

Adult Immunization Board Technical meeting

# ***Vaccine records and recall systems in Europe to strengthen adult vaccination***

Summary

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# Meeting objectives



- **Objective 1:** Assess the current landscape of adult vaccination records across Europe to understand existing systems and data infrastructures.
- **Objective 2:** Exchange lessons learned from national and regional vaccination record systems, focusing on implementation experiences, challenges, and innovations across European contexts.
- **Objective 3:** Discuss differences in data completeness, interoperability, and accessibility, and highlight how vaccination record data have or should inform vaccination policy decisions.
- **Objective 4:** Explore data utilization, existing gaps, and research opportunities arising from vaccination registers, and identify areas for cross-border collaboration to strengthen European systems and comparability.
- **Objective 5:** Address data security, ethical, and legal considerations in health record management, including personal health data protection, consent mechanisms, and compliance with the European Health Data Space framework to ensure secure and privacy-preserving data exchange.
- **Objective 6:** Discuss the added value and feasibility of a European Vaccination Card (EVC).
- **Objective 7:** Evaluate and share effective reminder and recall strategies for adult vaccination, comparing approaches used across Europe and identifying communication and outreach strategies that effectively improve vaccine uptake and public engagement.

# Objective 1: Assess the current landscape of adult vaccination records across Europe to understand existing systems and data infrastructures



- **WHO Definitions:** Immunization Information System (IIS) broader than an Electronic Immunization Registry (EIR):
  - IIS can include registries of eligible populations, vaccinated people, vaccine supply, VPD surveillance, and AEFI/pharmacovigilance systems.
- **In a narrow definition, IIS  $\approx$  EIR,**
- **WHO European (2024) EIR landscape:**
  - **43.4%** use electronic immunization registries
- **Digitalization of IIS:** leveraging digital technologies to transform data collection, reporting and analysis process. *Why?*
  - *Supports continuum of care (e.g. status checks, reminders, completion of schedules)*
  - *Provides valid proof of vaccination (e.g. school, work, travel requirements)*
  - *Can monitor immunization programme performance (e.g. coverage, inequities, safety monitoring, outbreak response)*
- Fast acceleration of digitalization during COVID-19 pandemic, not always as efficient as hoped (need for parallel systems)
- Considerations of EIR's for Adult Vaccination:
  - Multiple providers and e-systems create fragmented records; Eligible adults are spread across separate databases; Fragmentation limits automated reminders and recall; Diverse vaccines, risk groups, and indications complicate decision support;
- Designing an IIS requires **inputs, processes, and outputs:** legislation, human resources, SOPs, funding, defined indicators, data-quality assurance, data management, analysed data, and evidence products.

# Objective 1: Assess the current landscape of adult vaccination records across Europe to understand existing systems and data infrastructures



## Systematic Review of Immunization Information Systems' Implementation and Characteristics

- Reviewed **238 studies** describing **264 IISs** globally.
  - **84.5%** of IISs were electronic immunization registries.
  - Only **36%** operated nationally; **62.8%** remained mainly subnational.
  - Only **11%** supported real-time or near-real-time data entry.
  - Only **26.1%** covered life-course vaccination; **most systems remain focused on childhood vaccination.**
  - Citizen access is limited: only **11.7%** allow vaccinees direct access to their data.
  - Reminder functions are underused: **12.1%** send automatic reminders to vaccinees; **11.7%** reach providers.
- **Europe's key gaps:** IIS/EIR systems are increasingly digital, but still fragmented, inconsistently evaluated, and often not designed around adult or life-course vaccination.

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## EU Council Recommendations to strengthen adult vaccination data systems

- **Steering Group on the Prevention of Respiratory Infections** is calling for a new EU Council Recommendation on respiratory immunisation.
- The proposed Council Recommendation should include **digital infrastructure and expanded data monitoring as core implementation tools**.
- Adult vaccination targets require accurate data on disease burden, vaccine uptake, and coverage gaps.
- Robust IIS/EIR systems can help countries identify under-vaccinated groups, reach vulnerable populations, evaluate programme effectiveness, and guide resource allocation across Member States.
- Current systems are limited by fragmented and delayed reporting, especially for adult risk groups.

## IIS architecture an example with the adult pneumococcal pathway

- OpenSky frames adult vaccination records as part of a wider **vaccination pathway**, not just a record-keeping system
- Adult pneumococcal vaccination was shown as a **test case** for adult IIS weaknesses. Current records often fail to connect the full pathway: **eligibility → invitation → vaccination → recording → follow-up**.
- Key data gaps: incomplete eligibility data, fragmented systems, delayed capture, limited interoperability.
- Country systems differ in registry architecture, timeliness, provider access, pharmacy role, funding, and coverage reporting
- Similar gaps observed for HPV, systematic issue not disease specific

# Objective 2: Exchange lessons learned from national and regional vaccination record systems, focusing on implementation experiences, challenges, and innovations across European contexts



## France - MesVaccins / SYADEM

- A **patient-centred digital vaccination record model** designed to make vaccination data interpretable, interoperable and actionable.
- The ecosystem combines document digitisation, vaccine nomenclature (NUVA; unified nomenclature of vaccines), decision support, a digital vaccination record, operational tools and dashboards.
  - NUVA acts as a pivot terminology to align different vaccine coding systems and interpret vaccines by valence.
  - Champollion uses AI/OCR to convert paper or unstructured records into structured data.
  - VADES transforms vaccination history and patient characteristics into personalised recommendations.
- The system supports **patients, healthcare professionals and public health authorities** through shared records, decision support, real-time indicators and improved programme management.
- **Key implementation challenge:** historical records are often paper-based, fragmented or incomplete, making digitisation and validation essential.
- **Key interoperability challenge:** countries use different coding systems and data-sharing rules, so shared semantic standards are needed for cross-border exchange.

**Lessons learnt:** future vaccination record systems should be not only digital, but also **interpretable, interoperable and patient-centred.**

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## ***Denmark — Danish Vaccination Registry (IIS)***

- The Danish Vaccination Registry shows how IIS can move from **data collection to public health impact**.
- The IIS is used for: Surveillance; Research; Invitations and reminders; Monitoring vaccine uptake

### **Invitation and reminder systems**

- Childhood reminder experience informed adult vaccination invitation systems.
- Adults aged **65+** receive digital invitations (e-box) for influenza and COVID-19 vaccination.

### **Impact on uptake**

- High coverage achieved among 65+ adults:
  - **75%** influenza coverage (25% in pregnant women); **73%** COVID-19 coverage; **77%** pneumococcal coverage during the temporary programme, (ended in Jan 2023); **73%** RSV coverage in pregnant women (without invitation).

### **Targeted risk-group pilot**

- Registry-based invitations were piloted for adults aged **50–64 years with severe COPD**.
  - **95%** found the approach acceptable
  - Uptake increased for both influenza and COVID-19
- Demonstrated that registry-based targeting can reach medically at-risk adults below age-based eligibility thresholds.

**Lesson learnt:** Personal invitations plus reminders can increase uptake, especially when supported by strong IIS infrastructure.

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### *Belgium / Flanders — Vaccinnet*

- **Vaccinnet** links vaccine ordering, stock management and registration within the Flemish vaccination programme. This creates a strong incentive to register

#### **Scale and provider use**

- Widely used across Flemish vaccinators:
  - **8,000+ organisations** and **10,000+ individual caregivers**

#### **Data exchange and patient access**

- Vaccination data feed into **Vitalink**, the Flemish health data vault.
- Planned exchange across Belgian regional vaults, with longer-term alignment with the **European Health Data Space**.
- Citizens can view registered vaccinations through patient-facing health viewers.
- Older records less likely to be digitally available.

#### **Data quality**

- Data quality is strongest for **free Flemish programme vaccines**, where registration is linked to stock. Historical, adult and non-programme vaccines remain less complete.

**Lessons learnt:** Integrating registration into **provider workflow and vaccine supply** can improve completeness. Remaining challenges include interoperability, historical data gaps and cross-regional exchange.

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## *Sweden — NVR*

- The **National Vaccination Register (NVR)** includes: Childhood immunisations ; COVID-19 vaccination; Some risk-group vaccines

### **Data quality and reporting**

- Early validation showed underreporting in NVR compared with administrative data:
- Underreporting was linked to: Children lacking personal ID numbers ; Vaccines received abroad ; Small providers without automatic data transfer; Families moving between regions

### **Use and remaining gaps**

- During COVID-19, the NVR enabled monitoring by **region, age and population group**, supporting targeted interventions.
- Important gaps remain: travel vaccines, some regional vaccines such as TBE, herpes zoster, pregnancy vaccination, RSV monoclonal antibodies for infants, and direct individual access.
- A parallel privately owned platform, **MittVaccin**, supports booking, documentation and reminders in **13 of 21 regions**

**Lessons learnt:** Sweden shows the value of **legal registry infrastructure and automatic reporting**, while also highlighting persistent challenges around data gaps, regional variation and multiple stakeholders. Moving from manual reporting to a national digital register is **an implementation challenge, not just a technical change.**

# Objective 3: Discuss differences in data completeness, interoperability, and accessibility, and highlight how vaccination record data have or should inform vaccination policy decisions



## EU-JAV Work Package 5 Findings: Strengthening IIS Interoperability in Europe

- **Data completeness of IIS varies widely across Europe:** only **10/17 countries** had operational IIS; routine vaccination completeness ranged from **60–95%**.
- **Data gaps** include private provider data, historical records, vaccinations given abroad, and population denominators.
- **Interoperability gaps include legal, organisational, semantic and technical interoperability** — not just IT problems.
- Technical and semantic barriers include inconsistent vaccine coding, limited FHIR/API use, manual data entry, different definitions of “vaccination date,” and inconsistent dose/booster numbering.
- **Policy relevance:** minimum standards are needed — unique identifier, denominator, vaccine product, dose, batch, date and provider/location.
- COVID-19 pandemic showed interoperability is possible with political will, but sustainable IIS interoperability needs legal, organisational and financial commitment.

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## Improving vaccination decision-making through data

High-quality vaccination records can strengthen NITAG and policy decisions, especially for adult vaccination.

### What adult records need to show

- Who is eligible, reached, missed or underserved
- What happens after vaccine rollout
- Where coverage, equity or implementation gaps remain

### Why adult data are harder

- Eligibility depends on multiple factors: Age, risk status and pregnancy; Occupation, travel and chronic illness; Immune status and clinical history

### How records should support decision-making

- Link registry, clinical, disease burden, behavioural, modelling and real-world outcome data through interoperable systems
- Support analysis of coverage, behaviour, equity, effectiveness and implementation pathways
- Inform decisions at all levels: clinical reminders, local service gaps, national recommendations and European preparedness

### Policy takeaway

NITAGs should retain GRADE/RCT evidence, but formally integrate real-world data, early signals, modelling and implementation evidence.

AI and big data can support forecasting, sentiment analysis, anomaly detection and dashboards — but should support, not replace, expert judgement. **Vaccination records should become a trusted learning system, not simply an archive of past vaccinations.**

## Objective 3: Discuss differences in data completeness, interoperability, and accessibility, and highlight how vaccination record data have or should inform vaccination policy decisions



**EMA Vaccine Monitoring Platform:** Vaccination registers can support real-world evidence, regulatory decisions, safety monitoring and preparedness.

- Granular data are needed: vaccine brand, indication, risk group, pregnancy, immune status and vaccination context
- Missing or misclassified exposure data can weaken safety and effectiveness analyses
- Sales or distribution data are not enough to understand real-world vaccine use
- Standardised observational data and trusted cross-country sources are essential for comparability
- DARWIN EU and EMA contracts can help generate real-world evidence across European datasets
- A future European Vaccination Card could support access and cross-border care, but should complement authoritative registries

Vaccination records must support more than coverage monitoring; they should enable benefit-risk assessment, signal detection, effectiveness studies and emergency preparedness.

## Objective 4: Explore data utilization, existing gaps, and research opportunities arising from vaccination registers, and identify areas for cross-border collaboration to strengthen European systems and comparability



**Federated analysis for privacy-preserving data utilization:** Estimating statistical models when individual patient data are not accessible

- A way to use vaccination and health data for research **without moving individual patient data** across institutions or borders.
  - Enables statistical modelling when individual patient data are not accessible
  - Keeps data local while sharing summary statistics only
  - Can generate model results comparable to pooled-data analyses
  - Supports risk-factor analysis, prediction, model comparison, and uncertainty estimates
  - Requires standardized variables and consistent data definitions across providers
- Federated methods could support European collaboration by allowing countries to generate comparable evidence while respecting privacy and data-governance constraints.

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**CareVax (Italy) as an example of** how vaccination registers can be linked with hospital data to identify missed opportunities and improve vaccination among frail adults.

- Connects hospital EHR data with regional vaccination registries
  - Uses an algorithm to identify eligible patients and vaccination gaps
  - Generates personalized recommendations for physician validation
  - Supports active recall rather than passive, opportunistic vaccination
  - Early pilot data show feasibility, but patient engagement, vaccine refusal, low increase in coverage, and resources remain challenges
- Vaccination registers become more useful when connected to clinical workflows, enabling real-time identification, recall, and evaluation of coverage gaps in high-risk groups.

# Objective 4: Explore data utilization, existing gaps, and research opportunities arising from vaccination registers, and identify areas for cross-border collaboration to strengthen European systems and comparability



## Estimating vaccine effectiveness using eHRs

- Electronic health records can strengthen vaccine effectiveness research, but only if bias, confounding, and data quality are actively addressed.
  - Routine health data can support real-world vaccine effectiveness and impact studies
  - **VEBIS** provides real-world vaccine effectiveness monitoring in Europe, building on I-MOVE and now sitting under the Vaccine Monitoring Platform, with links to ECDC and EMA mandates
  - VEBIS uses routinely collected health data and registries to estimate vaccine effectiveness and impact, especially for COVID-19 and other vaccine-preventable diseases, including through EHR-based analyses.
  - The model supports cross-border collaboration: national institutes collect and analyse data locally, while Epiconcept supports shared methods, code, meta-analysis and outputs.
- Vaccination registers linked to health outcomes can inform policy, but Europe needs harmonized methods, better confounder data, and sustained international monitoring

# Objective 4: Explore data utilization, existing gaps, and research opportunities arising from vaccination registers, and identify areas for cross-border collaboration to strengthen European systems and comparability



## Implementing a Clinical Decision Support (CDS) System

- Latvia pilot shows how vaccination records can be used for **decision support, continuity of care, and cross-border comparability.**

### Context

- Historically fragmented paper records and provider-held medical files
- COVID-19 accelerated digital vaccination records and certificates
- Since 2024, all administered vaccines should be entered into national e-health

### Remaining gap

The current system records vaccines, but does not provide:

- Personalised recommendations; Reminders for due or overdue doses; Decision support by age, risk status, occupation, or travel

### CDS pilot

- Part of the EUVABECO project, designed to generate personalized immunization recommendations and support future European Vaccination Card integration.
- Included **280+ patients**
- Completed verification phase for the **European Vaccination Card**

### Key lessons

- System was user-friendly and technically reliable
- Main challenges: translation, training, historical data migration, financing, and national integration

Objective 5: Address data security, ethical, and legal considerations in health record management, including personal health data protection, consent mechanisms, and compliance with the European Health Data Space framework to ensure secure and privacy-preserving data exchange



### European Health Data Space (EHDS)

**EHDS** provides the EU framework for secure, interoperable and privacy-preserving health data exchange. For vaccination records, it clarifies how data can be accessed, shared and reused while protecting patient rights and supporting cross-border use.

EHDS covers three areas:

- **Primary use:** access to health data for healthcare delivery
- **EHR system requirements:** common standards for interoperability, security and logging
- **Secondary use:** controlled access to health data for research, public health and policymaking

Vaccination registries are included for **secondary use**, allowing research and public health analysis under permits, safeguards and secure processing environments.

Implementation of the framework will be phased, with key rules developed by **2027** and major operational steps from **2029 onward**.

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### Panel Discussion

**From data to trust: building vaccination record systems that work for citizens, science and society** how vaccination record systems can be legally robust, technically useful, scientifically valuable, and trusted by citizens.

- **Trust requires visible value for citizens**
- **Transparency is essential**
- **Citizen control supports trust**
- **Privacy and public health must be balanced**
- **Governance barriers remain**
- **Interoperability is still a major challenge**
- **Participation and health literacy matter**

Objective 5: Address data security, ethical, and legal considerations in health record management, including personal health data protection, consent mechanisms, and compliance with the European Health Data Space framework to ensure secure and privacy-preserving data exchange



## Harmonization after the GDPR? Divergences in the rules for health data sharing

- **Core issue:** GDPR created a common baseline, but national “opening clauses” mean health data rules still differ across countries.
- **Vaccination records are health data:** they require clear legal bases, Article 9 safeguards, transparency, security, access control, and purpose limitation.
- **Primary vs secondary use matters:** data collected for care, documentation or recall cannot automatically be reused for research, surveillance, policy, or cross-border exchange without new legal assessment.
- **EHDS opportunity:** the European Health Data Space can standardise interoperability, access routes, secure processing, and minimum datasets, but national laws will still shape consent, secrecy, rights limits, and governance.

# Objective 6: Discuss the added value and feasibility of a European Vaccination Card (EVC)



## European Vaccination Card: concept, feasibility and benefits

- **Concept:** citizen-held, portable lifetime vaccination record for cross-border continuity of care
- **Positioning:** complements EHRs and IISs; does not replace authoritative national registries
- **Key enabler:** NUVA terminology supports vaccine-code translation across national systems
- **Expected benefits:** citizen empowerment, better access to vaccination history, improved continuity of care, and easier cross-border use
- **Challenges:** deduplication of existing records, signature/key management, master-record governance, privacy impact assessment, and long-term operational responsibility

# Objective 6: Discuss the added value and feasibility of a European Vaccination Card (EVC)



## Ethical, Legal and Social Implications of Vaccination Passports and Cards

- **Central question:** when, and under what conditions, can vaccination passports or cards be ethically and legally justified?
- **Discrimination argument:** may create unequal treatment, but can also restore freedoms when wider restrictions are in place
- **Equity is essential:** Certificates can worsen inequality if vulnerable groups face barriers to vaccination, testing, digital tools or healthcare access. The response should be better design: free or subsidised testing, accessible vaccination, paper alternatives and targeted outreach.
- **Scientific claims must be clear:** vaccination status is not always proof of non-infectivity
- **Legal use** must be proportionate, necessary, time-limited, and context-specific
- **Privacy** must be built in through data minimisation, purpose limitation, and appropriate verification

# Objective 6: Discuss the added value and feasibility of a European Vaccination Card (EVC)



## **EUVAC as implementor of the vision for a European Digital Vaccination Card**

- **Purpose:** EUVAC operationalises the European Digital Vaccination Card vision as a deployable **Vaccination History service** within MyHealth@EU
- **Why standalone:** vaccination history is kept separate from Patient Summaries to support data minimisation, faster access, scalability, and routine cross-border use
- **Technical basis:** built on existing MyHealth@EU infrastructure, avoiding the need for new infrastructure
  - **Use Case 1:** healthcare professionals in one country retrieve a patient's vaccination history from another country
  - **Use Case 2:** citizens retrieve vaccination history from their national registry and store or present a portable version through a health app or wallet
- **Expected benefits:** secure cross-border retrieval, citizen-controlled access, interoperability, auditability, and future compatibility with EHDS and EUDI Wallet
- **Future opportunities:** use beyond clinical care, including mobility, education, travel, and occupational health checks

Objective 7: Evaluate and share effective reminder and recall strategies for adult vaccination, comparing approaches used across Europe and identifying communication and outreach strategies that effectively improve vaccine uptake and public engagement



### **Effectiveness of email-based reminders to increase vaccine uptake (Systematic Review)**

- Email reminders increased vaccine uptake versus no reminder but does not consistently beat phone calls, SMS or paper
- Infrastructure of delivery matters more than the channel itself
- Multi-channel, behaviourally designed reminders work across channels

### **Text-messaging to Coverage of Influenza Vaccination Among Older Adults (Norway)**

- pRCT testing whether SMS reminders could increase influenza vaccination among adults aged 65+, including Polish and Ukrainian immigrant groups.
- Norwegian SMS reminders increased influenza vaccine uptake in the general older adult population 2 percentage points (effects non-significant among Polish and Ukrainian immigrant groups, although statistical power was low, so can't say it doesn't work).
- **Language finding:** sending SMS reminders in Polish or Ukrainian did **not** significantly improve uptake compared with standard care, suggesting language alone may not overcome access, trust, or structural barriers.
- **Implementation lesson:** SMS nudging is scalable, low-cost, and well accepted, but may need to be combined with broader outreach strategies to reach vulnerable or migrant populations effectively.

Objective 7: Evaluate and share effective reminder and recall strategies for adult vaccination, comparing approaches used across Europe and identifying communication and outreach strategies that effectively improve vaccine uptake and public engagement



## **Tailored reminder strategies for underserved populations: evidence from a randomized trial in breast cancer screening**

- Study with low-SES women, many with immigrant backgrounds, to redesign reminder letters using clearer language, better visuals, translated options, and culturally appropriate messaging.
- In the ENTER randomized trial, a tailored reminder letter increased breast cancer screening participation from **9.4% to 15.8%**, with an even larger effect among low-SES women.
- Reminder strategies should be simple, tailored, accessible, and equity-focused; written reminders can help, but must be combined with broader approaches addressing social, cultural, and institutional barriers

# Breakout Groups

## **Group 1: How can real time vaccination registers be better used to inform policy decisions in real-time**

- Real-time needs to be defined. Vaccination registers could support coverage monitoring, equity, adverse event response, resource allocation, pandemic preparedness, real-world evidence, and emergency response.

## **Group 2: How do we reach the adults through the current vaccination systems? What do the IIS and reminder strategies need to take into account?**

- Trusted messengers matter, especially GPs who know patients' medical history. IIS and reminders should provide clear cues to action, explain why vaccination is needed, support HCP awareness, and could utilize other professionals such as pharmacists, dentists, and possibly AI tools.

## **Group 3: Should Europe develop a unified IIS (with an EVC), and if so, what minimum standards (technical, legal and governance related) would be needed to ensure cross-border compatibility, seamless data exchange between national systems and full compliance with GDPR.**

- Debate about whether an EU-level IIS or EVC would deliver enough public health benefit for adult vaccination, especially given uncertainty about how many people would use it cross-border. However, EU standards could still support implementation of national systems, improve preparedness, enable secondary data use for research, and strengthen interoperability

# Summary and Conclusions



**Adult vaccination records need to move from documentation to action:** should not only record doses given, but support eligibility assessment, reminders, recall, coverage monitoring, policy decisions, safety monitoring and research.

**Adult IIS/EIR systems are more complex than childhood systems:** Adult vaccination involves multiple providers, fragmented settings, diverse risk groups, changing eligibility criteria and incomplete historical records.

**Interoperability is a central barrier and opportunity:** Common standards, shared terminology, unique identifiers, and agreed minimum datasets are needed to connect registries, clinical data, disease burden data and real-world outcomes.

**Country examples show what works:** Completeness improves when registration is embedded into provider workflows, linked to vaccine supply or legal requirements, supported by automatic reporting, and useful to patients and professionals.

**Data must be useful for decision-making:** High-quality vaccination records can support NITAG decisions, targeted outreach, vaccine effectiveness studies, benefit-risk assessment, outbreak response and European preparedness.

**Trust is essential:** Secure governance, transparency, patient access, clear purpose, citizen control and privacy-preserving approaches are needed for public confidence and cross-border data use.

**EHDS development focuses on technical details** but limited involvement from vaccine experts, preventative medicine and patient involvement

**Reminder and recall strategies work, but must be tailored:** email, SMS, letters and digital nudges can improve uptake, but effectiveness depends on infrastructure, trusted communication, equity and population needs



Thank You