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Vaccine Monitoring Platform (VMP) research agenda – update 2026

Background

The Vaccine Monitoring Platform (VMP) is a collaboration between EMA and ECDC for the timely generation of independent real-world evidence (RWE) on the safety and effectiveness of vaccines in use in EU/EEA immunisation programmes.

Scope

The VMP research agenda is intended to establish thematic areas and provide a foundational framework to guide and streamline the prioritisation of EU-funded, independent post-authorisation studies on vaccine use, effectiveness, and safety.

The research agenda was initially drafted by EMA and ECDC based on six identified categories of research including: evidence gaps such as long term monitoring and population impact; changes in vaccine composition; support to use during emergencies such as effectiveness and safety of mixed schedules; research breakthroughs indicating potential regulatory submission; investigations of safety and effectiveness of novel vaccine platforms; and known safety or efficacy/effectiveness concerns such as waning of vaccine effectiveness.

The initial VMP research agenda was published on both ECDC and EMA websites in September 2023.

This first comprehensive update to the research agenda is based on reviewing published peer-reviewed literature and grey literature to identify evidence gaps; scanning of new vaccines in the pipeline of vaccine developers; reviewing EU initiatives, and taking into account feedback provided by the VMP Immunisation and Vaccine Monitoring Advisory Board (IVMAB), both through the annual IVMAB meeting and through a survey with the IVMAB members. In this update, the various research questions have been grouped by disease/research topic together with a brief rationale supporting the selection of topics.

Following the IVMAB annual meeting in December 2025 where the updated research agenda was presented, the IVMAB members were requested to take part in a survey to prioritise the research topics. Please see the Annex at the end of the agenda for details on the prioritisation survey results.

This updated research agenda was formally endorsed in July 2026 by the VMP Steering Group. Its implementation will take into account further advice of the IVMAB and each agency's work planning. The research agenda is considered a 'living' document and will be kept up to date with the changing conditions and needs.

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Vaccine Monitoring Platform (VMP) Research Agenda Priorities

Disease/Topic	Proposed research	Rationale for research
SEASONAL INFLUENZA	**Gather further evidence on influenza vaccine effectiveness and impact of influenza vaccination on severity of disease in target populations**	Influenza vaccination programmes are revised annually in the EU/EEA with updates to vaccines to best match the circulating strains of that season. Continuous studies are important to estimate the effectiveness and impact that each influenza vaccination programme has on reducing severe outcomes such as hospitalisations, Intensive Care Unit (ICU) admissions and deaths in those at higher risk of severe disease and priority groups (such as older adults aged 65+ years, those with underlying conditions and pregnant women) in order to strengthen programmes, guide policy decisions on the most effective vaccination strategies and increase uptake and coverage. **Ongoing VMP vaccine effectiveness studies:** VE against hospitalisation with severe acute respiratory infections (SARI) laboratory-confirmed influenza Link
	Gather further evidence on the effectiveness of newer influenza vaccines compared to traditional influenza vaccines against severe disease in older adults i.e. those aged 65+ years	Newer types of influenza vaccines have been authorised in the EU and implemented in vaccination programmes. In order to guide policy decisions on the most effective types of vaccines and vaccination strategies to protect those population groups most at risk of severe disease, data on effectiveness of newer vaccines are continuously needed. Comparative vaccine effectiveness studies of the different newer influenza vaccines available (such as adapted, adjuvanted, combined, new platforms) vs traditional/standard-dose influenza vaccines in the older population are needed to guide vaccination strategies.
	Gather further evidence on the impact of repeated influenza vaccination in children	Children are a target group for annual seasonal influenza vaccination programmes in a number of EU/EEA countries. Vaccine effectiveness can depend on antigenic match, prior exposure history, and the child's immune maturation, with some evidence suggesting that repeated influenza vaccination may attenuate effectiveness through immune imprinting. It is important to further our understanding of the impact of repeated vaccination in children by studying the effects on future vaccine responses in order to guide the most effective strategy in subsequent seasons.

	Gather further evidence on the indirect protection of influenza vaccination conferred to the elderly by vaccinating younger populations	Given that children are recognised as playing a significant role in transmitting influenza, immunisation of younger population may confer considerable indirect protection to the broader population, especially older adults and those with underlying conditions. Based on previous data indirect effects are likely, but the effect size can be unclear and there are limited data on the quantitative correlation between direct effect, coverage and indirect effect on older adults. Although there are a number of ecological impact studies, there are limited studies analysing vaccine effectiveness on indirect protection using study designs such as the test-negative (TND) case-control design, or the cohort design. There is a need to better understand the public health value and effectiveness of vaccination programmes targeting children.
	Gather further evidence on the burden and impact of influenza disease outcomes	Estimates of influenza burden including hospitalisations, mortality, long-term complications (including secondary outcomes such as frailty, coronary incidents, deterioration of existing diseases) are important for vaccination programmes. This data provide information on which groups are most at risk of severe disease and can be used to measure the real-world impact of population-level reductions following vaccination programmes.
	Gather further evidence on the safety and effectiveness of different influenza vaccines by brand.	Generation of post-authorisation brand-specific vaccine effectiveness and safety data is a regulatory requirement. There are differences between vaccine products i.e. formulation of vaccines, hence monitoring by brand allows for detection of product-related vaccine effectiveness and safety signals.
RESPIRATORY SYNCYTIAL VIRUS (RSV)	**Gather further evidence on the safety and effectiveness of RSV immunisation in individuals targeted by programmes**	Different RSV immunisation products have been authorised in the EU in recent years including newer products to protect infants from RSV disease (long-acting monoclonal antibodies and maternal vaccination) and vaccines to protect adults from RSV disease. Following authorisation based on clinical trial efficacy and safety evidence, it is crucial to gather real-world data on safety and effectiveness to show how well the immunisations protect against severe disease hospitalisation and death across different target groups, such as older adults, infants and pregnant women. These data on safety and immunisation effectiveness support strategies, help to guide the optimal use of RSV immunisations in national programmes and to build public trust and confidence in RSV immunisations. **Ongoing or completed VMP studies:** VEBIS study: Effectiveness of long-acting monoclonal antibodies (mAB) against RSV-confirmed severe acute respiratory infections in eligible children Link
	Gather further evidence on the long-term safety and effectiveness of RSV	With the recently authorised RSV immunisation products there is a need to continue monitoring the vaccine effectiveness over time to provide information on the duration of immunity and protection that long-acting mAbs and vaccines provide in the long term and any evidence of significant waning. These data are needed to guide strategies on whether there will be a need for booster or

	mABs and vaccines in all immunised populations	revaccination in older age groups, length of protection provided by the long-acting mAbs in infants and strategies on the need for revaccination in subsequent pregnancies. Also, it is important to monitor the long-term safety of immunisation products and any signals of rare/very rare or long-term safety issues.
	Gather further evidence on the burden of severe RSV disease and the impact of RSV vaccination on preventing severe disease outcomes (i.e. hospitalisations and deaths) in the target populations stratified by age groups	Estimates of RSV disease burden provide vital information on which groups are most at risk of severe disease including hospitalisations, mortality, long-term complications and are crucial for developing targeted and effective immunisation programmes. Detailed burden data are required to measure the real-world population-level impact of RSV immunisation programmes on reducing severe disease in target groups stratified by age groups and other risk groups. Assessing the quantitative benefits of immunisation—specifically the absolute number of severe RSV outcomes prevented by immunisation programmes is essential for understanding their real-world impact, understanding the most cost-effective approaches between maternal, universal infant immunisation and targeted strategies. Measuring these population-level effects provides evidence of the value of immunisation, supports public health decision-making and communication and can help to build public trust and encourage higher vaccine uptake. **Completed VMP study:** Age specific incidence rates of RSV related disease in Europe Link
INVASIVE PNEUMOCOCCAL DISEASE	**Gather further evidence on the effectiveness, duration of protection and impact of pneumococcal vaccination on prevention of severe disease, taking into account mixed regimens, new vaccines, serotypes (cross-protection and strain replacement) in target populations**	There are several pneumococcal vaccines available, including in recent years the development and authorisation in the EU of newer higher valency pneumococcal conjugate vaccines (PCV). More recent products have been authorised based on non-inferiority immunogenicity end points and real-world effectiveness are needed. National EU/EEA country immunisation strategies against *Streptococcus pneumoniae* target different age groups and countries recommend different vaccine products against different serotypes. For example, vaccination strategies in the elderly have been recently modified in several countries to include the pneumococcal 20 valent conjugated vaccine (often in replacement of the pneumococcal 23 valent polysaccharide vaccine). There is a need for further data on how well each vaccine or combination of vaccines directly prevents disease, hospitalization and deaths and also preventing vaccine type carriage in target groups including infants/children, immunocompromised individuals and older adults. Evidence is also needed on the impact of different pneumococcal vaccination programmes on replacement of serotypes of *S. pneumoniae* at EU/EEA level.
	Gather further evidence on the burden of invasive pneumococcal disease including	*Streptococcus pneumoniae* has approximately 100 serotypes, and how these are distributed can change over time due to vaccination, population immunity and evolution of the bacteria. In order to help guide effective vaccination policies it is critical to monitor circulating serotype prevalence to identify those serotypes responsible for the highest disease burden and any emergence of non-vaccine or replacement serotypes. It is also important to monitor the prevalence of carriage and

	assessment of circulating serotypes	distribution of vaccine type and non-vaccine type carriage in children over time to help guide vaccination strategies.
HUMAN PAPILLOMAVIRUS (HPV)	**Gather further evidence on HPV vaccine effectiveness in preventing severe disease (cancer) in individuals by reduced dose schedules (one and two dose schedules)**	Immunisation schedules for available HPV preventive vaccines include two or three doses, depending on the age at vaccine initiation. There are some recent studies that report that a single dose results in lower antibody titers which could imply reduced immunogenicity and effectiveness. However other studies have shown that a single dose can maintain high seropositivity rates for high-risk HPV types as well as no difference in vaccine effectiveness compared to multi-dose schedules. Optimizing vaccination schedules can reduce the incidence of precancerous lesions and cancer, with reduced costs, alleviating any vaccine supply constraints and increase uptake and coverage. **Completed VMP study:** DARWIN EU® Effectiveness of Human Papillomavirus Vaccines (HPV) to prevent cervical cancer Link
INVASIVE MENINGOCOCCAL DISEASE	**Gather further evidence on the effectiveness and impact of meningococcal vaccination (by serogroups) on invasive disease, carriage, transmission, and the length of protection**	There is a continuing need to collect vaccine effectiveness data on how meningococcal vaccines protect against invasive disease by different serogroups to guide any changes to vaccination strategies. Evidence on how vaccination affects meningococcal carriage and transmission is important for understanding herd protection and overall population impact. There is evidence of MenC vaccine reducing meningococcal carriage, however it is still not completely clear about the impact of quadrivalent conjugate vaccines on nasopharyngeal carriage. For example, more evidence is needed on whether the adolescent dose of MenACWY may induce herd protection among infants. However, while this evidence gap is acknowledged, it is important to note that carriage and transmission studies are methodologically challenging and can involve substantial resources/costs to carry out these studies. Vaccine effectiveness studies over time to measure the duration of protection and waning effectiveness after meningococcal conjugate and protein-based vaccines is needed to determine the optimal timing of the booster doses in different target groups at different ages, such as adolescents or children.
	Gather further evidence on the effectiveness of newer serogroup B meningococcal vaccines	Due to low incidence of MenB the MenB vaccines were licensed based on safety and immunogenicity, rather than efficacy through RCTs. Real world studies on how effectively the MenB vaccines prevent invasive disease, the length of protection, and any effect on MenB carriage before and after vaccination with different MenB vaccines are important to guide vaccination strategies for timing of doses and booster doses across different population groups targeted for vaccination and cost efficiency.
	Gather further evidence on the impact and vaccine effectiveness of	Gonococcal infections can result in severe complications and in addition there is a high prevalence of *N. gonorrhoeae* strains resistant to antimicrobials. There are no licensed vaccines to prevent gonococcal infections, however there is some evidence that outer membrane vesicle (OMV) MenB vaccines provide some protection against gonococcal infections. Further research is needed on VE

	meningococcal B vaccine against gonorrhoea	and impact of MenB vaccines in order to support strategies for the effective management of gonococcal infections.
MEASLES	**Gather further evidence on the long-term effectiveness of measles vaccination**	The vaccine that prevents measles together with mumps and rubella (MMR) is given typically to children in two doses, and it is around 97% effective at preventing measles and provides long term protection. However, it is estimated that vaccine induced immunity and protection from measles wanes after around 15 years. To inform the need to any adjustment in the current vaccination schedule and protect public health, it is essential to collect data on vaccine effectiveness in the long term and measure any possible waning of vaccine protection against measles over time.
	Gather further evidence on the effectiveness of measles booster vaccination (without previous infection) as used during outbreak situations	As it has been shown that measles vaccination induced immunity is not life-long, booster doses may be offered to subjects without previous exposure to the virus to restore protection. The introduction of booster doses in fully vaccinated but not measles-seroprotected subjects is not well studied, but it is recommended in certain settings as to overcome outbreaks. It will therefore be important to collect more evidence on the use of booster doses which could inform implementation of vaccination schedules.
	Gather further evidence on genotype replacement linked to reduced measles vaccine effectiveness	Despite the success of vaccination campaign worldwide, endemic transmission of measles virus continues to occur including in Europe. It is not uncommon that new genotypes do replace indigenous genotypes. To determine relevant measles genotypes, molecular analysis can be done, and these genetic data can be useful to link cases to potential reduced vaccine effectiveness. In this context, it is relevant to continuously monitor changes in the measles virus genotype, which could help confirming measles outbreaks and identifying the epidemiological routes.
MATERNAL IMMUNISATION	**Gather further evidence on the effectiveness and safety of vaccination during pregnancy**	To protect the pregnant mother and/or infants from different diseases, countries are recommending various vaccines to be administered during pregnancy. These can include vaccines such as Tdap, influenza, COVID-19, pertussis and RSV. There is also the possibility of future maternal vaccines in the pipeline. It is crucial to gather evidence on the effectiveness and safety of providing vaccines during pregnancy in order to guide maternal vaccination strategies, build public trust and encourage higher vaccine uptake.
COVID-19	**Gather further evidence on the duration of immunity after repeated COVID-19 vaccination doses in all**	Duration of protection after COVID-19 vaccination can vary based on different factors such as prior immunity, age, underlying conditions and circulating variants. In order to identify the optimal timing and frequency of COVID-19 revaccination, such as annual vaccination or bi-annual vaccination and when and in which population groups repeated doses should be targeted such as older adults at different age cutoffs, immunocompromised individuals and pregnant women, studies on the duration

	populations of interest	of protection after repeated COVID-19 vaccine doses split by outcome and key groups is vital to guide effective vaccination strategies. **Ongoing or completed VMP studies:** Duration of immunity monitored under Vaccine effectiveness, burden and impact studies (VEBIS) Link; Link; Link; Link Comparative effectiveness of heterologous and homologous primary- and booster SARS-CoV-2 vaccination schedules in the Nordic countries Link Effectiveness of bivalent COVID-19 booster vaccines in the Nordic countries 2023 Link Effectiveness of bivalent COVID-19 booster vaccines in the Nordic countries 2024 Link
	Gather further evidence on the safety and effectiveness of variant-adapted COVID-19 vaccines, with special interest in target populations	COVID-19 vaccination programmes are revised annually with updates to vaccines to best match the circulating strains of that season. Studies are important to monitor the safety of the updated vaccines and the safety of repeated doses in different population groups. It is also crucial to estimate the effectiveness and impact that a COVID-19 vaccination programme has on reducing severe outcomes such as hospitalisations, ICU admissions and deaths in those at higher risk of severe disease. These studies help to strengthen vaccination programmes, increase trust, uptake and coverage and to guide policy decisions. **Ongoing or completed VMP studies:** Vaccine effectiveness in elderly and other target groups for vaccination Link; Vaccine effectiveness in children Link; Vaccine effectiveness against confirmed SARS-CoV-2 Link; Comparative effectiveness of heterologous and homologous primary- and booster SARS-CoV-2 vaccination schedules in the Nordic countries Link; Effectiveness of heterologous and booster COVID-19 vaccination in (non-Nordic) European countries (CoVE) Link; Effectiveness of bivalent Covid-19 booster vaccines in the Nordic countries 2023 Link Early cohort-event monitoring of COVID-19 vaccines in European countries (ECVM) Link; Cohort-event monitoring of COVID-19 vaccines in European countries (CVM, continued from ECVM) Link; Rapid Safety Assessment of SARS-CoV-2 vaccines in EU Member States using electronic healthcare data sources (CVM Covid19-Vaccine-Monitor-EHR) Link; Association between COVID-19 vaccines and thromboembolic events Link; Association between COVID-19 vaccines and paediatric safety outcomes in children and adolescents in the Nordic countries. Link
	Gather further evidence on the effectiveness of vaccines against post COVID-19 condition (long COVID)	Post COVID-19 condition can affect a number of infected people, causing long term complications. It is important to analyse how much vaccination reduces the risk of post COVID-19 condition, and the severity and long-term symptoms attributed to this. Estimating the effectiveness and duration of protection can help guide effective vaccination strategies and can also provide evidence of additional benefit of vaccination that can support risk-benefit assessments and cost effectiveness studies.

	Gather further evidence on the burden of severe COVID-19 disease and the impact of COVID-19 vaccination on preventing severe disease outcomes (i.e. hospitalisation and deaths) particularly in the older population stratified by age groups and in those with underlying health conditions	Estimates of COVID-19 burden provide vital information on which groups are most at risk of severe disease including hospitalisations, mortality, long-term complications and are crucial for developing targeted and effective vaccination programmes. Detailed burden data are required to measure the real-world population-level impact of COVID-19 vaccination programmes on reducing severe disease. Assessing the quantitative benefits of vaccination—specifically the absolute number of severe COVID-19 outcomes prevented by vaccination campaigns is essential for understanding their real-world impact. Measuring these population-level effects provides evidence of the value of vaccination, supports public health decision-making and communication and can help to build public trust and encourage higher vaccine uptake.
	Gather further evidence on the safety and effectiveness of different COVID-19 vaccines by brand	Post-authorisation brand-specific vaccine effectiveness and safety data is a regulatory requirement. There are differences between vaccine products i.e. formulation of vaccines, hence monitoring by brand allows for detection of product-related vaccine effectiveness and safety signals.
HERPES ZOSTER	**Gather further evidence on the duration of protection conferred by vaccination against herpes zoster (HZ) incidence and related complications in adults in different age and risk groups**	Evidence from the recombinant vaccine shows continued effectiveness against herpes zoster and related complications after 11 years in individuals aged 50 years and older. There is limited evidence of vaccine effectiveness after 11 years or more, in populations below 50 years of age and by risk group. Gathering this information is important to help guide vaccination recommendations.
	Gather further evidence on the impact of vaccination on the incidence of	Recent evidence suggests that HZ vaccination is associated with a reduction of all-cause mortality, and a lower risk of neurological and cardiovascular events. The target population of older age groups for HZ vaccination is highly vulnerable to such events. These findings should be confirmed to inform decision-making.

	non-herpes zoster attributable events	
BORDETELLA PERTUSSIS	**Gather further evidence on pertussis vaccine effectiveness against hospitalisation for laboratory confirmed pertussis in infants aged less than one year, by age group (0-3 months, 4-12 months), number of doses (vaccine product)**	Pertussis, or whooping cough, still causes significant hospitalisation primarily in infants and young children due to their immature immune systems and incomplete vaccination status. To protect neonates, some countries are offering maternal immunisation to protect newborns by transferring maternal antibodies. Despite general high vaccination coverage, neither vaccination nor infection provides long-lasting immunity, and booster doses are needed. Post-COVID-19 pandemic, a sharp rise in numbers of pertussis disease were registered across Europe, Asia, and the United States, reiterating the importance of vaccination during pregnancy. Because of recurring epidemics, it remains relevant to continuously gather evidence on the effectiveness conferred by the pertussis vaccines against hospitalization in young children by age group, and the vaccine effectiveness after primary series and each booster dose.
	Gather further evidence on pertussis vaccine effectiveness against disease, severe disease and hospitalisation in adolescents	As immunity to pertussis wanes over time, booster doses in adolescents and in adulthood aim to maintain protection. Pertussis may be milder in adolescents compared to children, but symptoms can range from asymptomatic infection to a very prolonged, debilitating cough. Real world studies are crucial to assess vaccine effectiveness in adolescents and to inform vaccination strategies.
CO-ADMINISTRATION OF VACCINES IN OLDER ADULTS	**Gather further evidence on the safety and effectiveness of co-administration of vaccines in target older adult populations**	Life course vaccination, especially for older age groups, is becoming increasingly more important. With an ageing population who are at increased risk of severe disease, including hospitalisations and deaths, EU/EEA countries are recommending a number of vaccines for older adults to improve healthy ageing, such as influenza, COVID-19, pneumococcal and RSV. It is programmatically easier and more likely to increase uptake and coverage if vaccines can be given at the same time, in one visit. For this there is a need for further evidence on the safety and effectiveness of administering different vaccines concurrently.

ZOONOTIC INFLUENZA	**Safety and effectiveness of human influenza A(H5) vaccines**	At this time real world VE and safety studies cannot be conducted, as the vaccines are only introduced for risk-groups in some countries, however this is a high priority topic and the need for data is high due to the pandemic potential. In the EU so far, only one country (Finland) has implemented an A(H5) vaccination programme for at-risk groups. Low incidence of the disease and very low vaccine use has limited the conduct of post authorisation studies of effectiveness.
MPOX	**Gather further evidence on the safety, effectiveness and duration of protection of mpox vaccination according to different vaccination schedules/vaccines (including doses 1 vs 2, timing, fractional doses administrated by intradermal route, prior smallpox vaccination)**	Mpox was a WHO declared Public Health Emergency of International Concern up until September 2025, and it still remains a public health threat today. Currently, only one vaccine is authorised for use in the EU with limited supply. Given the issues and in response to outbreaks, different vaccination strategies have been adopted and not always clearly differentiated during data collection. Furthermore, breakthrough infections have been reported possibly due to waning immunity, suggesting the need to evaluate booster dose strategies or adjust dosing intervals to enhance the immune response. **Completed VMP studies:** Safety and effectiveness of MVA-BN (Modified Vaccinia Ankara-Bavarian Nordic) vaccination against monkeypox virus (MPXV) infection in at-risk individuals in Germany Link Effectiveness and safety of MVA-BN vaccination against MPXV infection in at–risk individuals in US Link Effectiveness of historical smallpox vaccination against mpox clade II in men in Denmark, France, the Netherlands and Spain, 2022 Link
	Gather further evidence on the safety and effectiveness of mpox vaccination against severe disease in population vaccinated since 2022 PHEIC with special interest in immunocompromised individuals, children and pregnancy	There is very limited evidence on the safety and effectiveness of MVA-BN in population of special interest that are at highest risk of severe disease. Other available vaccines approved elsewhere have a safety profile of concern, particularly for the most vulnerable populations. MVA-BN has been administered to populations of special interest during outbreaks, but outside of study frameworks. Post-authorization data are a requirement by regulatory authorities. It is critical to obtain robust evidence for regulatory and public-health decision-making and to guide vaccination recommendations for the most vulnerable populations. **Completed VMP studies:** Safety and effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany Link Effectiveness and safety of MVA-BN vaccination against mpox in at –risk individuals in US Link Effectiveness of historical smallpox vaccination against mpox clade II in men in Denmark, France, the Netherlands and Spain, 2022 Link

	Gather further evidence on the safety and effectiveness of new mpox vaccines to prevent disease	Assessing the impact of vaccination on transmission is not currently a priority, as the combination with other public health interventions has proven highly effective in containing mpox outbreaks. Furthermore, vaccination is only recommended in high-risk populations groups. New vaccines are under development, but conducting clinical trials to demonstrate efficacy is unlikely to be feasible mainly due to ethical concerns and epidemiology dynamics. Post-authorization data will be an obligation imposed by regulatory authorities. RWE studies will be essential to confirm safety in larger populations and vaccine effectiveness.
	Gather further evidence on the long-term effectiveness of mpox vaccination in population vaccinated since the 2022 PHEIC	The durability of protection after mpox vaccination remains to be determined. Although no correlate of protection has been established for mpox, the humoral response is considered a good proxy for vaccine efficacy. In this sense, the humoral response to monkeypox virus seems to wane over time, potentially impacting long-term vaccine effectiveness. Nevertheless, other elements of the immune response may play a relevant role and contribute to long-term effectiveness. Post authorisation real world studies are essential to assess the long-term effectiveness of vaccination, specifically against clade Ib, across broader populations to better define vaccination strategies.
CHIKUNGUNYA	**Gather further evidence on the safety and effectiveness of chikungunya vaccination**	Currently, two chikungunya vaccines are approved for use in the EU, with their use primarily in travellers to high-risk regions. However, climate change is expanding the geographic range of chikungunya by enabling vectors to survive in previously uninhabitable regions. This shift has led to an increase in locally acquired cases within the European region, including a recent outbreak in La Reunion, where local authorities recommended vaccination for at-risk populations. It is reasonable to foresee that vaccination recommendations could extend beyond travellers to include broader population groups. RWE studies will be essential to support regulatory and public-health decision making and to guide future strategies in the context of changing epidemiological patterns.
DIPHTHERIA	**Gather further evidence on the long-term protection from diphtheria vaccination**	There is no lifelong protection conferred by the diphtheria vaccines and vaccine induced immunity wanes over time. Understanding the durability of vaccine-induced immunity is critical for selecting the appropriate time interval between booster vaccinations. Many countries recommend booster doses every 10 years in adults to maintain protection against diphtheria to prevent the resurgence of the disease, as seen in outbreaks among populations with lower vaccination rates and particularly in older age groups. Collecting additional evidence on the long-term protection conferred by the diphtheria vaccination will help identifying if and when to administer booster doses to maintain protection against diphtheria.
DENGUE	**Gather further evidence on the safety and effectiveness of dengue vaccination**	There is only one dengue vaccine approved for use in the EU for non-seropositive populations outside of endemic regions, which is being used for travellers to high-risk areas. However, climate change is expanding the geographic range of dengue by enabling vectors to survive in previously uninhabitable regions. This shift has led to continuous increase in locally acquired cases within the European region and it is an emerging health concern specially in Southern Europe. RWE studies will

		be essential to support regulatory and public-health decision making and to guide future strategies in the context of changing epidemiological patterns.
HEPATITIS B VIRUS	**Gather further evidence on the impact of hepatitis B vaccination on the prevention of liver cancer**	Hepatitis B virus (HBV) infection is associated with hepatocellular carcinoma. Vaccines have proven to be highly effective in preventing HBV infection, leading to a subsequent decline in liver cancer incidence among children and young adults. However, because the protective antibody response induced by the hepatitis B vaccine decreases over time and there is limited evidence regarding its impact on liver cancer mortality, the long-term vaccine effectiveness in adults should be further studied.
TUBERCULOSIS (TB)	**Gather further evidence of the burden of TB severity and secondary complications**	Tuberculosis (TB) in humans is an airborne bacterial infection due to Mycobacterium tuberculosis, which most often affects the lungs but can also affect other parts of the body. Patients with active pulmonary TB may spread TB bacilli by coughing to close contacts who need to inhale only a few of these bacilli to become infected. TB incidence has been declining in many EU/EEA countries; however, recent trends show a reversal, with increases reported across the EEA. This increase also reflects the growing number of drug-resistant TB cases. Importantly, there are wide detection gaps in children, where clinical diagnosis is challenging. Also, vulnerable groups like migrants, the homeless, and drug abusers are significantly affected. HIV co-infection remains a persistent issue for TB patients in Europe, which emphasises the need for continued efforts to improve the reporting of HIV co-infection. In this context, it is also important to ensure that surveillance, early detection, and infection control measures are effectively implemented, particularly for populations in congregate settings due to the high risk of reinfection. Therefore, continuing to gather evidence on the burden of disease in the various affected groups remains relevant to support evidence-based decisions making at regulatory and public health level.
	If new authorised vaccines come on the market, gather further evidence on the post-authorisation safety and effectiveness in individuals targeted by the TB vaccination programmes	At the present time there is only one TB vaccine approved, a live attenuated vaccine, which is given by the intradermal route at birth in most TB endemic countries. In infants, this vaccine is considered to afford protection against disseminated forms of TB, but it is contraindicated in immunocompromised individuals. Importantly, it has limited to no protective efficacy against pulmonary TB in adulthood and is, therefore, not recommended for use in this population. Pulmonary TB in adolescents and adults is a major contributor to the burden of disease and also drives transmission. A number of vaccines are being developed. One candidate has obtained promising results in a Phase 2b controlled study. If vaccines will be authorised and marketed, adequate studies should be developed to monitor the vaccine safety and effectiveness in the various target groups, including any (potential) impact on antimicrobial resistance.

Vaccines not authorised but which are of interest and in advanced stage of clinical development		
BORRELIA BURGDORFERI/ LYME DISEASE	**Gather further evidence of the burden of Lyme disease**	Lyme borreliosis (LB) is the most reported tick-borne infection in Europe and North America. Cases are increasing in the last years, particularly in Scandinavia. In most cases, Lyme disease can be effectively treated with a course of antibiotics. However, if left untreated, the infection can spread to the heart, joints and nervous system. Some people suffer from long-term symptoms after being treated for Lyme disease, while others do not. The disease burden is primarily driven by patients with persistent symptoms. Importantly it is still not known how often and why this happens. Better characterization of the burden of disease, particularly in subjects with persisting symptoms, would allow a clearer understanding of the impact of Lyme borreliosis to public health and any effectiveness and impact future vaccines may have on the burden.
	If an authorised vaccine comes on the market, gather evidence on post-authorisation safety and effectiveness in individuals targeted by the Lyme vaccination programmes	There are currently no vaccines available for Lyme disease, but a candidate vaccine administered to subjects five years and older in endemic settings is undergoing a Phase 3 clinical trial. Subjects living in areas with a high incidence of Lyme disease are considered a primary target group for the vaccination. If the vaccine is authorised, gathering safety and effectiveness data on the use of the vaccine in real world setting will be needed.
GROUP A STREPTOCOCCUS (GAS)	**Gather burden of GAS disease data in older adults and children, severity and secondary complications**	Group A Streptococcus bacteria can be carried in human throats and skin, without necessarily resulting in illness. It can cause both non-invasive and invasive disease, as well as long-term sequelae, including immune-mediated syndromes. Despite being a major cause of death and disability in LMICs, recently there has been an increase in the number of cases of cases of invasive group A streptococcus disease and scarlet fever also in some EU MS. Children under 10 years of age appear the most affected group. Additionally, GAS poses risks to older adults, and immunocompromised individuals, and carries a high potential for developing antimicrobial resistance. Deriving accurate and reliable estimates of the disease burden is crucial to inform public health decision making and for providing the basis for measuring the effectiveness and impact of any future vaccination programmes.
	If an authorised vaccine comes on market, gather further evidence on the post-	There is no GAS vaccine currently available, but there are a few candidates in development, with the prevention of GAS infections and their complications through the use of GAS vaccines as the public health goal. Importantly, the use of a safe and effective GAS vaccine may also reduce (sore throat-associated) antibiotic use. If vaccines will be authorised and marketed, adequate studies should be

	authorization safety and effectiveness in individuals targeted by the GAS vaccination programmes	developed to monitor the vaccine safety and effectiveness in the various target groups and to define the impact of vaccine introduction on the reduction of antibiotic use.
GROUP B STREPTOCOCCUS (GBS)	**Gather burden of GBS disease data in older adults and children, severity and secondary complications**	GBS is one of the main causes of preterm birth and neonatal death. Early-onset GBS disease is prevented through intrapartum antibiotic prophylaxis, however this has no effect on late onset disease and contributes to antimicrobial resistance. Invasive GBS disease is also a substantial cause of morbidity and mortality in people older than 65 years. Better characterizing the burden of disease in older adults and children is important also given the concerning antibiotic resistance rates of GBS and will provide the basis for measuring the effectiveness and impact of any future vaccination programmes.
	If an authorised vaccine comes on market, gather further evidence on the post-authorisation safety and effectiveness in individuals targeted by the GBS vaccination programmes	Approval of GBS vaccines will be likely based on surrogate efficacy markers, given the unfeasibility of conducting clinical efficacy studies in realistic timelines. Generating post approval effectiveness and safety data would be instrumental to ascertain the capacity of the vaccine to protect infants from early and late onset GBS disease in real world and identify any rare/very rare safety issue.

ANNEX:

Summary of the research agenda prioritisation survey

The VMP research agenda is intended to establish thematic areas and provide a foundational framework to guide and streamline the prioritisation of post-authorisation vaccine studies, including studies on vaccine use, effectiveness, and safety.

To support this effort, the VMP Secretariat conducted a survey among IVMAB members requesting them to provide two levels of prioritisation under the research agenda: firstly, diseases or thematic research areas, and secondly, specific research questions. Based on the response from 22 of 35 IVMAB members (63% response rate), a summary of the survey findings is presented below. It should be noted that the final decision regarding studies to be undertaken by EMA or ECDC under the VMP will be made by the VMP Steering Group, in alignment with each Agency's work plan and taking into consideration the advice provided by the IVMAB.

The top eight priority research diseases/pathogens/topics that were identified as the main areas of focus for the VMP included: seasonal influenza, respiratory syncytial virus (RSV), invasive pneumococcal disease, human papillomavirus (HPV), invasive meningococcal disease, measles, maternal immunisation, and COVID 19. Collectively, these diseases/topics represent the highest priorities requiring evidence generation to support regulatory and public health decisions for the EU/EEA Member States.

When asked which specific research should be prioritised for different studies, survey respondents generally focused on further evidence generation around preventing severe vaccine-preventable diseases across the life-course.

Three research areas that received the highest and equal number of responses, and were therefore classified as joint top priorities by the IVMAB member respondents included:

- Effectiveness of newer seasonal **influenza vaccines** relative to standard vaccines in adults aged ≥65 years. **Pneumococcal** vaccine effectiveness against severe pneumococcal disease over time, considering heterogeneous vaccination histories, mixed and sequential schedules, and the introduction of higher-valent conjugate vaccines. In addition, studies on pneumococcal vaccine serotype-specific effectiveness, the extent of cross-protection, and the population-level consequences of serotype replacement will help evaluating long-term programme impact in disease epidemiology following vaccination implementation. **HPV** effectiveness of reduced dose vaccination schedule, including both one-dose and two-dose regimens, in preventing HPV-related cancer.

Beyond these top three prioritised topics, IVMAB members indicated that research should also prioritise the long-term safety, effectiveness, and duration of protection conferred by recently introduced **RSV monoclonal antibodies and vaccines**. Also, additional data would be required to better quantify the burden of severe RSV disease and to evaluate the impact of RSV immunisation strategies on hospitalisations, intensive care admissions, and mortality, stratified by age, risk group, and comorbidity profile.

Subsequently, respondents also prioritised further evidence generation on:

- Effectiveness and safety of vaccination during **pregnancy**, with specific attention to both maternal and infant outcomes, including protection against severe disease in early life;

- Long-term effectiveness of **measles vaccination,** particularly with respect to waning immunity, the need for booster doses, and the duration of protection; and
- **Meningococcal vaccination**, including serogroup-specific effectiveness against invasive disease, effects on carriage and transmission dynamics, duration of protection, and the implications for long-term herd immunity.

Other diseases and related research questions received lower ratings and were classified as lower priority.