groups; 4) maintaining the timing of vaccination to the autumn.** In spite of the increase in rates of seasonal influenza vaccines distributed during the COVID-19 pandemic, globally, the rate of influenza dose distribution is sub-optimal, and a considerable proportion of the influenza infections remains preventable. To sustain the benefits from increased uptake of influenza vaccines, governments need to sustain the efforts made during the COVID-19 pandemic, and a number of global policy endeavours should be undertaken, including developing a clear global roadmap for achieving influenza control objectives, adopted by a WHA resolution, in line with the strategic objective 3 of the Global Influenza Strategy 2030, embedded in the Immunization Agenda 2030 (IA2030).

*3.5.3 ECDC. **Seasonal influenza vaccination strategies**. 2023.*

Summary: 1. Protecting the vulnerable, 2. Protecting healthy children, adolescents and adults, 3. Reducing overall influenza transmission, Yearly updates of influenza vaccines.

*3.5.4 WHO. **Vaccines against influenza: WHO position paper – May 2022**; 2022 https://iris.who.int/bitstream/handle/10665/354264/WER9719-eng-fre.pdf*

Extract: While many countries may need to rely on regional data to assess the epidemiological situation, individual national decisions on the use of influenza vaccines should take into consideration **national immunization coverage goals, capacity to deliver services and resource availability**. Individual country decision-making is of particular importance in regard to the target groups for influenza vaccination. Selection of target groups: Influenza vaccination aims primarily to protect high-risk groups against severe influenza-associated disease and death. That said, influenza causes considerable morbidity worldwide even beyond these risk groups. Further, vaccination of certain populations, such as health workers and children, may be beneficial for reasons beyond individual protection, for example, to safeguard health systems and reduce transmission. For countries considering the initiation or expansion of programmes for seasonal influenza vaccination, WHO recommends that the following target groups should be considered for vaccination (not in order of priority): health workers, individuals with comorbidities and underlying conditions, older adults and pregnant women. Depending on **national disease goals, capacity and resources, epidemiology, national policies and priorities, and disease burden, countries may consider additional (sub)populations for vaccination, such as children**. Other groups to be considered for vaccination include people at high risk of severe influenza living in congregate-living settings, such as prisons, refugee camps and group homes. Programmes should pay particular attention to vaccine equity by considering disadvantaged populations and indigenous populations with a high

burden of disease. Countries may prioritize these groups on the basis of the local context and programme feasibility.

3.6 Assessing and improving the accuracy of target population estimates for immunization coverage

Potential questions/outcomes: *How to prioritize vaccine interventions and target populations while accounting for the limited financial and programmatic capacities? What are the main challenges identified in assessing the accuracy of target population estimates for vaccination coverage based on administrative data? What methods are proposed to improve the accuracy of target population estimates for vaccine coverage in the short and long term? What are the differences and considerations to take when targeting age-based vs. high-risk group strategies?*

Related articles:
Source: Proposed by AIB secretariat

*3.6.1 Stashko LA, Gacic-Dobo M, Dumolard LB, Danovaro-Holliday MC. **Assessing the quality and accuracy of national immunization program reported target population estimates from 2000 to 2016**. PLoS One. 2019 Jul 9;14(7):e0216933. doi: 10.1371/journal.pone.0216933.*

Abstract: **Background** A common means of vaccination coverage measurement is the administrative method, done by dividing the aggregated number of doses administered over a set period (numerator) by the target population (denominator). To assess the quality of national target populations, we defined nine potential denominator data inconsistencies or flags that would warrant further exploration and examination of data reported by Member States to the World Health Organization (WHO) and UNICEF between 2000 and 2016. **Methods and findings:** We used the denominator reported to calculate national coverage for BCG, a tuberculosis vaccine, and for the third dose of diphtheria-tetanus-pertussis-containing (DTP3) vaccines, usually live births (LB) and surviving infants (SI), respectively. Out of 2,565 possible reporting events (data points for countries using administrative coverage with the vaccine in the schedule and year) for BCG and 2,939 possible reporting events for DTP3, 194 and 274 reporting events were missing, respectively. Reported coverage exceeding 100% was seen in 11% of all reporting events for BCG and in 6% for DTP3. Of all year-to-year percent differences in reported denominators, 12% and 11% exceeded 10% for reported LB and SI, respectively. The implied infant mortality rate, based on the country's reported LB and SI, would be negative in 9% of all reporting events i.e., the country reported more SI than LB for the same year. Overall, reported LB and SI tended to be lower than the UN Population Division 2017 estimates, which would lead to overestimation of coverage, but this difference seems to be decreasing over time. Other inconsistencies were identified using the nine proposed criteria. **Conclusions:** Applying a set of criteria to assess reported target populations used to estimate administrative vaccination coverage can flag potential quality issues related to the national denominators and may be useful to help monitor ongoing efforts to improve the quality of vaccination coverage estimates.

*3.6.2 WHO Technical document. **Assessing and improving the accuracy of target population estimates for immunization coverage.***

Overview: Calculating vaccination coverage from administrative data on numbers of vaccinated persons requires corresponding target population estimates. The accuracy of available target population estimates may be problematic. **Evidence of low accuracy includes coverage estimates far in excess of 100%, erratic**

year-to-year fluctuations, and disease outbreaks in areas with high estimated coverage. The problem has grown more acute as coverage rates have risen, requiring more accurate target population estimates to monitor changes in coverage. This manual provides a systematic approach to assessing and improving the accuracy of target population estimates. It describes long-term, best practice methods as well as shorter-term expedients.

3.7 Target population of COVID-19 adult vaccination in Europe: evolution and current status

Potential questions/outcomes: *What are the adult target groups for COVID-19 vaccination in Europe? How were they defined and how did they change over time? What can we expect in the future? Are the differences among countries understandable or should we better align the target populations? What insights can we gain from defining target populations for COVID-19 vaccination strategies that could be applied to other vaccine-preventable diseases in adults?*

Related articles:
Source: Proposed by AIB secretariat

*3.7.1 ECDC. **Interim COVID-19 vaccination coverage in the EU/EEA during the 2023–24 season campaigns.** Feb 2024.*

Executive summary: During the reporting period (between 1 September 2023 and January 2024), 24/30 EU/EEA countries reported data on COVID-19 vaccination coverage for at least one target group (people aged 60 years and above, people aged 80 years and above, healthcare workers, individuals with chronic conditions, pregnant women). During this period, approximately 19.4 million people aged 60 years and above received one COVID-19 vaccine dose. Approximately 5.5 million people aged 80 years and above received one COVID-19 vaccine dose. **The median COVID-19 vaccination coverage among people aged 60 years and above was 11.1% (range: 0.01–65.8%), with high variation among countries. For people aged 80 years and above, the median coverage was 16.3% (range: 0.01–88.2%), with high variation among countries.** Among the 24 reporting countries, three countries reported a vaccination coverage ≥50% for the age group 60 years and above, while eight countries reported a vaccination coverage ≥50% for the age group 80 years and above. Most of the approximately 22.7 million COVID-19 vaccine doses administered in the EU/EEA during this period in the overall population were the Comirnaty Omicron XBB.1.5 (Pfizer BioNTech) vaccine (around 22 million doses; 97% of the total doses administered). These preliminary results must be interpreted with caution. A higher degree of data consolidation and data completeness is expected in the coming weeks and months.

*3.7.2 Wang W, Wu Q, Yang J, Dong K, Chen X, Bai X, Chen X, Chen Z, Viboud C, Ajelli M, Yu H. **Global, regional, and national estimates of target population sizes for covid-19 vaccination: descriptive study**. BMJ. 2020 Dec 15;371:m4704..*

Abstract Objective: To provide global, regional, and national estimates of target population sizes for coronavirus disease 2019 (covid-19) vaccination to inform country specific immunisation strategies on a global scale. Design: Descriptive study. Setting: 194 member states of the World Health Organization. Population: Target populations for covid-19 vaccination based on country specific characteristics and vaccine objectives (maintaining essential core societal services; reducing severe covid-19; reducing symptomatic infections and stopping virus transmission). Main outcome measure: Size of target populations for covid-19 vaccination.

Estimates use country specific data on population sizes stratified by occupation, age, risk factors for covid-19 severity, vaccine acceptance, and global vaccine production. These data were derived from a multipronged search of official websites, media sources, and academic journal articles. Results: Target population sizes for covid-19 vaccination vary markedly by vaccination goal and geographical region. Differences in demographic structure, presence of underlying conditions, and number of essential workers lead to highly variable estimates of target populations at regional and country levels. **In particular, Europe has the highest share of essential workers (63.0 million, 8.9%) and people with underlying conditions (265.9 million, 37.4%);** these two categories are essential in maintaining societal functions and reducing severe covid-19, respectively. In contrast, South East Asia has the highest share of healthy adults (777.5 million, 58.9%), a key target for reducing community transmission. Vaccine hesitancy will probably impact future covid-19 vaccination programmes; based on a literature review, 68.4% (95% confidence interval 64.2% to 72.6%) of the global population is willing to receive covid-19 vaccination. Therefore, the adult population willing to be vaccinated is estimated at 3.7 billion (95% confidence interval 3.2 to 4.1 billion). Conclusions: The distribution of target groups at country and regional levels highlights the importance of designing an equitable and efficient plan for vaccine prioritisation and allocation. Each country should evaluate different strategies and allocation schemes based on local epidemiology, underlying population health, projections of available vaccine doses, and preference for vaccination strategies that favour direct or indirect benefits.

3.8 Leveraging lessons learned from the COVID-19 vaccine rollout to improve the introduction and implementation of vaccines for adults and ensure their sustainability and resilience

Potential questions/outcomes: *How can countries leverage the lessons learned from the COVID-19 vaccine rollout to improve the planning, budgeting, and implementation frameworks for new adult vaccines, ensuring rapid, equitable, and sustainable access for their citizens at a national level? What organizational best practices can be adopted to navigate the complexities of vaccine distribution, ensuring timely and widespread access across diverse adult populations? How can national policies improve cooperation across different sectors to make vaccine delivery systems more sustainable, robust and efficient?*

Related articles:
Source: Proposed by AIB secretariat

*3.8.1 Forman R, Shah S, Jeurissen P, Jit M, Mossialos E. **COVID-19 vaccine challenges: What have we learned so far and what remains to be done?** Health Policy. 2021;125(5):553-567. doi:10.1016/j.healthpol.2021.03.013*

Abstract: Developing and distributing a safe and effective SARS-CoV-2 (COVID-19) vaccine has garnered immense global interest. Less than a year after COVID-19 was declared a pandemic, several vaccine candidates had received emergency use authorization across a range of countries. Despite this scientific breakthrough, the journey from vaccine discovery to global herd immunity against COVID-19 continues to present significant policy challenges that require a collaborative, global response. We offer a framework for understanding remaining and new policy challenges for successful global vaccine campaigns against COVID-19 as well as potential solutions to address them. Decision-makers must be aware of these challenges and strategize solutions that can be implemented at scale. These include challenges around maintaining R&D incentives, running clinical trials,

authorizations, post-market surveillance, manufacturing and supply, global dissemination, allocation, uptake, and clinical system adaption. Alongside these challenges, financial and ethical concerns must also be addressed.

*3.8.2 Forman R, Jit M, Mossialos E. **Divergent vaccination policies could fuel mistrust and hesitancy.** Lancet. 2021 Jun 19;397(10292):2333. doi: 10.1016/S0140-6736(21)01106-5. Epub 2021 Jun 1. PMID: 34087111; PMCID: PMC8169059.*

Text: With reports of a possible risk of rare blood clots in people receiving AstraZeneca's COVID-19 vaccine (Vaxzevria), concerns have risen about its use in younger adults. As of May 26, 2021, country stances on the use of this vaccine generally fall into one of five response types. **Why countries continue to respond so differently in response to adverse events with this vaccine is unclear**, but we are concerned that divergent vaccination policies could fuel mistrust and hesitancy around immunisation. **One response** is to warn of potential risks, but otherwise no set restrictions on use of Vaxzevria. The European Medicines Agency and WHO have issued warnings about the rare possibility of blood clots within 2 weeks of vaccination. While more data are being collected, the agencies encourage the continuation of the vaccine in all adults since current evidence suggests the benefits outweigh the risks. Many countries, including Poland, Mexico, and Brazil are following this guidance. **A second response** is to not permit use. Denmark has decided to remove Vaxzevria from its vaccination programmes, whereas in Norway, further administration of the vaccine has been paused. **A third response** is to advise that only older adults receive Vaxzevria; however, the age cutoff varies. In the Netherlands, Portugal, Singapore, and Spain, the vaccine is given to adults aged 60 years and older, whereas in Belgium it is given to adults aged 55 years and older, and in Australia to those aged 50 years and older. **A fourth response** is to encourage younger adults to accept a different type of COVID-19 vaccine if possible. Greece is encouraging adults younger than 30 years to take alternative vaccines to Vaxzevria. Similar recommendations exist in the UK and Pakistan for those younger than 40 years (in the UK, this age cutoff was recently increased from 30 years). **A fifth response** is to use a mix-and-match approach for younger adults who have already received one dose of Vaxzevria. France and Germany have limited use of Vaxzevria to older adults and announced that those younger than 55 years (in France) and 60 years (in Germany) who received one dose of Vaxzevria should be given the vaccine produced by Pfizer–BioNTech or Moderna for their second dose. The divergent responses might reflect risk tolerance, the availability of alternative vaccinations, and whether safety calculations consider the risk of the vaccine and of the virus in conjunction. Although some variation could be justified by the underlying risk–benefit calculations because of a country's age profile and its COVID-19 infection rates, we are concerned that public trust in vaccines will wane and exacerbate existing hesitancy because of these divergences. In Europe, willingness to take the vaccine has already decreased after the temporary suspensions of Vaxzevria: between February and March, 2021, one survey found that respondents who believed the vaccine was unsafe increased by 18 percentage points in France (from 43% to 61%) and by 15 percentage points in Germany (from 40% to 55%). Coordinated and strengthened risk communication efforts between regulatory agencies and policy makers could help improve the situation. Governments should stress the safety and importance of vaccines and agree on common lines to explain adverse events that have occurred with the Vaxzevria vaccine and similar problems that are emerging with other non-replicating viral vector COVID-19 vaccines. Communication from experts to the public should be transparent, simple, and consistent. Statements about the risks associated with the vaccines should offer perspective, acknowledging the risks associated with COVID-

19 and other common medications and substances, demonstrating how extremely rare these risks are, and referring to current evidence that the authorised vaccines are safe, effective, and key to ending the pandemic.

*3.8.3 Forman R, Anderson M, Jit M, Mossialos E. **Ensuring access and affordability through COVID-19 vaccine research and development investments: A proposal for the options market for vaccines**. Vaccine. 2020;38(39):6075-6077. doi:10.1016/j.vaccine.2020.07.068*

Abstract:

- Currently, unconditional investment is being made into COVID-19 vaccine R&D COVID-19 vaccine R&D investments should also ensure access and affordability.
- The options market for antibiotics, could be adapted for use with COVID-19 vaccines.
- This could help fund R&D, boost manufacturing capacity and secure fair prices.
- Further research on the OMV model in the current COVID-19 crisis is warranted.

3.9 Introduction of Respiratory Syncytial Virus Vaccines in Older Adults and Pregnant Women in the US (focus on organizational aspects)

Potential questions/outcomes: *What are the current RSV vaccination recommendations for adults in the US? Specifically, what are the guidelines for older adults and pregnant women? How was the RSV vaccine introduced, and what organizational challenges were encountered? How is it integrated with the delivery of other vaccines? Do you expect an impact on other vaccines?*

Related articles:
Source: Proposed by AIB secretariat

*3.9.1 La EM, Bunniran S, Garbinsky D, et al. **Respiratory syncytial virus knowledge, attitudes, and perceptions among adults in the United States**. Hum Vaccin Immunother. 2024;20(1):2303796. doi:10.1080/21645515.2024.2303796*

Abstract: Respiratory syncytial virus (RSV) is associated with considerable morbidity and mortality among older adults (aged ≥60 years) and adults with certain chronic conditions in the United States (US). Despite this burden, no previous studies have assessed the knowledge, attitudes, and perceptions (KAP) of RSV among these populations. This study evaluates RSV-related KAP among US adults at increased risk of severe RSV infection. A cross-sectional, web-based survey was administered from May to June 2022 to better understand respiratory infection- and RSV-related KAP among US adults who are at risk of severe RSV infection. The survey included ≥200 adults in each of 4 subgroups: adults aged 60-89 years, and adults aged 18-59 years with ≥1 chronic cardiovascular condition, chronic pulmonary condition, or diabetes mellitus. Survey responses were analyzed descriptively overall and by subgroup, with exploratory logistic regression modeling used to evaluate characteristics associated with RSV awareness and concern. Among the 827 survey respondents, only 43.3% had ever heard of RSV (n = 358/827). The study identified key knowledge gaps (e.g. bacterial vs. viral nature of respiratory infections, RSV seasonality, common RSV symptoms, extent to which RSV causes respiratory infections in specific patient populations). Although 33.7% of RSV-aware adults (n = 120/356) reported being worried/very worried about RSV,

67.3% (n = 241/358) rarely consider RSV as a potential cause of their cold/flu-like symptoms. Results from this study highlight important knowledge gaps related to RSV, perceived risk, and severity of RSV. Findings can be used to support the development of tailored education efforts to support RSV prevention.

*3.9.2 CDC Centers for Disease Control and Prevention. Healthcare Providers: **RSV Vaccination for Adults 60 years of age and over**. 2023.*

Summary: Vaccine recommendations; Risk Factors for Severe RSV disease; Timing of RSV Vaccination and number of doses; Contraindications and precautions; Types and Composition of RSV vaccines; Vaccine efficacy; Vaccine safety; Storage and handling for RSV vaccines; Administration with other vaccines; Resources

*3.9.3 Melgar M, Britton A, Roper LE, Talbot HK, Long SS, Kotton CN, Havers FP. **Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices - United States, 2023**. MMWR Morb Mortal Wkly Rep. 2023 Jul 21;72(29):793-801. doi: 10.15585/mmwr.mm7229a4.*

Abstract: Respiratory syncytial virus (RSV) is a cause of severe respiratory illness in older adults. In May 2023, the Food and Drug Administration approved the first vaccines for prevention of RSV-associated lower respiratory tract disease in adults aged ≥60 years. Since May 2022, the Advisory Committee on Immunization Practices (ACIP) Respiratory Syncytial Virus Vaccines Adult Work Group met at least monthly to review available evidence regarding the safety, immunogenicity, and efficacy of these vaccines among adults aged ≥60 years. On June 21, 2023, ACIP voted to recommend that adults aged ≥60 years may receive a single dose of an RSV vaccine, using shared clinical decision-making. This report summarizes the body of evidence considered for this recommendation and provides clinical guidance for the use of RSV vaccines in adults aged ≥60 years. RSV vaccines have demonstrated moderate to high efficacy in preventing RSV-associated lower respiratory tract disease and have the potential to prevent substantial morbidity and mortality among older adults; postmarketing surveillance will direct future guidance.

*3.9.4 Fleming-Dutra KE, Jones JM, Roper LE, et al. **Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices - United States, 2023**. MMWR Morb Mortal Wkly Rep. 2023;72(41):1115-1122. Published 2023 Oct 13. doi:10.15585/mmwr.mm7241e1*

Abstract: Respiratory syncytial virus (RSV) is the leading cause of hospitalization among U.S. infants. Nirsevimab (Bevfortus, Sanofi and AstraZeneca) is recommended to prevent RSV-associated lower respiratory tract infection (LRTI) in infants. In August 2023, the Food and Drug Administration (FDA) approved RSVpreF vaccine (Abrysvo, Pfizer Inc.) for pregnant persons as a single dose during 32-36 completed gestational weeks (i.e., 32 weeks and zero days' through 36 weeks and 6 days' gestation) to prevent RSV-associated lower respiratory tract disease in infants aged <6 months. Since October 2021, CDC's Advisory Committee on Immunization Practices (ACIP) RSV Vaccines Pediatric/Maternal Work Group has reviewed RSV epidemiology and evidence regarding safety, efficacy, and potential economic impact of pediatric and maternal RSV prevention products, including RSVpreF vaccine. On September 22, 2023, ACIP and CDC recommended RSVpreF vaccine using seasonal administration (i.e., during September through end of January in most of the continental United States) for pregnant persons as a one-

time dose at 32-36 weeks' gestation for prevention of RSV-associated LRTI in infants aged <6 months. Either maternal RSVpreF vaccination during pregnancy or nirsevimab administration to the infant is recommended to prevent RSV-associated LRTI among infants, but both are not needed for most infants. All infants should be protected against RSV-associated LRTI through use of one of these products.

*3.9.5 CDC Centers for Disease Control and Prevention. Healthcare Providers: **RSV Vaccination for Pregnant People**. 2023.*

Abstract: not available

*3.9.6 Engmann C, Fleming JA, Khan S, et al. Closer and closer? **Maternal immunization: current promise, future horizons.** J Perinatol. 2020;40(6):844-857. doi:10.1038/s41372-020-0668-3*

Abstract: This state-of-the art manuscript highlights our current understanding of maternal immunization-the practice of vaccinating pregnant women to confer protection on them as well as on their young infants, and thereby reduce vaccine-preventable morbidity and mortality. Advances in our understanding of the immunologic processes that undergird a normal pregnancy, studies from vaccines currently available and recommended for pregnant women, and vaccines for administration in special situations are beginning to build the case for safe scale-up of maternal immunization. In addition to well-known diseases, new diseases are emerging which pose threats. Several new vaccines are currently under development and increasingly include pregnant women. In this manuscript, targeted at clinicians, vaccinologists, scientists, public health practitioners, and policymakers, we also outline key considerations around maternal immunization introduction and delivery, discuss noninfectious horizons for maternal immunization, and provide a framework for the clinician faced with immunizing a pregnant woman.

*3.9.7 WHO. **How to implement influenza vaccination of pregnant women**. 2017*

Abstract: not available

3.10 Introduction and implementation of pertussis vaccination for pregnant women in Denmark (focus on organizational aspects)

Potential questions/outcomes: *How can the Danish model of temporary free whooping cough vaccination for pregnant women inform broader European strategies for the implementation of maternal vaccination programs, particularly in response to outbreaks of vaccine-preventable diseases? What lessons can other European countries draw from Denmark's experience in extending, assessing, and potentially making permanent the whooping cough vaccination offer for pregnant women, especially regarding organizational aspects, vaccine uptake and public health outcomes?*

Related articles:
Source: Proposed by AIB secretariat

3.10.1. *Nordholm Anne Christine, Emborg Hanne-Dorthe, Nørgaard Sarah Kristine, Nygaard Ulrikka, Ronayne Aoife, Nielsen Lise Birk, Søborg Bolette, Andersen Peter H, Dalby Tine. Pertussis epidemic in Denmark, August 2023 to February 2024. Euro Surveill. 2024;29(14)*

Pertussis (whooping cough) is a highly contagious respiratory infection caused by Bordetella pertussis. The disease affects all ages, but infants (children < 1 year) experience the highest risk of severe disease and death. From August 2023 to February 2024, there has been a pertussis epidemic in Denmark, which is described here with data up to 22 March 2024 from our national surveillance system. Relevant public health measures are highlighted.

3.10.1 Cremer M, Kaempfen S, Lapaire O, Hoesli IM, Heininger U. ***Interventional study to improve pertussis and influenza vaccination uptake in pregnant women****. Eur J Obstet Gynecol Reprod Biol. 2024 Apr;295:201-209.*

Abstract Objectives: Pertussis and influenza are endemic infections and associated with relevant morbidity and mortality in newborns and young infants. The Swiss Federal Office of Public Health has recommended influenza vaccination since 2011 and pertussis vaccination in pregnancy (ViP) since 2013 and expanded to repetition in each pregnancy since 2017. ViP is safe and effective in preventing severe diseases, but implementation is a challenge. We hypothesized that the proportion of women receiving ViP is persistently low despite existing national recommendations. Our primary objective was to compare the proportion of pertussis and influenza vaccine recommendations for and its acceptance by pregnant women before and after an information campaign tailored to obstetricians. Secondly, we aimed to identify reasons for missing or declining ViP. **Study design**: We conducted a prospective, single-center, single-arm implementation study in the maternity ward at the University Women's Hospital Basel. We performed standardized interviews with women hospitalized for postpartum care before (October to December 2019, Phase 1, n = 262) and after an information campaign (October to December 2020, Phase 2, n = 233) and compared categorical variables using chi-squared or Fisher's exact test and continuous variables using Whitney Mann U test. **Results:** We found no significant differences in the proportion of recommendation for pertussis ViP (80 % vs. 84 %, p = 0.25) and implementation (76 % vs. 78 %, p = 0.63) between Phase 1 and 2. Main reasons for missing or declining vaccinations were lack of recommendation (62.8 %) and safety concerns regarding the unborn child (17.7 %). In contrast, the proportion of recommendation for influenza ViP (45 % vs. 63 %, p < 0.001) and implementation (29 % vs. 43 %, p < 0.001) increased significantly. **Conclusion**: Proactive recommendations by obstetricians play a key role in the implementation of ViP but is still insufficient in our setting. We believe that future efforts should aim to explore possible hurdles that impede recommendations by obstetricians for ViP. The focus should be on the needs and experiences of obstetricians in private practice, but also other health care professionals involved in care of pregnant women. Local campaigns do not seem effective enough, therefore national campaigns with new strategies are desirable.

3.10.2 Anraad C, van Empelen P, Ruiter RAC, Rijnders M, van Groessen K, van Keulen HM. ***Promoting informed decision making about maternal pertussis vaccination: the systematic development of an online tailored decision aid and a centering-based group antenatal care intervention****. Front Public Health. 2024;12:1256337. Published 2024 Feb 15.*

Abstract: Introduction: Maintaining and enhancing vaccine confidence continues to be a challenge. Making an informed decision not only helps to avoid potential future regret but also reduces susceptibility to misinformation. There is an urgent need for interventions that facilitate informed decision-making about vaccines. This paper describes the systematic development of two interventions designed to promote informed decision making and indirectly, acceptance of maternal pertussis vaccination (MPV) in the Netherlands. **Materials and methods:** The 6-step Intervention Mapping (IM) protocol was used for the development of an online tailored decision aid and Centering Pregnancy-based Group Antenatal Care (CP) intervention. A needs assessment was done using empirical literature and conducting a survey and focus groups (1), intervention objectives were formulated at the behavior and determinants levels (2), theoretical methods of behavior change were selected and translated into practical applications (3), which were further developed into the two interventions using user-centered design (4). Finally, plans were developed for implementation (5), and evaluation (6) of the interventions. **Results:** The needs assessment showed that pregnant women often based their decision about MPV on information sourced online and conversations with their partners, obstetric care providers, and peers. Responding to these findings, we systematically developed two interactive, theory-based interventions. We created an online tailored decision aid, subjecting it to four iterations of testing among pregnant women, including those with low literacy levels. Participants evaluated prototypes of the intervention positively on relevance and usability. In addition, a CP intervention was developed with midwives. **Conclusion:** Using IM resulted in the creation of an online decision aid and CP intervention to promote informed decision making regarding MPV. This description of the systematic development of the interventions not only serves to illustrate design rationales, it will also aid the interpretation of the evaluation of the interventions, the development of future interventions promoting informed decision and acceptance of vaccines, and comparisons with other interventions.

*3.10.3 Bagcchi S. **Pertussis cases rise in Denmark** [published correction appears in Lancet Infect Dis. 2024 Jan;24(1):e13]. Lancet Infect Dis. 2023;23(11):e469. doi:10.1016/S1473-3099(23)00645-X*

Abstract: not available

*3.10.4 Dalby T. **Clarifying pertussis in Denmark**. Lancet Infect Dis. 2024;24(2):e77. doi:10.1016/S1473-3099(23)00757-0*

Abstract: not available

*3.10.5 Statens Serum Institut. No 28/31 – 2023. **New temporary free whooping cough vaccination offer for pregnant women.***

Summary: Denmark reintroduces a temporary, free whooping cough vaccination for pregnant women from 1 August to 31 December 2023, due to a resurgence in cases, with plans to make it permanent. Initially launched in 2019 during an epidemic, its effectiveness, while proven internationally, was hard to evaluate in Denmark. The recent rise in cases, especially among infants, underscores the vaccine's importance for newborn protection. Pregnant women are advised to get vaccinated during the 2nd or 3rd trimester to prevent hospitalization of newborns. The offer also extends to those at risk of premature birth, with vaccinations possible from 16 weeks gestation.

*3.10.6 Immink MM, van Zoonen K, Jager NM, et al. **Maternal vaccination against pertussis as part of the national immunization program: a qualitative evaluation among obstetric care providers one year after the***

implementation in December 2019. BMC Health Serv Res. 2023;23(1):311. Published 2023 Mar 30. doi:10.1186/s12913-023-09274-1

Abstract: Background: Immunization of pregnant women with a tetanus-diphtheria-and-acellular-pertussis (Tdap) vaccine is an effective and safe way to protect infants from pertussis before their primary vaccinations. Vaccine uptake among pregnant women is influenced by their care providers' attitudes toward maternal vaccination. This qualitative study aimed to evaluate the implementation of the maternal Tdap vaccination under the National Immunization Program of the Netherlands from the perspective of obstetric care providers. **Methods:** In this qualitative and explorative study, we conducted in-depth interviews by telephone with obstetric care providers who were selected from a pool of respondents (convenience sampling) to a questionnaire in a previous study. The interviews were based on a semi-structured interview guide that covered three aspects of the implementation strategy: providers' overall experience with the implementation of maternal Tdap vaccination in the Netherlands; implementation logistics and counseling, and pregnant women referrals to municipal Youth Healthcare Centers. The interviews were recorded, pseudonymized and transcribed verbatim. Transcripts were analyzed according to the Thematic Analysis approach by two researchers independently in two phases of iterative coding, categorizing, reviewing and redefining until ultimately, emergent themes regarding maternal Tdap vaccination implementation were identified. **Results:** Interviews with 11 midwives and 5 OB-GYN physicians yielded 5 major themes regarding the Tdap vaccination implementation strategy: challenges throughout the implementation process, views on maternal Tdap vaccination, general versus tailored counseling, provider responsibilities in vaccine promotion, and impact of materials for information delivery. Participants indicated that to improve provider attitudes toward Tdap vaccination, its implementation requires **clear and transparent information about what is entailed**, i.e., what is expected from obstetric care providers, how they can obtain information, and when their actions must be initiated. Participants demanded **involvement throughout the implementation planning process.** They preferred tailored communication with pregnant women over a generalized approach. **Conclusion:** This study emphasized the importance of involving all relevant healthcare professionals in planning the implementation of maternal Tdap vaccination. Possible barriers perceived by these professionals should be taken into account in order to improve their attitudes toward vaccination, thus to increase uptake among pregnant women.

*3.10.7 Michelle L. Giles, Pauline Paterson, Flor M. Munoz, Heidi Larson, Philipp Lambach. Chapter 5 - **Global considerations on maternal vaccine introduction and implementation**. Editor(s): Elke E. Leuridan, Marta C. Nunes, Christine E. Jones, Maternal Immunization, Academic Press, 2020, Pages 87-111, ISBN 9780128145821,*

Abstract: Despite the substantial progress over the past two decades in reducing under-five deaths, progress in protecting newborns has been comparatively slower. A priority of the United Nations Sustainable Development Goals is to end preventable newborn deaths by 2030. One of the main causes of mortality in this group is infection, therefore, maternal immunization has emerged as a key intervention and strategy to address this problem. Maternal tetanus vaccination provides the proof of concept for successfully administering vaccines during pregnancy and as a strategy to prevent neonatal deaths. Maternal tetanus vaccination programs have also provided an opportunity to understand the operational challenges that may hamper achieving high vaccine coverage. Operational challenges, along with significant gaps in local burden of disease data, have become evident with maternal influenza vaccine programs that are not yet

widely introduced in low and middle-income countries. **Tetanus and influenza vaccination demonstrate the relevance of careful planning an implementation of national immunization strategies, and also inform on the impact that vaccine hesitancy can have on the uptake of vaccine by pregnant women.** With regards to **implementation planning, identifying the optimal service delivery must include defining the optimal timing of vaccination during pregnancy and platform of service delivery, including a careful assessment of existing service delivery capacity.** Furthermore, it is crucial to identify and **address questions** and concerns among pregnant women as well as among health care workers. With the emergence of new vaccines for use during pregnancy, such as Group B Streptococcus and Respiratory Syncytial Virus, other key issues common to all maternal vaccines need to be considered during implementation. Such issues include education, **training and communication of key target groups including pregnant women and health workers**. In addition, policy makers often rely on disease burden data to estimate the potential magnitude of benefit when deciding on the introduction of a new vaccine. This information is also crucial to inform the effect after implementation of the vaccine strategy. In addition to the key information required for policy makers, the education and training requirements, implementers need also to develop **clear plans including capacity for maintaining supply and cold chain requirements, dosing recommendations and optimal service delivery in the context of antenatal care practices.** Finally, ensuring **safety vigilance**, and evaluation of the proportional benefit to the mother and/or newborn is essential to ensure safe and sustainable use of vaccines in pregnant women.

*3.10.8 Kochhar S, Edwards KM, Ropero Alvarez AM, Moro PL, Ortiz JR. **Introduction of new vaccines for immunization in pregnancy - Programmatic, regulatory, safety and ethical considerations**. Vaccine. 2019 May 31;37(25):3267-3277. doi: 10.1016/j.vaccine.2019.04.075.*

Abstract: Immunizing pregnant women is a promising strategy to reduce infectious disease-related morbidity and mortality in pregnant women and their infants. Important pre-requisites for the successful introduction of new vaccines for immunization in pregnancy include political commitment and adequate financial resources: trained, committed and sufficient numbers of healthcare workers to deliver the vaccines; close integration of immunization programs with antenatal care and Maternal and Child Health services; adequate access to antenatal care by pregnant women in the country (especially in low and middle-income countries (LMIC)); and a high proportion of births occurring in health facilities (to ensure maternal and neonatal follow-up can be done). The framework needed to advance a vaccine program from product licensure to successful country-level implementation includes establishing and organizing evidence for anticipated vaccine program impact, developing supportive policies, and translating policies into local action. International and national coordination efforts, proactive planning from conception to implementation of the programs (including country-level policy making, planning, and implementation, regulatory guidance, pharmacovigilance) and country-specific and cultural factors must be taken into account during the vaccines introduction.

3.11 Equipping healthcare professionals and students: The role of training for implementing adult vaccines

Potential questions/outcomes: *What approaches can European public health authorities take to tailor immunization training programs that accommodate the diverse backgrounds and roles of healthcare professionals, ensuring effective vaccine delivery across the country/ Europe? What mechanisms can be established at the European level to facilitate cross-country sharing of best practices and*

lessons learned from immunization training programs, aiming to drive continuous improvement in vaccine coverage and public health outcomes? How has the COVID-19 pandemic influenced the methodologies and content of vaccine training programs in Europe?

Related articles:
Source: Proposed by AIB secretariat

*3.11.1 De Waele A, Hendrickx G, Valckx S, Domínguez À, Toledo D, Castilla J, Tuells J, Van Damme P. **The Vaccine Training Barometer: Assessing healthcare providers' confidence to answer vaccine-related questions and their training needs.** Vaccine. 2024 Mar 7:S0264-410X(24)00254-8.*

Abstract Healthcare providers (HCP) are seen by the public as the most trustworthy source of information about vaccination. While HCPs could be a valuable partner to increase vaccine confidence in general, it is not clear whether they feel confident themselves to address questions concerning vaccination. In the context of the EU Joint Action on Vaccination (EU-JAV), the Vaccine Training Barometer, an online survey tool, was developed to assess how frequently HCPs receive questions about vaccination, how confident they feel to answer these questions, and to what extent they are willing to follow extra training. After a pilot test in Flanders, Belgium, the Barometer was launched and completed by 833 HCPs in Flanders and 291 HCPs in the Spanish regions of Catalonia, Navarre and Valencian Community from November 2020 until January 2021, during the COVID-19 pandemic, just before and during the start of the first COVID-19 vaccination campaigns. In both countries, HCPs frequently received questions about vaccination (mostly on a daily or weekly basis), and about two thirds of them indicated that the frequency of questions had increased during the three months prior to completing the survey. Most questions were about the side effects and safety of vaccines. In both countries, a considerable proportion of HCPs did not feel confident to answer vaccine-related questions (31.5% felt confident in Flanders, 21.6% in Spain). A large proportion of HCPs received questions in the last three months before the survey that they could not answer (52.4% of respondents in Flemish sample, 41.5% in Spanish sample). Only 11.4% (Flanders) and 11.3% (Spain) of the respondents felt they gained sufficient knowledge through their standard education to be able to answer questions about vaccination. Almost all respondents were willing to follow extra training on vaccination (Flanders: 95.4%, Spain: 96.6%). The Vaccine Training Barometer is thus a useful tool to monitor HCPs' confidence to answer questions about vaccination and to capture their training needs.

*3.11.2 WHO. Network for Education and Support in Immunisation (NESI). **Framework for Immunization Training and Learning.***

Introduction: The global community allocates considerable human and financial resources to immunization training. The delivery of this training, however, has not kept pace with the increasing cost and complexity of vaccination programs. Funders, implementing partners, and national program managers have the opportunity to support and improve the training and performance of immunization ***Global Vaccinology Training Collaborative. Advanced vaccinology training globally: Update and impact of the COVID-19 crisis*** professionals by taking advantage of developments in learning science and instructional design, and by adapting, where appropriate, new tools and technologies to facilitate learning. The Framework for Immunization Training and Learning (FITL) is a shared conceptual framework that can be used by a wide range of stakeholders to support improved performance of managers and healthcare workers who deliver vaccination services, by creating a better environment for training and learning. The framework is not

intended to specify or prescribe the types of training or support to be implemented but is intended to provide guidance on areas that may be addressed at different levels throughout the system. FITL offers an initial structure while leaving space for individual organizations and countries to develop their own specific strategies and implementation plans. The hope is that organizations and countries will use this framework as a shared resource to collaborate on and improve their immunization training programs.

3.11.3 Dochez C, Duclos P, MacDonald N, Steffen C, Lambert PH; ***Global Vaccinology Training Collaborative. Advanced vaccinology training globally: Update and impact of the COVID-19 crisis****. Vaccine. 2022 Sep 16;40(39):5683-5690. doi: 10.1016/j.vaccine.2022.08.029.*

Abstract: The rapid development of innovations and new technologies, the focus on the life-course approach to immunization and equity, and the prevalent hesitancy towards vaccines requires immunization staff to be well-trained and updated regularly in order to deliver quality immunization services to the public. The need for advanced vaccinology training is therefore paramount. In preparation for a second Global Workshop on Advanced Vaccinology Training that took place in March 2022, this paper presents the results of a survey aiming to provide a thorough update of a landscape analysis on advanced vaccinology courses conducted in 2018 and a look at the impact of the COVID-19 crisis. Thirty-three course organizers responded to a survey to provide information on their respective course. Of those, 17 courses are short courses, 11 post-graduate courses and 5 are Master level courses. Most courses are organized on an annual basis. Even though some courses were not sustained overtime, the number of courses has been increasing during the last few years, and at least one vaccinology course is now being offered in each WHO region. **Although the training capacity has increased tremendously, the need still exceeds the capacity and many courses have way more applicants than they can select. The most frequent challenges reported included sustainable funding and identifying faculty.** The COVID-19 pandemic impacted the delivery of several vaccinology courses, which have been postponed or reformatted to an online or hybrid training event. An e-portal of the global collaboration has been established to facilitate communication between the different courses and to assist future course participants to identify the most suitable course for their needs.

3.11.4 Duclos P, MacDonald NE, Dochez C, Thacker N, Steffen CA, Nohynek H, Lambert PH, Wharton M; all participants of the Global Vaccinology Training Workshop (See Annex 1). ***Report of the 2nd workshop of the International Collaboration on advanced vaccinology training****. Vaccine. 2022 Nov 8;40(47):6689-6699. doi: 10.1016/j.vaccine.2022.09.091.*

Abstract: At a workshop on 22-24 March 2022, leaders of 33 advanced vaccinology courses were invited to meet with partners to further the aims of the International Collaboration on Advanced Vaccinology Training (ICAVT) initiated in 2018 to assist courses in addressing challenges in priority areas and facilitate interactions and exchange of information. This included: an update to the landscape analysis of advanced vaccinology courses conducted in 2018, sharing experiences and good practices in the implementation of virtual training, reviewing the training needs of target audiences, informing courses of the principles, challenges, and added value of accreditation, discussing course evaluations and measurement of course impact, reviewing principles and support needed for quality cascade training, reviewing COVID-19 impact on training and identifying remaining related training needs, and identifying solutions to facilitate refresher courses and ways to facilitate networking of courses' alumni (particularly for virtual courses). The aims were to identify needs and impediments and implement necessary actions to facilitate sharing of

information and resources between courses, to identify need for further developments of the e-Portal of the Collaboration (icavt.org) established to facilitate communication between the different courses and assist future course participants identify the most suitable course for them, and to discuss the formalization of the Collaboration. During the workshop, participants looked at several reports of surveys completed by courses and courses' alumni or partners. The COVID-19 pandemic impacted the delivery of some vaccinology courses leading to postponement, delivery online or hybrid training events. Lack of sustainable funding remained a major constraint for advanced vaccinology training and needs to be addressed. The Collaboration was consolidated with responsibilities and benefits for the members better defined. There was strong support for the Collaboration to continue with the organization of educational sessions at future workshops. The meeting re-enforced the view that there was much enthusiasm and commitment for the Global Collaboration and its core values.

3.11.5 Kernéis S, Jacquet C, Bannay A, May T, Launay O, Verger P, Pulcini C; EDUVAC Study Group. ***Vaccine Education of Medical Students: A Nationwide Cross-sectional Survey.*** *Am J Prev Med. 2017 Sep;53(3):e97-e104. doi: 10.1016/j.amepre.2017.01.014.*

Abstract: Physicians play a primary role in vaccination of the population. Strong initial training of medical students is therefore essential to enable them to fulfill this role. This cross-sectional nationwide online survey conducted between September 2015 and January 2016 obtained 2,118 completed surveys from 6,690 eligible respondents (response rate, 32%) at 27 of 32 medical schools in France regarding their education about vaccination. The data were analyzed in April-June 2016. The survey covered their knowledge, attitudes, practices, and perceptions, and assessed their level of perceived preparedness for their future practice as interns. Around a third of the students (n=708, 34%) felt insufficiently prepared for questions about vaccination, especially for communicating with patients on side effects (n=1,381, 66%) and strategies to respond to vaccine hesitancy (n=1,217, 58%). The mean knowledge score was 26/45 (SD=7.9). Lecture courses, which are the main education method used in French medical schools (1,891/5,660 responses, 33%), were considered effective by only 11% of students (693/6,155 responses), whereas practical training was significantly associated with better perceived preparedness (p<0.001). In conclusion, education about vaccination during medical school in France is not optimal. Methods based on practical learning methods (case-based learning, clinical placements, and other hands-on methods) appear to produce the best results and must be favored for improving students' preparedness.

3.12 Communicating with the public about vaccines: Implementation considerations

Potential questions/outcomes: *How can European health authorities effectively identify and address the diverse concerns and misconceptions among different population groups regarding vaccines, including COVID-19 and routine vaccinations, to tailor communication strategies that increase vaccination uptake across various demographics? Given the evidence on the mixed results of digital interventions in promoting vaccine uptake, what considerations should European countries make in integrating digital strategies, such as mobile messaging and social media campaigns, into their broader vaccine communication plans to ensure equity and access among all population groups, including those with limited digital literacy or access?*

Related articles:
Source: Proposed by AIB secretariat

3.12.1 European Commission. Directorate-General for Health and Food Safety. ***Factsheet - Implementation of EU actions to boost vaccine confidence. Strenghtening EU cooperation against vaccine preventable diseases.*** *2023 Dec.*

Extract: Prioritise communication on vaccination, explaining the benefits and combating the myths, misconceptions and scepticism that surround the issue.

3.12.2 Lorini C, Del Riccio M, Zanobini P, et al. ***Vaccination as a social practice: towards a definition of personal, community, population, and organizational vaccine literacy*** *[published correction appears in BMC Public Health. 2023 Aug 29;23(1):1658]. BMC Public Health. 2023;23(1):1501. Published 2023 Aug 8. doi:10.1186/s12889-023-16437-6*

Abstract: Background A comprehensive and agreed-upon definition of vaccine literacy (VL) could support the understanding of vaccination and help policymakers and individuals make informed decisions about vaccines. Methods To shed some light on this debate and provide clarity, a scoping review was conducted to collect, summarize, and analyse available definitions of VL. Based on the findings of the scoping review, a new and comprehensive definition was proposed by a panel of experts. Results Fifty-three articles were included, and two of them appeared to be the milestones around which the other definitions were grouped. The new definition proposed by the panel of experts included not only the personal perspective, but also the community, population, and organizational perspectives. Moreover, due to the increasing complexity of the social context with respect to the ability to navigate, understand, and use information and services, the definition of organizational vaccine literacy and the attributes of a vaccine literate healthcare organization have been proposed. Conclusion The new definition can contribute to the overall paradigm of health literacy and its distinct component of vaccine literacy, possibly improving the implementation of public health strategies to allow vaccination to be understood as a social practice by the entire community. This study describes the conceptual foundations, the competencies, and the civic orientation to be considered when developing measurement tools devoted to assessing VL at the different levels and in different contexts

3.12.3 Glenton C, Carlsen B, Lewin S, Wennekes MD, Winje BA, Eilers R; VITAL consortium. ***Healthcare workers' perceptions and experiences of communicating with people over 50 years of age about vaccination: a qualitative evidence synthesis.*** *Cochrane Database Syst Rev. 2021 Jul 20;7(7):CD013706. doi: 10.1002/14651858.CD013706.pub2.*

Abstract: Background: Infectious diseases are a major cause of illness and death among older adults. Vaccines can prevent infectious diseases, including against seasonal influenza, pneumococcal diseases, herpes zoster and COVID-19. However, the uptake of vaccination among older adults varies across settings and groups. Communication with healthcare workers can play an important role in older people's decisions to vaccinate. To support an informed decision about vaccination, healthcare workers should be able to identify the older person's knowledge gaps, needs and concerns. They should also be able to share and discuss information about the person's disease risk and disease severity; the vaccine's effectiveness and safety; and practical information about how the person can access vaccines. Therefore, healthcare workers need good communication skills and to actively keep up-to-date with the latest evidence. An understanding of their perceptions and experiences of this communication can help us train and support healthcare

workers and design good communication strategies. **Objectives:** To explore healthcare workers' perceptions and experiences of communicating with older adults about vaccination. **Search methods:** We searched MEDLINE, CINAHL and Scopus on 21 March 2020. We also searched Epistemonikos for related reviews, searched grey literature sources, and carried out reference checking and citation searching to identify additional studies. We searched for studies in any language. **Selection criteria:** We included qualitative studies and mixed-methods studies with an identifiable qualitative component. We included studies that explored the perceptions and experiences of healthcare workers and other health system staff towards communication with adults over the age of 50 years or their informal caregivers about vaccination. **Data collection and analysis:** We extracted data using a data extraction form designed for this review. We assessed methodological limitations using a list of predefined criteria. We extracted and assessed data regarding study authors' motivations for carrying out their study. We used a thematic synthesis approach to analyse and synthesise the evidence. We used the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach to assess our confidence in each finding. We examined each review finding to identify factors that may influence intervention implementation and we developed implications for practice. **Main results:** We included 11 studies in our review. Most studies explored healthcare workers' views and experiences about vaccination of older adults more broadly but also mentioned communication issues specifically. All studies were from high-income countries. The studies focused on doctors, nurses, pharmacists and others working in hospitals, clinics, pharmacies and nursing homes. These healthcare workers discussed different types of vaccines, including influenza, pneumococcal and herpes zoster vaccines. The review was carried out before COVID-19 vaccines were available. We downgraded our confidence in several of the findings from high confidence to moderate, low or very low confidence. One reason for this was that some findings were based on only small amounts of data. Another reason was that the findings were based on studies from only a few countries, making us unsure about the relevance of these findings to other settings. Healthcare workers reported that older adults asked about vaccination to different extents, ranging from not asking about vaccines at all, to great demand for information (high confidence finding). When the topic of vaccination was discussed, healthcare workers described a lack of information, and presence of misinformation, fears and concerns about vaccines among older adults (moderate confidence). The ways in which healthcare workers discussed vaccines with older adults appeared to be linked to what they saw as the aim of vaccination communication. Healthcare workers differed among themselves in their perceptions of this aim and about their own roles and the roles of older adults in vaccine decisions. Some healthcare workers thought it was important to provide information but emphasised the right and responsibility of older adults to decide for themselves. Others used information to persuade and convince older adults to vaccinate in order to increase 'compliance' and 'improve' vaccination rates, and in some cases to gain financial benefits. Other healthcare workers tailored their approach to what they believed the older adult needed or wanted (moderate confidence). Healthcare workers believed that older adults' decisions could be influenced by several factors, including the nature of the healthcare worker–patient relationship, the healthcare worker's status, and the extent to which healthcare workers led by example (low confidence). Our review also identified factors that are likely to influence how communication between healthcare workers and older adults take place. These included issues tied to healthcare workers' views and experiences regarding the diseases in question and the vaccines; as well as their views and experiences of the organisational and practical implementation of vaccine services. **Authors' conclusions: There is little research focusing specifically on healthcare workers' perceptions and experiences of communication with older adults about vaccination.** The studies we identified suggest that healthcare workers differed among themselves in their perceptions about the aim of this communication and about the role of older adults in vaccine decisions. Based

on these findings and the other findings in our review, we have developed a set of questions or prompts that may help health system planners or programme managers when planning or implementing strategies for vaccination communication between healthcare workers and older adults.

3.12.4 Cochrane Effective Practice and Organisation of Care (EPOC). ***Communicating to the public about vaccines and using digital strategies to promote vaccine uptake: information for planners and implementers.*** *2021*

Summary: Based on evidence from systematic reviews, Cochrane Effective Practice and Organisation of Care (EPOC) has prepared three information leaflets for health systems planners and implementers involved in developing vaccine communication strategies.

- The first leaflet provides **prompts and questions for planners implementing strategies to improve vaccination communication between healthcare workers and older adults**.
- The second leaflet presents prompts and questions **for planners implementing communication strategies for all target groups, including parents, older adults and healthcare workers** and is based on four systematic reviews of qualitative research.
- The third leaflet presents what we know about the effectiveness of digital strategies to promote vaccine uptake and summarises evidence from four systematic reviews on this topic.

3.12.5 European Commission. Commission Communication. **Strenghtening EU cooperation against vaccine preventable diseases.** 2018

Extract:
Priority activities should aim to:

- Strengthen the monitoring of vaccine uptake across all age groups, including healthcare workers, according to common guidance and methodologies, and share such data at EU level;
- Strengthen the effective application of Union rules on protection of healthcare workers, in particular by ensuring adequate training of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary;
- Convene a Coalition for Vaccination to bring together European associations of healthcare workers to commit to delivering accurate information to the public, combating myths and exchanging best practice;
- Optimise awareness-raising activities, including through partnerships with the education sector, social partners and action directed towards the media;
- Combat the spread of disinformation in the digital era and counter disinformation spread across borders;
- Produce, in the context of the State of Health in the EU process, a State of Confidence in Vaccines in the EU report to generate data for action at national and EU level;
- Improve access to objective and transparent information on vaccines and their safety, following the assessment of information needs on the part of both public and healthcare workers;
- Identify the barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups;
- Foster behavioral research to better understand context-specific determinants of hesitancy from the end-user perspective, and design tailored intervention strategies;
- Develop evidence-based tools and guidance at EU level in order to support countries to anticipate, pre-empt or respond to crises situations.

3.13 The impact of pharmacist involvement on immunization uptake in Europe

Potential questions/outcomes: Does policy change to allow pharmacist provision of (adult) vaccination increase population uptake?

3.13.1 PGEU European Community Pharmacists Position paper: The role of community pharmacists in vaccination ***https://www.pgeu.eu/wp-content/uploads/2023/11/The-role-of-community-pharmacists-in-vaccination-PGEU-Position-Paper.pdf***

Community Pharmacists can contribute through diverse ways to vaccination strategies, protecting public health and contributing to a robust and sustainable healthcare system. Pharmacists are ideally placed at the heart of communities to provide information, advice, referral, treatment, and preventative actions to reduce the burden of communicable and vaccine-preventable diseases. As part of their wider public health mission, community pharmacists and pharmacy organisations are also involved in public awareness campaigns on topics such as antimicrobial resistance and vaccine hesitancy. In addition to their core activities, community pharmacists across Europe are increasingly providing new and innovative services to complement wider efforts within health services to reduce the transmission of communicable diseases, improve effectiveness of treatment and increase vaccination coverage of the population. At national and local level, community pharmacists engage in a number of activities and provide a range of services to increase vaccination coverage including screening and signposting in the pharmacy, advocacy on availability and benefits of vaccination and ensuring pharmacists themselves are vaccinated. Many countries worldwide are moving towards expanding the scope of practice of pharmacists, namely through implementing pharmacist-led vaccination programmes. Currently, pharmacists can vaccinate in their pharmacies in 15 European countries (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Latvia, Luxembourg, Poland, Portugal, Norway, Romania, Switzerland, and the United Kingdom), for influenza and/or COVID-19. In 9 of these countries (Denmark, France, Greece, Ireland, Italy, Norway, Portugal, Switzerland, and the United Kingdom) pharmacists are able to administer other vaccines and medicines such as Pneumococcal, Travel vaccines, Herpes Zoster (shingles), Cholera, Diphtheria, Tetanus and Pertussis, Anti-Tetanus Serum injection, Meningococcal, Tick-borne Encephalitis, Typhoid Fever and Hepatitis A, Japanese-Encephalitis, Hepatitis A, Hepatitis B, Human Papillomavirus (HPV), Rabies, Human rotavirus, and Varicella. Apart from these, in at least 3 other countries (Croatia, Estonia, the Netherlands) other healthcare professionals (e.g., physicians or nurses) can provide the vaccination service in a pharmacy. Enabling pharmacists to administer vaccines increases accessibility, increases convenience for patients and most of all it improves overall vaccination rates. For example, evidence has shown that pharmacy-based vaccination services have led to increase flu vaccination rates among people who had missed their vaccination in the previous year and in those who would not have otherwise received a vaccine. Evidence also shows that one third of the vaccines were administered outside working days, highlighting the accessibility of the community pharmacies network and the contribution in decreasing work absenteeism. In this position paper PGEU suggests a number of policy recommendations to maximise the contribution that community pharmacists make to tackling vaccines-preventable diseases and improving vaccination coverage.

3.13.2 Aarnes RV, Nilsen MK. ***Norwegian Community Pharmacists' Experiences with COVID-19 Vaccination-A Qualitative Interview Study.*** *Pharmacy (Basel). 2023 Nov 19;11(6):181.*

Abstract Background: Immunising the population became important during the COVID-19 pandemic. Community pharmacies in Norway collaborated with municipalities to offer a vaccination services to increase the vaccination rate. Only some pharmacies were allowed to offer this service in the pandemic's early phase. This study learns about pharmacists' experiences during this first period of COVID-19 vaccination services in community pharmacies, which is relevant for informing policy and organisational decision makers about the feasibility and acceptability of pharmacy vaccination. Methods: Individual interviews were conducted with 13 pharmacists in community pharmacies offering a COVID-19 vaccination service. Informants were recruited from the eleven pharmacies that first offered COVID-19 vaccinations. The key themes in the interview were COVID-19 vaccination, what the pharmacists think about the vaccination service, and how it is performed. The data were analysed using systematic text condensation. Results: Three main themes and eight subthemes were identified. The main themes were creative solutions, organising and making resources available, and professionally satisfying and an important mission. The interviewed pharmacists experienced the COVID-19 vaccination service as hectic but something important that they would prioritise. They experienced their efforts to be substantial in the pandemic's early phase. Conclusions: Pharmacists in community pharmacies were a resource for increasing the vaccination rate during the COVID-19 pandemic. The pharmacies' easy accessibility and the pharmacists' ability to adjust their daily workflow for a new service should be considered when an expanded healthcare service is needed.

3.14.3 Le LM, Veettil SK, Donaldson D, Kategeaw W, Hutubessy R, Lambach P, Chaiyakunapruk N. ***The impact of pharmacist involvement on immunization uptake and other outcomes: An updated systematic review and meta-analysis****. J Am Pharm Assoc. 2022 Sep-Oct;62(5):1499-1513.e16.*

Abstract Background: The underutilization of immunization services remains a big public health concern. Pharmacists can address this concern by playing an active role in immunization administration. Objective: We performed a systematic review and meta-analysis to assess the impact of pharmacist-involved interventions on immunization rates and other outcomes indirectly related to vaccine uptake. Methods: A systematic literature search was conducted using MEDLINE, Embase, and Cochrane Central Register of Controlled Trials databases from inception to February 2022 to identify randomized controlled trials (RCTs) and observational studies in which pharmacists were involved in the immunization process. Studies were excluded if no comparator was reported. Two reviewers independently completed data extraction and bias assessments using standardized forms. Meta-analyses were performed using a random-effects model. Results: A total of 14 RCTs and 79 observational studies were included. Several types of immunizations were provided, including influenza, pneumococcal, herpes zoster, Tdap, and others in a variety of settings (community pharmacy, hospital, clinic, others). Pooled analyses from RCTs indicated that a pharmacist as immunizer (risk ratio 1.14 [95% CI 1.12-1.15]), advocator (1.31 [1.17-1.48]), or both (1.14 [1.12-1.15]) significantly increased immunization rates compared with usual care or non-pharmacist-involved interventions. The quality of evidence was assessed as moderate or low for those meta-analyses. Evidence from observational studies was consistent with the results found in the analysis of the RCTs. Conclusion: Pharmacist involvement as immunizer, advocator, or both roles has favorable effects on immunization uptake, especially with influenza vaccines in the United States and some high-income countries. As the practice of pharmacists in immunization has been expanded globally, further research on investigating the impact of pharmacist involvement in immunization in other countries, especially developing ones, is warranted.

*3.14.4 Spinks J, Bettington E, Downes M, Nissen L, Wheeler A. **Does policy change to allow pharmacist provision of influenza vaccination increase population uptake?** A systematic review. Aust Health Rev. 2020 Aug;44(4):582-589.*

Abstract - Objective The aims of this study were to estimate the effect of pharmacists' vaccinating for influenza on overall vaccination rates and to assess whether any effect differs for at-risk subgroups compared with the general population. Methods A systematic review was undertaken, adhering to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. Databases were searched during July 2019 and included Medline (Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus and the Cochrane Library. Results The largest difference reported in overall population vaccination rates associated with pharmacists undertaking influenza vaccinations was an increase of 10%; the smallest showed no discernible effect. The effect was graduated: pharmacists with the most autonomy demonstrated the largest rate increases. There was evidence of substitution by pharmacists, but the effect size was small. Conclusions The effect of allowing pharmacists to administer influenza vaccinations appears positive, but small. Given that pharmacists are likely to provide vaccinations at a lower cost than doctors, there may be cost-savings to the health system and consumers. Future research may include evaluating pharmacist-provided vaccinations compared with (or in combination with) other strategies, such as advertising, to increase access and uptake across the range of providers, as well as ongoing research to address vaccine hesitancy. What is known about the topic? In Australia, and many other countries, community pharmacies provide an alternative and accessible option for influenza vaccination; however the effect on overall vaccination rates remains unclear. What does this paper add? This systematic review of the international literature suggests that pharmacist-provided vaccinations increase uptake; substitution of doctors by pharmacists may result in cost savings. What are the implications for practitioners? The findings of this study are important for health policy makers and health workforce researchers aiming to maximise population vaccination rates and workforce efficiency. In the absence of available Australian data, data from the international experience of legislating pharmacists to vaccinate against influenza are summarised and critiqued. Results can be used when determining the best health workforce and policy mix with regard to the vaccination workforce.

Session 4: Monitoring – impact assessment

4.1 From insights to implementation: using behavioral and cultural insights to increase vaccine uptake

Potential questions/outcomes: *What are the key lessons learned from the implementation of the WHO Tailoring Immunization Programmes (TIP) approach in different countries? How has the TIP approach enhanced the understanding of community and individual perspectives, and what are the implications for improving immunization programs? What are the challenges and opportunities associated with implementing TIP findings to devise tailored immunization strategies at the local level?*

Session 4: Monitoring – impact assessment	4.1 From insights to implementation: using behavioural and cultural insights to increase vaccine uptake	Tiina Likki

	4.2 Adult vaccination program as part of the life-time vaccination in Spain - its cost/investment	Laura Sánchez Cambronero
	4.3 Monitoring Influenza/COVID-19 Vaccine Effectiveness in Europe – I-MOVE/VEBIS	Esther Kissling
	4.4 Safety Monitoring of COVID-19 and other vaccines for adults in the EU	Jean-Michel Dogné

Related articles:
Source: Proposed by AIB secretariat

4.1.1 - TIP: Tailoring Immunization Programmes

Extract - Vaccination is an excellent health intervention, saving millions of lives and even more pain and suffering. It can reduce inequalities, increase access to health services in general and even reduce poverty. So why are many people not fully protected from vaccine-preventable diseases? There is no simple answer. People may find that their health worker does not provide the support they need. Some may find opening hours and the waiting time inconvenient; others may have concerns about vaccine safety, or do not trust the health authorities. Some may not have been properly informed about when and where to go for vaccination.

To achieve high and equitable vaccination uptake, it is necessary to understand the barriers to vaccination among the population groups with suboptimal coverage. Then solutions can be designed that support, motivate and enable people to be vaccinated. Solutions that ensure all population groups are vaccinated, regardless of their income, education, age, geography, ethnicity, religion or philosophical beliefs.

The Tailoring Immunization Programmes (TIP) approach was developed by the WHO Regional Office for Europe to support countries to do this. It is grounded in scientific evidence and country experience and aims to integrate people-centred research and behavioural insights into immunization programme planning and policy. The TIP approach is founded on three main pillars:

- six values and principles;
- a theoretical model; and
- a phased process with detailed exercises.

The phases and steps of a TIP process are described in detail in this publication, supported by inspiration examples and exercises for TIP planning workshops.

4.1.2 - WHO. ***Human-centred design for tailoring immunization programmes.*** 2022.

Abstract: not available

*4.1.3 - Dubé E, Leask J, Wolff B, et al. **The WHO Tailoring Immunization Programmes (TIP) approach: Review of implementation to date**. Vaccine. 2018;36(11):1509-1515. doi:10.1016/j.vaccine.2017.12.012*

Abstract - Introduction: The WHO Regional Office for Europe developed the Guide to tailoring immunization programmes (TIP), offering countries a process through which to diagnose barriers and motivators to vaccination in susceptible low vaccination coverage and design tailored interventions. A review of TIP implementation was conducted in the European Region.
Material and methods: The review was conducted during June to December 2016 by an external review committee and was based on visits in Bulgaria, Lithuania, Sweden and the United Kingdom that had conducted a TIP project; review of national and regional TIP documents and an online survey of the Member States in the WHO European Region that had not conducted a TIP project. A review committee workshop was held to formulate conclusions and recommendations.
Results: The review found the most commonly cited strengths of the TIP approach to be the social science research as well as the interdisciplinary approach and community engagement, enhancing the ability of programmes to "listen" and learn, to gain an understanding of community and individual perspectives. National immunization managers in the Region are generally aware that TIP exists and that there is strong demand for the type of research it addresses. Further work is needed to assist countries move towards implementable strategies based on the TIP findings, supported by an emphasis on enhanced local ownership; integrated diagnostic and intervention design; and follow-up meetings, advocacy and incentives for decision-makers to implement and invest in strategies.
Conclusions: Understanding the perspectives of susceptible and low-coverage populations is crucial to improving immunization programmes. TIP provides a framework that facilitated this in four countries. In the future, the purpose of TIP should go beyond identification of susceptible groups and diagnosis of challenges and ensure a stronger focus on the design of strategies and appropriate and effective interventions to ensure long-term change.

4.2 Adult vaccination program as part of the life-time vaccination in Spain - its cost/investment

Potential questions/outcomes: *How do the costs and benefits of adult vaccination programs compare, and what factors contribute to their economic viability? Enhanced understanding of the economic impact of adult vaccination programs, including their return on investment and cost-benefit ratios; identification of the factors that influence the profitability and financial viability of adult vaccination programs. Considering the significant cost variations introduced by new vaccines and expanded vaccination schedules, what innovative financing models can European countries explore to sustainably fund their vaccination programs without compromising on the scope and quality of public health services? How can European health systems leverage digital technologies and data analytics, as suggested by Spain's experience, to enhance the efficiency of vaccine distribution, track vaccination outcomes, and optimize the cost-effectiveness of vaccination programs across diverse populations?*

Related articles:
Source: Proposed by AIB secretariat

*4.2.1 - Bencina G, Bento-Abreu A, Sabale U, et al. **Estimating the lifetime cost of vaccination in 23 European Countries: a modeling study**. Expert Rev Vaccines. 2023;22(1):148-160. doi:10.1080/14760584.2023.2157266*

Abstract - Background - All European countries have national immunization programs (NIPs) to protect against infectious diseases. We aimed to estimate the individual lifetime cost of vaccination in 23 European countries, assuming full compliance with NIP schedules. **Research design and methods** - We used publicly available data to estimate the individual lifetime cost of vaccination with the vaccines that are currently recommended and funded in each country for healthy individuals and for individuals with underlying medical conditions. We included a scenario analysis for healthy individuals in which all currently recommended vaccines were universally funded, and compared the annual costs per person of vaccination to the annual per-capita costs of all-cause hospitalization and anti-infective medications. **Results** - The individual lifetime cost of vaccination was €592–3,504 for healthy individuals (median: €1,663; 13–20 diseases), €744–9,081 for individuals with underlying conditions (median: €2,992; 13–21 diseases), and €1,225–4,832 (median: €2,565; 21–22 diseases) in the scenario analysis, with median values for vaccine acquisition of €1,203, €1,731, and €1,788, respectively. **Conclusions** - Our estimates show that the maximum potential cost of vaccination requires a relatively low level of investment assuming full compliance. These data could be useful for policymakers in future financial planning and evaluation of NIPs.

4.2.2 - Fernández Conde S, Cifo Arcos D, Sánchez-Cambronero Cejudo L, et al. ***Actualización del coste de vacunar a lo largo de toda la vida en España para el año 2023 [Updated cost of vaccinating throughout life in Spain in 2023].*** *Rev Esp Salud Publica. 2023;97:e202312116. Published 2023 Dec 29.*

Abstract: Objective: Four modifications were introduced in the Lifetime Vaccination Schedule of the Interterritorial Council of the National Health System (CISNS) in 2023. The aim of this study was to estimate the cost of vaccinating a healthy person and people with certain risk conditions throughout life in Spain and to compare with a previous estimation from 2019. Methods: A descriptive study of the cost of administering the vaccines included in the Lifetime Vaccination Schedule for the year 2023 and in the schedule for risk groups was carried out. Results: The estimated cost to immunize a healthy person throughout life in 2023 is 1,541.56€ for a woman and 1,498.18€ for a men, which corresponds to an increase of 125% compared to the cost in 2019. The risk conditions with the highest cost are asplenia and complement deficiency and primary immunodeficiencies, with a cost of 3,159.82 euros and 2,566 euros respectively on average. The cost of vaccinating the whole healthy population in Spain in a year is around 565M€. Moreover, the cost of vaccinating the new-borns cohort of 2023 was estimated at 500M€. Conclusions: Despite the cost increase in 2023, immunization is still a very cheap intervention, considering the economic impact of vaccine preventable diseases in the society. The relative low cost of immunization throughout life makes this health intervention useful and worthwhile.

4.2.3 - Leidner AJ, Murthy N, Chesson HW, et al. ***Cost-effectiveness of adult vaccinations: A systematic review.*** *Vaccine. 2019;37(2):226-234. doi:10.1016/j.vaccine.2018.11.056*

Abstract Background: Coverage levels for many recommended adult vaccinations are low. The cost-effectiveness research literature on adult vaccinations has not been synthesized in recent years, which may contribute to low awareness of the value of adult vaccinations and to their under-utilization. We assessed research literature since 1980 to summarize economic evidence for adult vaccinations included on the adult immunization schedule. **Methods:** We searched PubMed, EMBASE, EconLit, and Cochrane Library from 1980 to 2016 and identified economic evaluation or cost-effectiveness analysis for vaccinations targeting persons aged

≥18 years in the U.S. or Canada. After excluding records based on title and abstract reviews, the remaining publications had a full-text review from two independent reviewers, who extracted economic values that compared vaccination to "no vaccination" scenarios. **Results:** The systematic searches yielded 1688 publications. After removing duplicates, off-topic publications, and publications without a "no vaccination" comparison, 78 publications were included in the final analysis (influenza = 25, pneumococcal = 18, human papillomavirus = 9, herpes zoster = 7, tetanus-diphtheria-pertussis = 9, hepatitis B = 9, and multiple vaccines = 1). Among outcomes assessing age-based vaccinations, the percent indicating cost-savings was 56% for influenza, 31% for pneumococcal, and 23% for tetanus-diphtheria-pertussis vaccinations. Among age-based vaccination outcomes reporting $/QALY, the percent of outcomes indicating a cost per QALY of ≤$100,000 was 100% for influenza, 100% for pneumococcal, 69% for human papillomavirus, 71% for herpes zoster, and 50% for tetanus-diphtheria-pertussis vaccinations. **Conclusions:** The majority of published studies report favorable cost-effectiveness profiles for adult vaccinations, which supports efforts to improve the implementation of adult vaccination recommendations.

4.2.4 - Ozawa S, Portnoy A, Getaneh H, et al. ***Modeling The Economic Burden Of Adult Vaccine-Preventable Diseases In The United States****. Health Aff (Millwood). 2016;35(11):2124-2132. doi:10.1377/hlthaff.2016.0462*

Abstract

Vaccines save thousands of lives in the United States every year, but many adults remain unvaccinated. Low rates of vaccine uptake lead to costs to individuals and society in terms of deaths and disabilities, which are avoidable, and they create economic losses from doctor visits, hospitalizations, and lost income. To identify the magnitude of this problem, we calculated the current economic burden that is attributable to vaccine-preventable diseases among US adults.

We estimated the total remaining economic burden at approximately $9 billion (plausibility range: $4.7–$15.2 billion) in a single year, 2015, from vaccine-preventable diseases related to ten vaccines recommended for adults ages nineteen and older. Unvaccinated individuals are responsible for almost 80 percent, or $7.1 billion, of the financial burden. These results not only indicate the potential economic benefit of increasing adult immunization uptake but also highlight the value of vaccines. Policies should focus on minimizing the negative externalities or spillover effects from the choice not to be vaccinated, while preserving patient autonomy.

4.2.5 - Wateska AR, Nowalk MP, Zimmerman RK, Smith KJ, Lin CJ. ***Cost-effectiveness of increasing vaccination in high-risk adults aged 18-64 Years: a model-based decision analysis****. BMC Infect Dis. 2018;18(1):52. Published 2018 Jan 25. doi:10.1186/s12879-018-2967-2*

Abstract: Background - Adults aged 18–64 years with comorbid conditions are at high risk for complications of certain vaccine-preventable diseases, including influenza and pneumococcal disease. The 4 Pillars™ Practice Transformation Program (4 Pillars Program) increases uptake of pneumococcal polysaccharide vaccine, influenza vaccine and tetanus-diphtheria-acellular pertussis vaccine by 5–10% among adults with high-risk medical conditions, but its cost-effectiveness is unknown. Methods - A decision tree model estimated the cost-effectiveness of implementing the 4 Pillars Program in primary care practices compared to no program for a population of adults 18–64 years of age at high risk of illness complications over a 10 year time horizon. Vaccination rates and intervention costs were derived from a randomized controlled cluster trial in diverse practices in 2 U.S. cities. One-way and probabilistic sensitivity analyses were conducted. Results

- From a third-party payer perspective, which considers direct medical costs, the 4 Pillars Program cost $28,301 per quality-adjusted life year gained; from a societal perspective, which adds direct nonmedical and indirect costs, the program was cost saving and more effective than no intervention. Cost effectiveness results favoring the program were robust in sensitivity analyses. From a public health standpoint, the model predicted that the intervention reduced influenza cases by 1.4%, with smaller decreases in pertussis and pneumococcal disease cases. Conclusion - The 4 Pillars Practice Transformation Program is an economically reasonable, and perhaps cost saving, strategy for protecting the health of adults aged < 65 years with high-risk medical conditions.

4.3 Monitoring Influenza/COVID-19 Vaccine Effectiveness in Europe – I-MOVE/VEBIS

Potential questions/outcomes: *How is the surveillance system structured to monitor the effectiveness of influenza and COVID-19 vaccines in the EU, and what key indicators are being tracked? What are the main challenges in monitoring vaccine effectiveness, and which strategies are being implemented to address these challenges? What are the priority areas for future research in monitoring vaccine effectiveness, and how can international collaboration further enhance these efforts? What lessons can be learned about monitoring vaccine effectiveness (VE) for other vaccine-preventable diseases (VPDs) in adults? How does this data influence the implementation of influenza vaccines in subsequent years and the introduction of new vaccines?*

Related articles:
Source: Proposed by AIB secretariat

4.3.1 - I-MOVE (Influenza – Monitoring Vaccine Effectiveness in Europe)

Extract: The I-MOVE (Influenza – Monitoring Vaccine Effectiveness in Europe) network aims to measure influenza vaccine effectiveness (VE) in Europe. The project started in 2007 and has carried out multicentre and other studies since the 2008–9 influenza season. The network consists of 29 partners including ECDC, WHO-EURO, regional and national public health institutes, hospitals, small and medium enterprises, and universities from 15 European Union/European Economic Area Member States. The I-MOVE network measures VE in a way that is scientifically and financially independent from vaccine manufacturers. The I-MOVE network includes a multicentre study at primary care level to measure influenza VE and a multicentre study carried out at hospital level to measure VE against severe influenza. Within the I-MOVE network we also carry out studies measuring the impact of influenza vaccination campaigns.

4.3.2 - Vaccine Effectiveness, Burden and Impact Studies (VEBIS) of COVID-19 and Influenza.

Introduction: The objective of the project is to provide technical support to the European Center for Disease Prevention and Control to build an infrastructure to allow regular monitoring of COVID-19 and influenza vaccine effectiveness over time, using a multi-country approach. The VEBIS platform includes vaccine effectiveness studies implemented in different settings.

*4.3.3 - de Waure C, Gärtner BC, Lopalco PL, Puig-Barbera J, Nguyen-Van-Tam JS. **Real world evidence for public health decision-making on vaccination policies: perspectives from an expert roundtable**. Expert Rev Vaccines. 2024;23(1):27-38. doi:10.1080/14760584.2023.2290194*

Abstract: **Introduction:** Influenza causes significant morbidity and mortality, but influenza vaccine uptake remains below most countries' targets. Vaccine policy recommendations vary, as do procedures for reviewing and appraising the evidence. **Areas Covered:** During a series of roundtable discussions, we reviewed procedures and methodologies used by health ministries in four European countries to inform vaccine recommendations. We review the type of evidence currently recommended by each health ministry and the range of approaches toward considering randomized controlled trials (RCTs) and real-world evidence (RWE) studies when setting influenza vaccine recommendations.
Expert Opinion: Influenza vaccine recommendations should be based on data from both RCTs and RWE studies of efficacy, effectiveness, and safety. Such data should be considered alongside health-economic, cost-effectiveness, and budgetary factors. Although RCT data are more robust and less prone to bias, well-designed RWE studies permit timely evaluation of vaccine benefits, effectiveness comparisons over multiple seasons in large populations, and detection of rare adverse events, under real-world conditions. Given the variability of vaccine effectiveness due to influenza virus mutations and increasing diversification of influenza vaccines, we argue that consideration of both RWE and RCT evidence is the best approach to more nuanced and timely updates of influenza vaccine recommendations.

*4.3.4 - Maurel M, Howard J, Kissling E, et al. **Interim 2023/24 influenza A vaccine effectiveness: VEBIS European primary care and hospital multicentre studies, September 2023 to January 2024**. Euro Surveill. 2024;29(8):2400089. doi:10.2807/1560-7917.ES.2024.29.8.2400089*

Abstract: Influenza A viruses circulated in Europe from September 2023 to January 2024, with influenza A(H1N1)pdm09 predominance. We provide interim 2023/24 influenza vaccine effectiveness (IVE) estimates from two European studies, covering 10 countries across primary care (EU-PC) and hospital (EU-H) settings. Interim IVE was higher against A(H1N1)pdm09 than A(H3N2): EU-PC influenza A(H1N1)pdm09 IVE was 53% (95% CI: 41 to 63) and 30% (95% CI: -3 to 54) against influenza A(H3N2). For EU-H, these were 44% (95% CI: 30 to 55) and 14% (95% CI: -32 to 43), respectively.

*4.3.5 - Maurel M, Pozo F, Pérez-Gimeno G, et al. **Influenza vaccine effectiveness in Europe: Results from the 2022-2023 VEBIS (Vaccine Effectiveness, Burden and Impact Studies) primary care multicentre study**. Influenza Other Respir Viruses. 2024;18(1):e13243. Published 2024 Jan 10. doi:10.1111/irv.13243*

Abstract: Background - Influenza A(H3N2) viruses dominated early in the 2022–2023 influenza season in Europe, followed by higher circulation of influenza A(H1N1)pdm09 and B viruses. The VEBIS primary care network estimated the influenza vaccine effectiveness (VE) using a multicentre test-negative study. **Materials and Methods** - Primary care practitioners collected information and specimens from patients consulting with acute respiratory infection. We measured VE against any influenza, influenza (sub)type and clade, by age group, by influenza vaccine target group and by time since vaccination, using logistic regression. **Results** - We included 38 058 patients, of which 3786 were influenza A(H3N2), 1548 influenza A(H1N1)pdm09 and 3275 influenza B cases. Against influenza A(H3N2), VE was 36% (95% CI: 25–45) among all ages and ranged between 30%

and 52% by age group and target group. VE against influenza A(H3N2) clade 2b was 38% (95% CI: 25–49). Overall, VE against influenza A(H1N1)pdm09 was 46% (95% CI: 35–56) and ranged between 29% and 59% by age group and target group. VE against influenza A(H1N1)pdm09 clade 5a.2a was 56% (95% CI: 46–65) and 79% (95% CI: 64–88) against clade 5a.2a.1. VE against influenza B was 76% (95% CI: 70–81); overall, 84%, 72% and 71% were among 0–14-year-olds, 15–64-year-olds and those in the influenza vaccination target group, respectively. VE against influenza B with a position 197 mutation of the hemagglutinin (HA) gene was 79% (95% CI: 73–85) and 90% (95% CI: 85–94) without this mutation **Conclusion** - The 2022–2023 end-of-season results from the VEBIS network at primary care level showed high VE among children and against influenza B, with lower VE against influenza A(H1N1)pdm09 and A(H3N2).

4.3.6 - Poukka E, van Roekel C, Turunen T, et al. ***Effectiveness of Vaccines and Monoclonal Antibodies Against Respiratory Syncytial Virus: Generic Protocol for Register-Based Cohort Study.*** *J Infect Dis. 2024;229(Supplement_1):S84-S91. doi:10.1093/infdis/jiad484*

Abstract: Several immunization products are currently being developed against respiratory syncytial virus (RSV) for children, pregnant females, and older adults, and some products have already received authorization. Therefore, studies to monitor the effectiveness of these products are needed in the following years. To assist researchers to conduct postmarketing studies, we developed a generic protocol for register-based cohort studies to evaluate immunization product effectiveness against RSV-specific and nonspecific outcomes. To conduct a study on the basis of this generic protocol, the researchers can use any relevant databases or healthcare registers that are available at the study site.

4.3.7 - Rose AM, Nicolay N, Sandonis Martín V, et al. ***Vaccine effectiveness against COVID-19 hospitalisation in adults (≥ 20 years) during Omicron-dominant circulation: I-MOVE-COVID-19 and VEBIS SARI VE networks, Europe, 2021 to 2022****. Euro Surveill. 2023;28(47):2300187. doi:10.2807/1560-7917.ES.2023.28.47.2300187*

Abstract: Introduction - The I-MOVE-COVID-19 and VEBIS hospital networks have been measuring COVID-19 vaccine effectiveness (VE) in participating European countries since early 2021. **Aim** - We aimed to measure VE against PCR-confirmed SARS-CoV-2 in patients ≥ 20 years hospitalised with severe acute respiratory infection (SARI) from December 2021 to July 2022 (Omicron-dominant period). **Methods** - In both networks, 46 hospitals (13 countries) follow a similar test-negative case–control protocol. We defined complete primary series vaccination (PSV) and first booster dose vaccination as last dose of either vaccine received ≥ 14 days before symptom onset (stratifying first booster into received < 150 and ≥ 150 days after last PSV dose). We measured VE overall, by vaccine category/product, age group and time since first mRNA booster dose, adjusting by site as a fixed effect, and by swab date, age, sex, and presence/absence of at least one commonly collected chronic condition. **Results** - We included 2,779 cases and 2,362 controls. The VE of all vaccine products combined against hospitalisation for laboratory-confirmed SARS-CoV-2 was 43% (95% CI: 29–54) for complete PSV (with last dose received ≥ 150 days before onset), while it was 59% (95% CI: 51–66) after addition of one booster dose. The VE was 85% (95% CI: 78–89), 70% (95% CI: 61–77) and 36% (95% CI: 17–51) for those with onset 14–59 days, 60–119 days and 120–179 days after booster vaccination, respectively. **Conclusions** - Our results suggest that, during the Omicron period, observed VE against SARI hospitalisation improved with first mRNA

booster dose, particularly for those having symptom onset < 120 days after first booster dose.

*4.3.8 - Dean NE, Hogan JW, Schnitzer ME. **Covid-19 Vaccine Effectiveness and the Test-Negative Design**. N Engl J Med. 2021;385(15):1431-1433. doi:10.1056/NEJMe2113151*

Abstract: not available

*4.3.9 - Andrews N, Stowe J, Kirsebom F, et al. **Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant**. N Engl J Med. 2022;386(16):1532-1546. doi:10.1056/NEJMoa2119451*

Abstract: Background: A rapid increase in coronavirus disease 2019 (Covid-19) cases due to the omicron (B.1.1.529) variant of severe acute respiratory syndrome coronavirus 2 in highly vaccinated populations has aroused concerns about the effectiveness of current vaccines. **Methods:** We used a test-negative case-control design to estimate vaccine effectiveness against symptomatic disease caused by the omicron and delta (B.1.617.2) variants in England. Vaccine effectiveness was calculated after primary immunization with two doses of BNT162b2 (Pfizer-BioNTech), ChAdOx1 nCoV-19 (AstraZeneca), or mRNA-1273 (Moderna) vaccine and after a booster dose of BNT162b2, ChAdOx1 nCoV-19, or mRNA-1273. **Results:** Between November 27, 2021, and January 12, 2022, a total of 886,774 eligible persons infected with the omicron variant, 204,154 eligible persons infected with the delta variant, and 1,572,621 eligible test-negative controls were identified. At all time points investigated and for all combinations of primary course and booster vaccines, vaccine effectiveness against symptomatic disease was higher for the delta variant than for the omicron variant. No effect against the omicron variant was noted from 20 weeks after two ChAdOx1 nCoV-19 doses, whereas vaccine effectiveness after two BNT162b2 doses was 65.5% (95% confidence interval [CI], 63.9 to 67.0) at 2 to 4 weeks, dropping to 8.8% (95% CI, 7.0 to 10.5) at 25 or more weeks. Among ChAdOx1 nCoV-19 primary course recipients, vaccine effectiveness increased to 62.4% (95% CI, 61.8 to 63.0) at 2 to 4 weeks after a BNT162b2 booster before decreasing to 39.6% (95% CI, 38.0 to 41.1) at 10 or more weeks. Among BNT162b2 primary course recipients, vaccine effectiveness increased to 67.2% (95% CI, 66.5 to 67.8) at 2 to 4 weeks after a BNT162b2 booster before declining to 45.7% (95% CI, 44.7 to 46.7) at 10 or more weeks. Vaccine effectiveness after a ChAdOx1 nCoV-19 primary course increased to 70.1% (95% CI, 69.5 to 70.7) at 2 to 4 weeks after an mRNA-1273 booster and decreased to 60.9% (95% CI, 59.7 to 62.1) at 5 to 9 weeks. After a BNT162b2 primary course, the mRNA-1273 booster increased vaccine effectiveness to 73.9% (95% CI, 73.1 to 74.6) at 2 to 4 weeks; vaccine effectiveness fell to 64.4% (95% CI, 62.6 to 66.1) at 5 to 9 weeks. **Conclusions:** Primary immunization with two doses of ChAdOx1 nCoV-19 or BNT162b2 vaccine provided limited protection against symptomatic disease caused by the omicron variant. A BNT162b2 or mRNA-1273 booster after either the ChAdOx1 nCoV-19 or BNT162b2 primary course substantially increased protection, but that protection waned over time. (Funded by the U.K. Health Security Agency.).

4.4 Safety Monitoring of COVID-19 and other vaccines for adults in the EU

***Potential questions/outcomes:** Who is responsible for the safety monitoring of vaccines for adults in the EU, and what specific measures are in place to ensure comprehensive oversight? How are suspected adverse events following*

immunization (AEFI) reported and assessed in the EU, and what actions are taken based on this reporting? How is safety information on vaccines communicated to health care professionals and the public in the EU, and what efforts are made to ensure transparency and public confidence? How can the methodologies developed for real-time safety monitoring of COVID-19 vaccines, including the integration of EudraVigilance data and real-world evidence, be applied or adapted for the surveillance of other vaccines' safety in the European context? What can be done better in the future? And what lessons can we learn from specific examples?

Related articles:
Source: Proposed by AIB secretariat

4.4.1 - **EMA: Safety of COVID-19 vaccines**

Extract: The European Medicines Agency (EMA) monitors the safety of COVID-19 vaccines authorised in the European Union (EU) extremely carefully. With hundreds of millions of people already vaccinated in the EU, this enables the continued detection of any rare side effects.

*4.4.2 - Clothier HJ, Shetty AN, Mesfin Y, Mackie M, Pearce C, Buttery JP. **What would have happened anyway? Population data source considerations when estimating background incident rates of adverse events following immunisation to inform vaccine safety**. Vaccine. 2024 Feb 15;42(5):1108-1115.*

Abstract: Introduction: Understanding background incident rates of adverse events following immunisation (AEFI) is essential to rapidly detect, evaluate, respond to, and communicate about vaccine safety concerns, especially for new vaccines. Creating estimates based on geographic specific population level data is increasingly important, as new AEFI presentations will be subject to the same local influences of population demography, exposures, health system variations and level of health care sought. **Methods:** We conducted a retrospective cohort analysis of hospital admissions, emergency department presentations and general practice consultations from 2015 to 2019-before introduction of COVID-19, Mpox or Shingrix vaccination-to estimate background incident rates for 37 conditions considered potential AEFI of special interest (AESI). Background incident rates per 100,000 population were calculated and presented as cases expected to occur coincidentally 1 day, 1 week and 6 weeks post-vaccination, by life-stage age-groups and presenting healthcare setting. We then assessed the proportional contribution of each data source to inform each AESI background rate estimate. **Results:** 16,437,156 episodes of the 37 AESI were identified. Hospital admissions predominantly informed 19 (51%) of AESI, including exclusively ADEM and CVST; 8 AESI (22%) by primary care, and 10 (27%) a mix. Four AESI (allergic urticaria, Bell's palsy, erythema multiform and sudden death) were better informed by emergency presentations than admissions, but conversely 11 AESI (30%) were not captured in ICD-10 coded emergency presentations at all. **Conclusions:** Emergent safety concerns are inevitable in population-wide implementation of new vaccines, therefore understanding local background rates aids both safety signal detection as well as maintaining public confidence in vaccination. Hospital and primary care data sources can be interrogated to inform expected background incident rates of adverse events that may occur following vaccination. However, it is necessary to understand which data-source provides best intelligence according to nature of condition and presenting healthcare setting.

*4.4.3 - Durand J, Dogné JM, Cohet C, et al. **Safety Monitoring of COVID-19 Vaccines: Perspective from the European Medicines Agency**. Clin Pharmacol Ther. 2023;113(6):1223-1234. doi:10.1002/cpt.2828*

Abstract - Prior to deployment of coronavirus disease 2019 (COVID-19) vaccines in the European Union in 2021, a high vaccine uptake leading to an unprecedented volume of safety data from spontaneous reports and real-world evidence, was anticipated. The European Medicines Agency (EMA) implemented specific activities to ensure enhanced monitoring of emerging vaccine safety information, including intensive monitoring of reports of adverse events of special interest and the use of observed-to-expected analyses. The EMA also commissioned several independent observational studies using a large network of electronic healthcare databases and primary data collection via mobile and web-based applications. This preparedness was key for two high-profile safety signals: thrombosis with thrombocytopenia syndrome (TTS), a new clinical entity associated with adenovirus-vectored vaccines, and myocarditis/pericarditis with messenger RNA vaccines. With no existing case definition nor background rates, the signal of TTS posed particular challenges. Nevertheless, it was rapidly identified, evaluated, contextualized and the risk minimized thanks to close surveillance and an efficient use of available evidence, clinical expertise and flexible regulatory tools. The two signals illustrated the complementarity between spontaneous and real-world data, the former enabling rapid risk identification and communication, the latter enabling further characterization. The COVID-19 pandemic has tremendously enhanced the development of tools and methods to harness the unprecedented volume of safety data generated for the vaccines. Areas for further improvement include the need for better and harmonized data collection across Member States (e.g., stratified vaccine exposure) to support signal evaluation in all population groups, risk contextualization, and safety communication.

*4.4.4 - Willame C, Dodd C, Durán CE, et al. **Background rates of 41 adverse events of special interest for COVID-19 vaccines in 10 European healthcare databases - an ACCESS cohort study**. Vaccine. 2023;41(1):251-262. doi:10.1016/j.vaccine.2022.11.031*

Abstract: Background: In May 2020, the ACCESS (The vACCine covid-19 monitoring readinESS) project was launched to prepare real-world monitoring of COVID-19 vaccines. Within this project, this study aimed to generate background incidence rates of 41 adverse events of special interest (AESI) to contextualize potential safety signals detected following administration of COVID-19 vaccines. **Methods:** A dynamic cohort study was conducted using a distributed data network of 10 healthcare databases from 7 European countries (Italy, Spain, Denmark, The Netherlands, Germany, France and United Kingdom) over the period 2017 to 2020. A common protocol (EUPAS37273), common data model, and common analytics programs were applied for syntactic, semantic and analytical harmonization. Incidence rates (IR) for each AESI and each database were calculated by age and sex by dividing the number of incident cases by the total person-time at risk. Age-standardized rates were pooled using random effect models according to the provenance of the events. **Findings:** A total number of 63,456,074 individuals were included in the study, contributing to 211.7 million person-years. A clear age pattern was observed for most AESIs, rates also varied by provenance of disease diagnosis (primary care, specialist care). Thrombosis with thrombocytopenia rates were extremely low ranging from 0.06 to 4.53/100,000 person-years for cerebral venous sinus thrombosis (CVST) with thrombocytopenia (TP) and mixed venous and arterial thrombosis with TP, respectively. **Interpretation:** Given the nature of the AESIs and the setting (general practitioners or hospital-based databases or both), background rates from databases that show the highest level of

completeness (primary care and specialist care) should be preferred, others can be used for sensitivity. The study was designed to ensure representativeness to the European population and generalizability of the background incidence rates.

4.4.5 - Lopalco PL, Johansen K, Ciancio B, De Carvalho Gomes H, Kramarz P, Giesecke J. ***Monitoring and assessing vaccine safety: a European perspective****. Expert Rev Vaccines. 2010;9(4):371-380. doi:10.1586/erv.10.20 g/10.1586/erv.10.20*

Abstract: The success of vaccination programs is an uncontroversial reality – in Europe as well as worldwide. On the other hand, the perceived risk of adverse events in the general public is the most important threat for implementing successful vaccination programs in Europe. For this reason, monitoring and assessing vaccine safety is a priority for public health. Vaccine safety is assessed both before and after vaccine authorization. In postmarketing settings, different activities related to vaccine safety usually involve several different stakeholders. In 2005, a new EU agency, the European Centre for Disease Prevention and Control, was established with the aim to strengthen Europe's defences against infectious diseases. Implementing stable links between different stakeholders and defining clear roles in the EU is paramount in order to provide optimal and transparent information on adverse reactions following immunization, with the final goal of increasing compliance to safe and effective vaccination programs.

4.4.6 - Zanoni G, Berra P, Lucchi I, et al. ***Vaccine adverse event monitoring systems across the European Union countries: time for unifying efforts****. Vaccine. 2009;27(25-26):3376-3384. doi:10.1016/j.vaccine.2009.01.059*

Abstract: A survey conducted among 26 European Countries within the Vaccine European New Integrated Collaboration Effort (VENICE) project assessed the status of organization in prevention and management of adverse events following immunization (AEFI) and level of interconnection, with the aim at individuating points of strength and weakness. The emerging picture is for a strong political commitment to control AEFIs in Member States (MS), but with consistent heterogeneity in procedures, regulations and capacity of systems to collect, analyze and use data, although with great potentialities. Suggestions are posed by authors to promote actions for unifying strategies and policies among MS.