Building the backbone:
IIS and digital technologies for vaccination in Europe

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Editorial

The Italian health data system is broken

Check for updates

oa OPEN ACCESS

The Lancet Regional Health - Europe 2025;48: 101206
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The population of Italy is projected to decrease by approximately 8% by 2050, falling from 59 million in 2022 to 54.4 million, due to increased ageing and a declining birth rate. By 2050, more than 35% of Italians will be older than 65 years, while children younger than 14 years will represent only 11.7% of the population. Without reforms, this demographic shift will strain health-care and social systems.

systems, hospitals in the north often cannot access patient records, resulting in repeated diagnostic tests and delayed care. This duplication inflates costs—interregional health-care mobility alone accounts for around €3.3 billion annually—and undermines patient outcomes.

The fragmented health data system in Italy also presents considerable challenges for research. Without

From individual record to population health

> *Immunization Information Systems are **an integral part of well-functioning health systems**.*
>
> - WHO European Vaccine Action Plan 2015–2020

Clinical care

Support providers in vaccine decisions; reduce missed opportunities.

Surveillance

Aggregate, anonymous data on coverage and vaccine-preventable diseases.

Programme management

Reminders, recall, coverage monitoring and policy evaluation.

Research & equity

Identify under-vaccinated groups; link to health outcomes for VE/safety.

YET A GLOBAL, COMPARATIVE PICTURE OF HOW IISS ARE IMPLEMENTED AND WHAT THEY DO IS STILL MISSING
there is a lack of clear standards on IISs and a unified framework to evaluate their functionalities.

Taylor & Francis
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Expert Review of Vaccines

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Immunization information systems' implementation and characteristics across the world: a systematic review of the literature

Giacomo Pietro Vigezzi, Elena Maggioni, Laura Clavario, Lorenzo Clerico Mosina, Eleonora Raso, Corina Marjin, Andrea Parrini, Matteo Carbone, Simone Fugazza, Alberto Marchisio, Manuela Martella, Giansanto Mosconi, Giuseppina Lo Moro, Fabrizio Bert, Corrado De Vito, Roberta Siliquini & Anna Odone

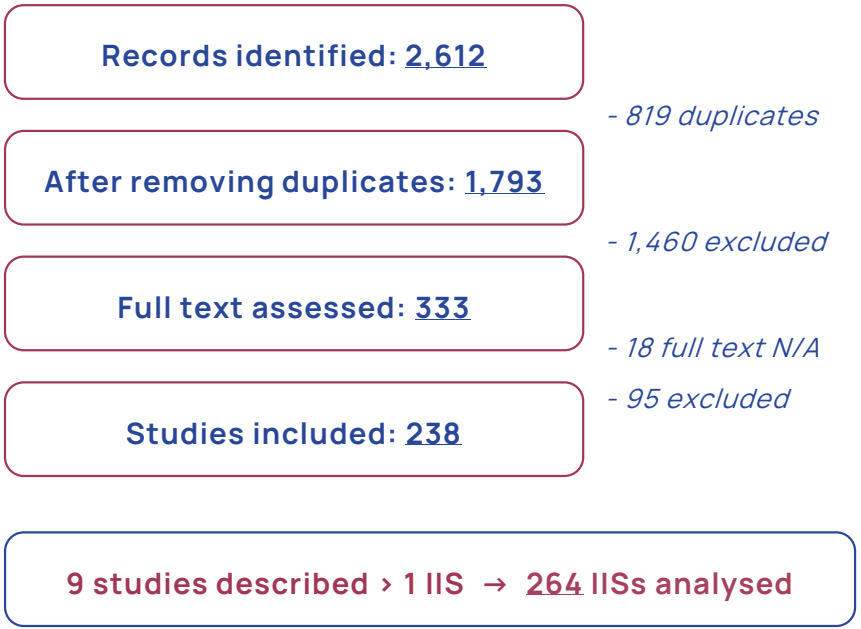
What we searched

Table 1. *A priori* defined inclusion and exclusion criteria according to the Population (P), intervention (I), comparison (C), outcomes (O), and study design (S) (PICOS) framework.

Search Strategy	Details
Inclusion criteria	P: general population (i.e., children, adults and older adults), travelers and other targeted populations for specific vaccination programmes (e.g., pregnant women, asplenic patients) I: IISs or vaccination records or registers, either paper-based or EIR C: if available, the absence of IIS or vaccination records/ registers O: IISs implementation at the European and international level S: both randomized controlled trials and observational studies, reporting original quantitative data or qualitative description of ISSs or vaccination records
Exclusion criteria	S: no original data (opinion papers, review articles, commentaries, letters, protocols)
Language filter	English, French, German, Spanish, Italian, Swedish
Time filter	From inception through 6th of June 2023
Database	PubMed/Medline, EMBASE, Web Of Science, Cochrane Library

Abbreviations: EIR, Electronic Immunization Register; IIS, Immunization information system.

PRISMA flowchart

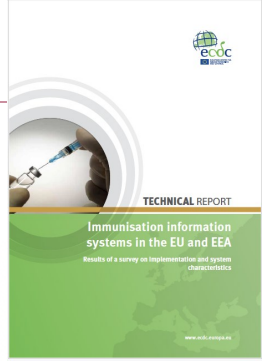


What we searched

2. European Centre for Disease Prevention and Control. Immunisation information systems in the EU and EEA: results of a survey on implementation and system characteristics. [Internet]. LU: Publications Office; 2017 [cited 2024 Jan 22]. Available from: https://data.europa.eu/doi/10.2900/519440

- **This comprehensive report provides one of the most detailed assessments of IIS implementation across EU/EEA countries, offering essential benchmarks for evaluating governance, interoperability, and data quality dimensions within the European context.**

What we searched



Methods

Two surveys were developed. The first more comprehensive survey was for countries that had an IIS in operation and included 11 sections and 100 questions. The other briefer survey (including three sections and nine questions) was for those countries that had no IIS or were in the initial stages of implementation. The sections covered in the comprehensive survey included current status of IIS implementation (national versus subnational), the governance, regulation and financial support of the IIS, the population covered and its identification, type of data recorded, technical solutions used for the IIS, linkage with other health information systems and outputs generated from the IIS to support individuals and vaccination programme monitoring. The final sections of the survey explored the challenges and barriers faced at various stages of IIS implementation and additional comments. Nominated country experts in the field of IIS were approached to complete the survey online. A draft version of the survey report with the analysed data was sent for revision to the respondents who completed the survey. At the request of the National Focal Points for Vaccine-Preventable Diseases (VPD), a second round of data validation was performed to enable minor corrections to information provided in the survey. The second, brief survey asked about barriers to implementation of IIS, whether there was a plan to develop/pilot one or more IIS in the next five years, and any areas where ECDC could potentially provide technical support with the implementation of IIS. For those countries that could not complete either of the two surveys by the deadline were asked to complete a basic set of five questions about IIS implementation.

What we extracted

Table 2. List of data extracted.

IISs' characteristics
- First author's name and journal
- Year of publication
- Country
- IIS name
- National or subnational IIS
- Subnational level of implementation
- Compliance with U.S. CDC definition of IIS
- PB or EIR
- IIS's year of establishement
- IIS's establishement before or after COVID-19 pandemic
- Target population
- Records collected (N.)
- Vaccines recorded
- Impact on vaccination coverages
- Other relevant information

Automatic reminders
- Automatic reminder to vaccine recipients
- Automatic reminder to vaccine providers

Additional information in the IIS
- Clinical or lifestyle factors recording
- AEFI recording

Data validation and update
- Data validation
- Time of information entry

Mandatory registration
- Mandatory vaccination registration by private providers
- Mandatory vaccination registration by public providers

Interoperability with other records
- Interoperability with subnational IISs
- Interoperability with PHR
- Interoperability with other health outcome registers
- Inventory function of vaccine procurement

Access to records
- Public access for vaccinees and guardians
- Access to official immunization records for vaccinees

Life-course vaccination recording
- Life-course vaccination registrer
- Past vaccinations recorded
- Recording of vaccinations administered abroad

Consent, automatic set-up and use for research
- Consent required from vaccinees
- Automatic set up of individual record at birth
- Automatic set up of individual record at immigration
- Use for research

Management of unvaccinated, vaccine refusal and hesitancy
- Identification of unvaccinated during an outbreak
- Retrival of incomple vaccination schedules
- Registration of vaccine refusal or hesitancy

Study design and quality
- Study design
- QS

What we extracted

Identification & geography

Country, IIS name, level (national/subnational).

Type & definition

PB vs EIR; CDC-compliance; year established.

Target population & coverage

Children / adults / specific groups ; N records; vaccines; impact on coverage.

Interoperability

With subnational IISs; PHR; health-outcome registers; vaccine inventory.

Mandatory registration & consent

By public / private providers; consent from vaccinees; automatic set-up at birth or immigration

Refusal, hesitancy & research

Recording of refusal / hesitancy; identification during outbreaks; use for research

Data validation & timeliness

Validation rules; near real-time vs batch entry.

Access to records

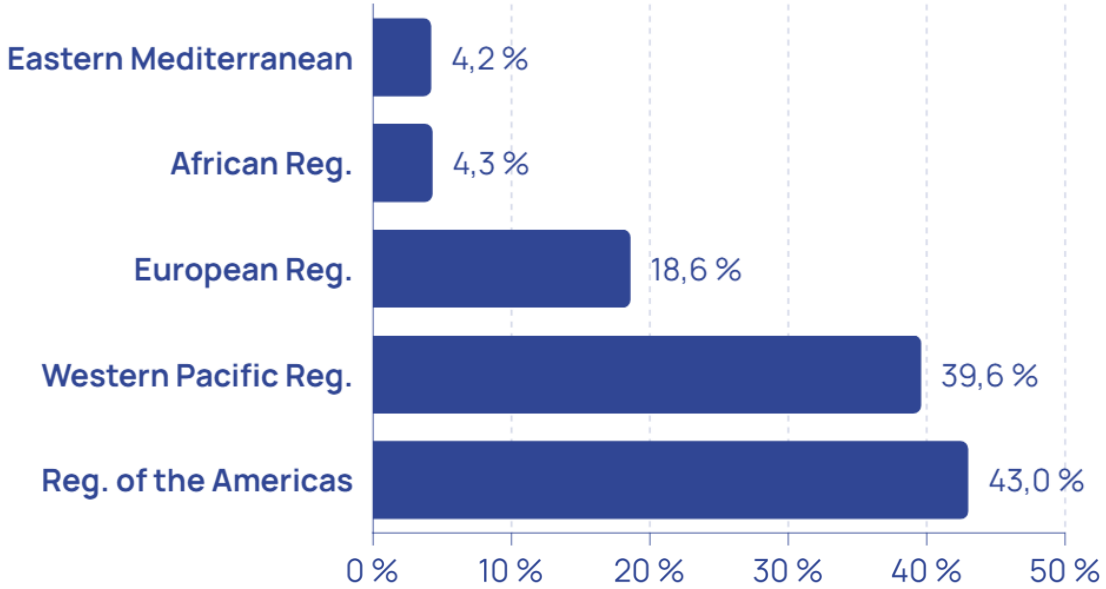
Public access for vaccinees / guardians; official websites.

Reminders & additional data

to recipients; to providers; AEFI; clinical / lifestyle factors

Where IISs are studied — and where they are not

Distribution of 264 IISs by WHO region



What this tells us

- Europe **under-represented** in peer-reviewed evidence, even where IIS exist, they are **rarely** formally **evaluated**.
- **Strong** concentration of literature in the **U.S.** and **Western Pacific**.
- **LMICs** are **catching up**, supported by WHO and PAHO frameworks.

Implementation level and digitalisation

84.5%

are Electronic Immunization Registers (EIRs)

Global shift from paper-based to digital infrastructure

Only 2 IISs (0.8%) remain

36%

operate at the national level

62.8% remain mainly subnational, fragmented governance

47,7%

meet the U.S. CDC definition of an IIS

8.7% explicitly do not

43.6% information is unclear

11%

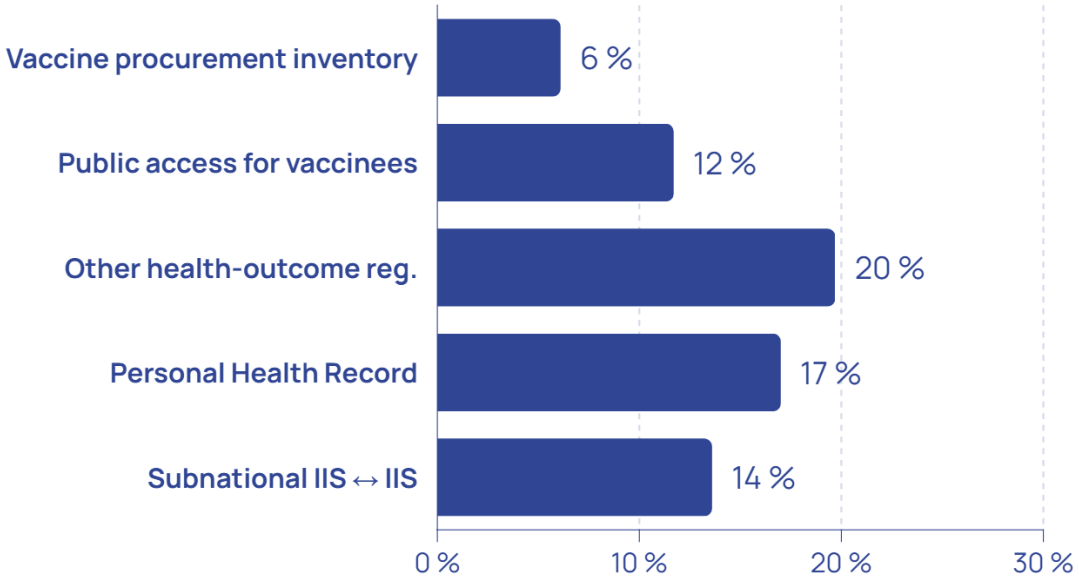
support real-time / near-RT data entry

Most still rely on delayed batch updates

According to the U.S. Centers for Disease Control and Prevention (CDC), IISs are confidential, population-based databases that record all immunization doses administered by participating providers to people living within a given geopolitical area [4] and can be used in the design and maintenance of effective immunization strategies [5]. Electronic immuniza-

Interoperability and citizen access remain limited

% of IISs reporting each interoperability/access feature



Reading the gap

- Most IISs still operate as silos: **less than 20% is interoperable** with a personal health record.
- **Only 11.7%** give vaccinees **direct access** to their own immunisation data.
- **Linkage** with health-outcome registers (19.7%) is the most developed dimension: the engine of vaccine effectiveness and safety research.
- **Transparency issue**: a big share of records lack reported information.

Functionalities that drive vaccine uptake

12.1%

Automatic reminder to vaccinees

11.7% also reach providers: the single most evidence-based IIS feature is the rarest

26.1%

Life-course vaccination registers

Most IISs are still child-focused; adults remain a blind spot

11.4%

Register vaccine refusal / hesitancy

12.1% can identify the unvaccinated during outbreaks

***GROOM ET AL. (J PUBLIC HEALTH MANAG PRACT, 2015)*: CLIENT REMINDER +6%, PROVIDER FEEDBACK +9%, PROVIDER REMINDERS IN CLINICAL SETTINGS +14.2%. THE FUNCTION EXISTS; IT IS JUST NOT TURNED ON.**

Data quality, governance and consent

Data quality & timeliness

34.1% have data validation / quality checks

11.0% support real-time / near-real-time entry

16.7% include socio-demographic / clinical variables

9.5% record adverse events following immunisation (AEFI)

Governance & consent

29.9% Mandatory registration by public providers (27.7% private)

19.7% Automatic record set-up at birth (7.2% at immigration)

7.6% Require consent from vaccinees

74.6% Allow access to data for research

From ECDC's 2017 survey to where we stand today

ECDC's EU/EEA survey was the most comprehensive picture of European IISs.
Almost a decade later, the field has moved, but the structural gaps are largely unchanged.

Where Europe has moved

- **COVID-19 accelerated** digital infrastructure: 17 IISs established post-pandemic, 3 during.
- Most countries have moved from standalone regional systems to **interoperable** national/subnational EIRs.
- Increasing use of IIS data for **vaccine effectiveness**, **safety** and **equity** research.
- WHO Digital Adaptation Kit and SAGE working group provide a unifying frame.

Where Europe is stuck

- **Cross-border interoperability**: 13.6% of IISs talk to other subnational IISs; almost none talk across borders.
- Adult and life-course recording: only 26% of IISs cover **all ages**, despite the EU adult immunisation agenda.
- **Standardised reporting** and definitions: 43.6% of IISs cannot be assessed against the CDC standard.
- **Cost-effectiveness evidence** is virtually absent — limiting the policy case for sustained investment.

From single registers to a European vaccination backbone

Real-time, person-centred data

Move from batch updates to event-driven, near-real-time records.

Interoperability with PHR & EHRs

Vaccinees own their record; clinicians and researchers can read it.

Active reminder/ recall by default

Patient + provider + behavioural design.

Life-course coverage of all vaccines

From childhood schedule to maternal, occupational, frail-elderly programmes.

Privacy-preserving cross-border use

Aligned with EHDS, GDPR, federated analytics.

TOWARD A EUROPEAN VACCINATION BACKBONE

- IIS as **foundational digital infrastructure** of national immunisation programmes, **embedded in surveillance.**
- Aligned with EHDS, EUVAC and the upcoming Council Recommendation on respiratory infection vaccination.
- **Co-designed with citizens:** access, transparency and consent are not add-ons.

Three messages for the AIB

01

IIS are universal in ambition, uneven in execution

84.5% are digital, but real-time data, life-course coverage, citizen access and reminder functions are present in only 10–25% of systems.

02

The European evidence base is thinner than the European reality

Only 18.6% of peer-reviewed IIS literature is European. We need standardised reporting and shared metrics to make our systems comparable, evaluable and improvable.

03

The backbone is digital, but the spine is governance

Interoperability, mandatory registration, consent and EHDS-compliant cross-border use will determine whether IIS can deliver on adult immunisation, life-course vaccination and pandemic preparedness.

Thank you

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PRIMARY SOURCE

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