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European Medicines Agency

Vaccine Monitoring Platform (VMP)

Summary of IVMAB meetings (Immunisation and Vaccine Monitoring Advisory Board)

This document provides a summary of each of the meetings of the *Immunisation and Vaccine Monitoring Advisory Board* (IVMAB) of the EU Vaccine Monitoring Platform (VMP). Most of the highlighted studies are included in the EMA VMP list of studies or the ECDC VMP list of studies and registered in the HMA-EMA Catalogue of real-world data studies.
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4th IVMAB meeting, 23/24 October 2024, hybrid

The introduction given by the IVMAB co-chairs highlighted the importance for the VMP to invest in communication and understand how the work of the VMP may support increased vaccine acceptance and uptake.

Session 1 – Addressing the mpox public health emergency
The European Centre for Disease Prevention and Control (ECDC) provided an update on the status of mpox epidemiology and vaccination in the EU/EEA. Mpox cases peaked in 2022 but sharply declined in 2023 and 2024, with some countries reporting no cases in 2024. ECDC also shared findings from a vaccine effectiveness study with WHO and EU/EEA Member States.

Key results from the EMA-funded VMP mpox studies[1] were presented, reflecting on lessons learned from primary data collection and secondary use of data for continued mpox vaccine monitoring. The SEMVAc/TEMVAc and USMVAc studies confirmed the effectiveness and safety profile of MVA-BN. More research on duration of protection of the vaccine remains a priority. The IVMAB reflected on implications for the current public health emergency and the VMP research agenda, and the need for capacity building for future emergency situations.

Session 2 - Recent evidence generated by the VMP: informing future work
The ECDC VEBIS project was presented and discussed for its role in regular monitoring of influenza and COVID-19 vaccine effectiveness.

[1] Prospective Cohort Study and Emulated Target Trial to Estimate the Safety and Effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany (SEMVAc/TEMVAc) | HMA-EMA Catalogues of real-world data sources and studies; Effectiveness and safety of MVA-BN vaccination against Mpox in at-risk individuals in the United States (USMVAc) | HMA-EMA Catalogues of real-world data sources and studies; Effectiveness and Safety of the MVA-BN Vaccine against Mpox in At-Risk Individuals in the United States (USMVAc) - PubMed

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The epidemiology of invasive meningococcal disease was reviewed, showing a rise in cases of certain serogroups post-2020.
Investigators in the VEBIS Spanish and Norwegian studies reflected on their experience with COVID-19 and influenza vaccine effectiveness studies.
Highlights from EMA studies and an update on activities were presented and discussed.

Session 3: Continuing to build a sustainable VMP
EMA is developing a safety monitoring framework, including tracking autoimmune disease flares and defining immunocompromised populations in electronic health records (EHRs). Monitoring focuses on COVID-19, RSV maternal immunization, mpox vaccines, and co-administration of respiratory vaccines. Challenges include identifying phenotypes for immunocompromised individuals and standardizing definitions across studies. The VMP is mapping post-authorization studies and vaccine infrastructure to address gaps. The VMP research agenda will be updated regularly, with an emphasis on capacity building, prioritization of research questions, and ongoing reviews, ensuring timely responses to emerging health threats.

Session 4: Further research in Europe that informs the VMP
Efforts are underway by EMA to explore the feasibility of generating vaccine effectiveness data for the 2024–2025 influenza season, using different evidence generation pathways.
Feedback from the European Commission included that the EU has advanced vaccine research through networks focusing on key questions related to vaccine safety, effectiveness, and factors impacting vaccination programs. The COVID-19 and mpox pandemic emphasized the need for strong evidence on vaccine safety and effectiveness to guide policy decisions. The established networks have provided valuable research, supporting effective vaccination strategies and preparedness for future health emergencies. By collaborating across various research groups and data sources, the EU has enhanced its vaccine monitoring and response capabilities, ensuring a more coordinated and evidence-based approach to managing public health challenges and improving vaccination outcomes across member states.

Discussion & conclusions
Next steps include building capacity for future vaccine research, particularly in emergency situations. This can include efforts to harmonise electronic health records and general pandemic preparedness. The Horizon Europe Partnership will play a key role in supporting clinical research and building an EU ecosystem for future collaborations in vaccine research.

IVMAB meeting, 16 May 2024 - cancelled

This meeting was cancelled due to unforeseen circumstances.

3rd IVMAB meeting, 18 September 2023, Stockholm (hybrid)

ECDC-coordinated studies
In addition to the VEBIS project which focuses on COVID-19 and influenza vaccine effectiveness, ECDC also monitors mpox vaccine uptake in EU/EEA countries.
In September 2023, a pilot project on genomic surveillance of invasive meningococcal disease was launched, with the aim of connecting genomic and epidemiological data for enhanced surveillance and subsequent public health actions. In Autumn 2023, the establishment of an EU Reference Laboratory Network started. Another project is exploring the impact of simultaneous administration of influenza and COVID-19 vaccines. The important challenges of collecting data to estimate vaccine effectiveness for each of the influenza vaccine brands were discussed for future action.

EMA-coordinated studies
Real-world data studies presented by EMA include studies on COVID-19 vaccine effectiveness in children, respiratory syncytial virus (RSV) epidemiology, human papillomavirus vaccine effectiveness, and Mpox vaccine effectiveness. Key results of the completed 2-year COVID-19 vaccine safety monitoring program were presented, which confirmed the favourable safety profile of the vaccines.

EMA generates evidence using various pathways, including DARWIN EU®. Future plans include the set-up of a framework for post-authorisation safety evaluation of vaccines, and continuing to address the VMP Research Agenda. The importance of lessons learned from the pandemic regarding methodological challenges for vaccine studies was highlighted.

Presentations from IVMAB members on topics addressing the Research Agenda
Presentations addressing the VMP Research Agenda included a hospital-based case-control study on COVID-19 vaccine effectiveness (Germany), RSV surveillance in the EU/EEA (ECDC), and COVID-19 vaccine effectiveness protocol for the paediatric population (part of VEBIS). Discussions focused on improving study methodologies, refining case definitions, and addressing challenges related to multiple vaccines and variants in circulation.

Strengthening the VMP infrastructure for the future
This was considered a priority and should include efforts to map existing data sources, leverage other European initiatives in vaccine research, and enhance communication and collaboration with all relevant stakeholders.

Discussion & conclusions
The VMP Research Agenda, which was published on the VMP webpages of ECDC and EMA following the meeting, will be updated annually and *ad hoc* as needed in order to reflect emerging needs for data. The IVMAB recommended to reflect on how to increase agility in terms of preparedness. Ways to generate type and brand-specific influenza vaccine effectiveness should be explored. The IVMAB could provide advice to encourage healthcare systems and the Member States to record data on vaccine uptake, and by vaccine brand.

2nd IVMAB meeting, 01 June 2023, virtual

The importance of conducting industry independent vaccine research to support maintaining vaccination confidence in the post-COVID-19 era was emphasised in introduction.

ECDC-coordinated studies
ECDC gave an update of its "Vaccine Effectiveness, Burden and Impact Studies" (VEBIS) project, in which studies focus on COVID-19 and influenza vaccine effectiveness. Challenges include data protection and timely approval by ethical committees. Specifically for COVID-19 studies, additional challenges are sample size for newer SARS-CoV-2 variants, impact of self-testing, and presence of hybrid immunity. Notable added values of VEBIS include capacity-building, efforts to increase sample sizes, and investigation of methodological issues.

EMA-coordinated studies
EMA outlined its plan for short- and long-term studies, which include studies on COVID-19 vaccine effectiveness, safety evaluation for all vaccines, and readiness for future RSV vaccine studies. The ongoing 3-component mpox research programme was discussed: SEMVAc (prospective, German centres); TEMVAc (retrospective, same German centres); USMVAc (retrospective, US data sources). The IVMAB emphasised that readiness activities are a priority to allow swift action in case of new public health emergencies.

VMP Research Agenda
Synergies/complementarity between the ECDC and EMA research programmes were discussed. The various COVID-19 VE studies coordinated by both Agencies are complementary as they use different data sources, different study designs and are conducted in different countries and population groups. The importance of brand-specific results was emphasised (especially for newer vaccines), and that DARWIN EU's role in supporting the VMP is expected to keep growing.

Discussion & conclusions
The Public health emergency of international concern caused by COVID-19 has officially ended. It is now crucial to continue research on COVID-19 vaccine effectiveness (especially newer/adapted vaccines) and long-

term monitoring. Priorities for research should focus on special populations (e.g. immunocompromised) and research on influenza, COVID-19, RSV and Streptococcus pneumoniae vaccines. The Research Agenda should remain flexible to allow adaptation to emerging circumstances.
Recommendations of the VMP Research Agenda included enhancing agility in preparedness and exploring type and brand-specific influenza vaccine effectiveness.
Potential topics for a next IVMAB meeting include methodological approaches for real-world data studies, safety of vaccination in pregnant people, and mapping ongoing vaccine research activities in the EU/EEA.

1st IVMAB meeting, 6/7 December 2022, Amsterdam (hybrid)

The Executive Director of EMA and the Director of ECDC gave opening statements highlighting the importance of the VMP as a forum of collaboration at EU level between stakeholders in vaccine research, where ideas, experiences and synergies are discussed. The platform should facilitate the generation of real-world evidence (RWE) on vaccines that is independent from industry.

Session 1: The EU vaccine monitoring landscape.
The VMP structure and the IVMAB's role were explained, along with the role of EMA's Emergency Task Force (ETF) under EU Regulation 2022/1263. The need to avoid duplication between post-authorisation studies as part of the VMP was highlighted. Selected relevant ECDC and EMA studies were presented, in the context of integrating such work into the VMP. IVMAB members presented a selection of their countries' vaccine studies and observational research experience, setting the stage for collaborative efforts. Key discussion points included horizon scanning for planned studies, compiling Member States' recommendations on vaccine monitoring, and capacity-building exercises.

Session 2: Evidence generation by the VMP, update and lessons learnt.
ECDC's procurement tools and selection process for awarding tenders related to vaccine effectiveness studies was presented, as well as EMA's pathways for generating Real-World Evidence through in-house databases, framework contracts, and DARWIN EU®.
ECDC presented a selection of their COVID-19 vaccine effectiveness studies conducted under the VEBIS project. EMA provided an overview of COVID-19 vaccine effectiveness and safety studies funded by EMA, including plans for 2023.
ECDC summarised the epidemiology of mpox and the status of mpox vaccination rollout in the EU. EMA outlined the published evidence on mpox vaccine effectiveness and safety, highlighting two VMP case studies: a primary data collection study in Germany (SEMVAc) and a secondary data analysis in US databases (USMVAc,).

Session 3: VMP Research Agenda
EMA and ECDC jointly presented the draft of the VMP Research Agenda, categorising research questions into short, medium, and long-term. Breakout sessions were organised to discuss the agenda's comprehensiveness, clarity, and prioritisation of research questions. Improvements were suggested regarding granularity and prioritisation criteria and included adding research topics on COVID-19 vaccine safety and effectiveness, hybrid immunity, and long-term effectiveness of various vaccines. Clarity on topics outside VMP's scope and the need for a robust communication plan were highlighted for effective stakeholder engagement.

Discussion & conclusions
Next steps included communication, finalisation of the Research Agenda and Terms of Reference of the IVMAB based on advice and feedback from the IVMAB, a potential post-meeting survey to gather further information on national infrastructures for vaccine evaluation, and next meetings/opportunities for consultation.