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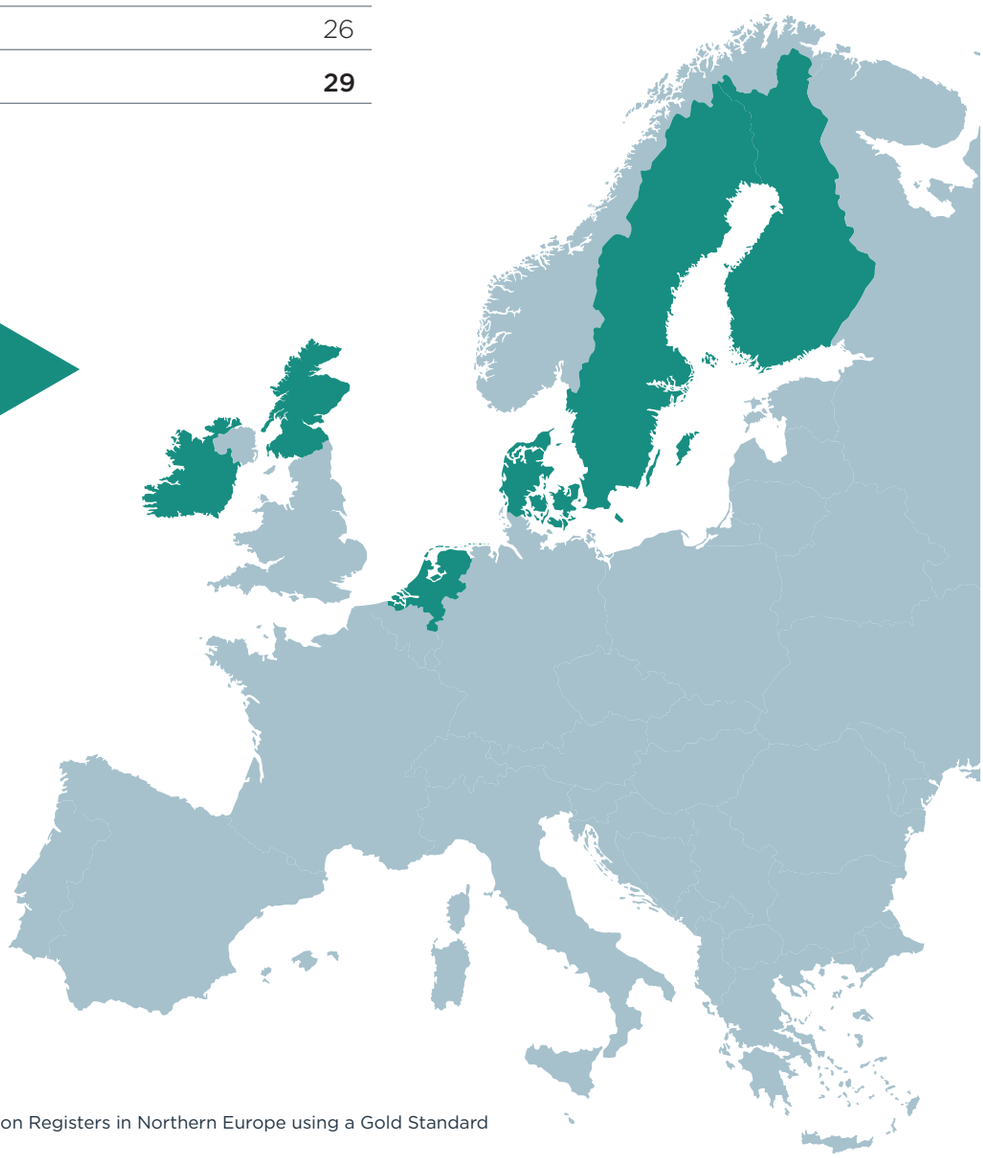
An In-depth Analysis of Six Electronic Vaccination Registers in Northern Europe Using a Gold Standard

15 January 2024



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ABBREVIATIONS

AORTA	Architectures, Design, Realisation, Testing of quality, Acceptance
API	application programming interface
ATC	Anatomical Therapeutic Chemical
BAN	British Approved Name
CHI	Community Health Index
CSPA	Common Statistical Production Architecture
ECDC	European Centre for Disease Prevention and Control
EHR	electronic health record
EMA	European Medicines Agency
EU	European Union
EVR	Electronic Vaccination Registry
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GP	general practitioner
GSBPM	Generic Statistical Business Process Model
GSIM	Generic Statistical Information Model
HL7	Health Level 7
HPV	human papillomavirus
HRI	health record identifier
HSE	Health Service Executive (Ireland)
IHI	Individual Health Identifier
INN	International Nonproprietary Name
MSD	Merck Sharp & Dohme
NHS	National Health Service (UK)
NIO	National Immunisation Office (Ireland)
NIP	national immunisation programme
PAEHRs	patient-accessible electronic health records
PPSN	Personal Public Service Number
QA	quality assurance
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment) (Netherlands)
SIS	Schools Immunisation System
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
T-SQL	Transact Structured Query Language
TESSy	European Surveillance System
TFEU	Treaty on the Functioning of the European Union
THL	Terveyden ja Hyvinvoinnin Laitos (National Institute for Health and Welfare) (Finland)
UK	United Kingdom
UNECE	United Nations Economic Commission for Europe
USAN	United States Adopted Name
VCR	vaccination coverage rate
Vnr	Nordic Article Number
WHO	World Health Organization

1. INTRODUCTION

For several years, electronic vaccination registries (EVRs) in Europe have developed in different formats and shapes due, among other factors, to the different paths and rhythms of healthcare digitalization. Up to this day, important disparities can be reported across the continent on the level of healthcare digitalization, as well as levels of digital solutions implementation. This means that at this very moment, very similar information (e.g. vaccination status, age, sex, etc.) is stored in a variety of ways and formats across the continent, sometimes even within the same country. Registries' fragmentation and lack of homogeneity is limiting their potential as data cannot be analyzed or used beyond the remits of its system, this is known as a lack of interoperability. This is not only limiting monitoring and VCR assessment accuracy but also tends to generate delays in data reporting, with their obvious public health implications.

As Covid-19 taught us, there is an increasing need of improving coordination across the European Union as part of the developing Health Union and health emergencies preparedness. This becomes even more important if we consider the ambitious and concrete goals the EU has set on vaccination and other areas, like the 90% Vaccination Coverage Rate (VCR) for HPV vaccination in girls (and increasingly boys) by 2030. It is obvious that assessing progress in such goals can only rely on accurate data across the Union, that is why EVRs interoperability is critical in the fight against vaccine-preventable cancers. Further than this, improving interoperability will help with all routine immunization vaccination assessment and long-term tendencies study, given the current data gaps.

With this particular context in mind, the aim of this document is to describe EVRs in selected countries in Northern Europe, comparing those with a defined gold standard in order to highlight drivers and barriers of the different systems. This own gold standard definition is based on previous international standards refined with the insights of specialists and public agencies involved. The countries selection is based on their performance in our previous report "The State-of-the-Art in Electronic Vaccination Registries in the European Union and the United Kingdom" (available here), that mapped out and ranked EVRs across Europe based on a number of technical criteria. This first report also proved that vaccination data interoperability was far from a reality in most of the cases as well as important differences were noted between EU countries.

We hope the outcomes and recommendations of this report will help technical specialists, public health experts and eventually decision-makers by sharing best practices and lessons learned from some of the most performant EVRs systems in Europe, if not the world. We also hope this report will get us a step closer to EVRs interoperability in Europe and the important public health applications it could enable.

2. KEY FINDINGS & RECOMMENDATIONS

This section aims to present in a synthetic way the main outcomes of this report. Based on these outcomes, we have also drafted some recommendations to support EVRs interoperability.

Data standards, access, and regulatory constraints

Despite efforts to harmonize data treatment across Europe, legal interpretations of the different national and EU level regulations are not always homogeneous. This reality goes well beyond health or vaccination data only. Conflicting legal and technical interpretations between countries sometimes can make interoperability hard and eventually confine systems. As an example: in Denmark a portal connects the patient (or guardian) with the EVR, a practice prohibited by law in Finland. It is worth noting that legal constrains can sometimes drive innovation and alternatives by emulating functionalities. Following the previous example, the Finnish system uses alternative methods to emulate the referred Danish functionalities.

Further than being coldly stored in some sleepy database, vaccination information can have a real impact on vaccination campaigns by enabling almost real-time vision and precise mapping across territories. To unleash their full potential, EVRs need their data to be accessible at multiple levels. There is an increasing need to connect data hubs to EVRs with timely data access so that quick corrective actions can be taken. An access level above the “raw data” can collate multisource information and act as a platform for analysis, for decision makers and stakeholders to optimize inputs and define policies or actions based on real world evidence. Additionally, EVRs could guide decision-making on assessing the performance of different vaccine delivery methods (school, GPs, pharmacies, etc.). If the system’s design allows to consider factors like age, comorbidity, and other social determinants of health, it could lead to identify low VCRs sectors in the population and potentially deploy tailor solutions.

Something else to consider is the usefulness of EVRs in the context of a health crisis. Performant, timely and accurate monitoring and register systems proved critical in the later phases of Covid-19 pandemic and supported decision-making with evidence. This is relevant for local, national and EU levels, as having a cross-country overview also proved vital in the European context given internal freedom of movement and the economic weight of services and tourism sectors.

Given the wide diversity of systems between and within countries, the lack of consensus on data structuring and categorization seems inevitable. This is further amplified by the fact that little attention has been paid to this issue and there is a lack of awareness of what the eventual applications and EU-level overview could bring. We believe that the adoption of certain classification systems, such as the ATC code, the INN, the USAN or the BAN, is a powerful basis for system interoperability. Last, but not least, information relevant to the supply chain might be included in EVRs given the potential applications for decision-makers across the system.

Diverse systems and common goals

Despite how diverse and different European healthcare and EVR systems are, it is obvious that a number of common challenges arise in all countries. That is why, creating meaningful, insightful comparisons between different vaccination systems is beneficial when it comes to designing optimal systems and best practices in EVRs. For the necessary and ambitious goal of interoperability at the European level, using common regional standards could only be a solution if widely adopted across countries and regions. Creating a single universal standard would be relatively straightforward; however, adapting and integrating legacy systems and standards will be a significant undertaking with many concerns around redundancy, duplication, database silos, ownership, system complexity and a number of other issues.

Similarly, the technical difficulties generated by using various different identifiers for the same person (ID, social security number, health identifier, etc.) can often cause suboptimal functionality of EVRs and the many other systems in which they are used. Using a dedicated unique identifier for health-care processes is not advisable because this is to be used along with the ID number and possibly other numbers, causing difficulties and errors when trying to create an EHR. Countries could avoid the potential risks related to using a single unique identifier for a person across all domains by using the very latest in data encryption, security protocols and cybersecurity measures.

Changes to existing systems could have drastic unforeseen consequences. A change in any one segment could have negative consequences for the overall system. For example, the use of informed consent in the Netherlands, starting on 1 January 2022, generated difficulties in VCR reporting with a cascade of other related consequences. That said, there are several approaches diverse systems can take towards supporting a universal format. The first is by adopting as many other standards as possible that underlie a shared system (for example, statistical modelling, architectural models and so on). Regarding the architectural model, for different statistical authorities, using UNECE standards such as GSBPM, GSIM and CSPA is beneficial, allowing integration of otherwise segregated data.

Our **primary recommendation** is that countries' health authorities use Health Level 7 (HL7) FHIR standard in their EVRs. This proven standard was developed in close contact with the WHO and the ECDC, and it was used in the WHO's vaccination card project. Countries that plan to implement FHIR-based systems include the United States, Canada, Australia, New Zealand, Denmark, Norway and the Netherlands. The HL7 FHIR standard undergoes regular updates to take into account secure vaccination protocols.

Our **second recommendation** is that countries establish a single, centralized repository for all EVR data. It is worthwhile, especially for vaccines such as the HPV vaccine, integrating the EVR with cancer and cancer-screening registers to assess the vaccination's impact on preventive diseases.

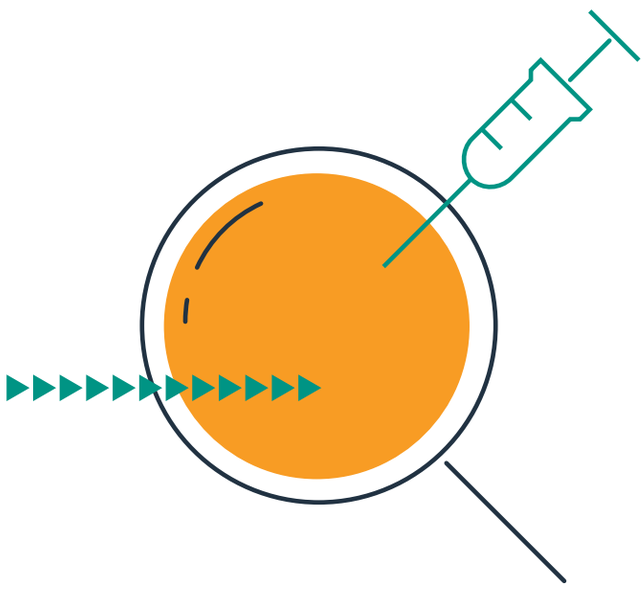
Cross-border cooperation and interoperability

Following the current and previous analysis on EVRs across Europe and beyond, it is worth noting that a country-wide integrated single EVR usually leads to higher VCR. Pilot projects are an excellent way to identify methods of increasing the maturity of an EVR system and integrating it with other registers. For example, in some of the countries examined in our analysis, there were concerns that the PolyData structure used in EVR pilot projects would not be sufficient to motivate a country-level implementation. Experimentation, monitoring and feedback would identify the gaps in the plan and inform a better policy or standard for the post-pilot phase of implementation at higher levels.

It is worth noting that a country-wide integrated single EVR usually leads to higher VCR.

However, it is important that cooperation around EVRs is not limited to intra or cross-country discussions between competent authorities. Dialogue should be open to the rest of involved stakeholders from patients to manufacturers. Only by opening the dialogue to all ecosystem stakeholders will it be possible to fine-tune registries at their best and unleash their full potential for societies, from boosting confidence to improved supply chains. The different research efforts we have conducted on the topic have proved that competent authorities are usually reluctant in such open dialogue engagement with other stakeholders.

It is also worth highlighting that interoperability will also require from true commitment by EVR authorities and could potentially require infrastructure update or extension in some cases. That is why we believe it is important that all actors, especially competent health authorities, become aware of the need to enhance EVRs and ensure interoperability to deploy their full potential. Covid-19 experience has led in some countries to non-traditional vaccination delivery points such as pharmacists, mobile units, vaccination at work or malls, etc. It is important that all these stakeholders and innovative delivery methods are also considered when designing or improving EVRs. They should have a direct connection to EVR both for feeding and consult relevant data. This will further contribute to an improved tracking of vaccination rates and, as Covid-19 proved, can support tailor engagement with some communities traditionally harder to reach.



3. THE GOLD STANDARD

The extreme diversity of technical solutions used in various health systems worldwide and the abundance of so-called ‘dirty’ data have made accomplishing a common standard in health care extremely difficult. The HL7 international standard for the transfer of clinical and administrative data, now in its third version, was created nearly thirty-five years ago to address the problem. HL7 includes the Fast Healthcare Interoperability Resources (FHIR) standard, developed a decade ago, which has been central to the work of the WHO in producing vaccination cards. It is also used in the vaccination registration systems of numerous countries and states.

After a thorough exploration of the HL7 FHIR standard, and consulting all significant stakeholders, such as the HL7 FHIR organisation, IT-EVR experts, immunisation offices and immunisation specialists, we developed our gold standard. In future research, OpenSky will discuss standard technicalities with HL7 Europe to explore how this component could interact with our gold standard. We will join specific working groups in the HL7 organisation to deepen our knowledge and be part of future European initiatives. HL7 Europe has confirmed that they would be happy to support and advertise our efforts if we focus on using the HL7 standard for the EVR analysis and development.



4. METHODOLOGY

Phase I of this research indicated a direct correlation between the maturity level of countries' vaccination systems and their VCRs. In other words, the more mature the system, the higher the rate of vaccination. The research's primary focus was on the HPV (human papillomavirus) vaccination as a use case, but our analysis covers many EVRs from a vaccine-agnostic perspective. The main goal was to assess the maturity level of the systems in use, using the data we collated to produce scorecards and heatmaps of the various countries' EVRs. The conclusions were both exciting and intriguing (see Fig. 1).

Country	Weighted score
Denmark	99%
Finland	96%
Netherlands	94%
Norway	94%
England	92%
Sweden	92%
Wales	90%
Ireland	86%
Scotland	86%
Northern Ireland	85%
Latvia	81%
Malta	81%
Slovenia	76%
Belgium	75%
Portugal	74%
France	73%
Spain	72%
Germany	70%
Romania	66%
Estonia	65%
Italy	64%
Hungary	60%
Slovakia	59%
Luxembourg	58%
Switzerland	53%
Serbia	51%
Lithuania	48%
Austria	44%
Czech Republic	40%
Croatia	38%
Greece	36%
Cyprus	36%
Poland	34%
Bulgaria	33%



Figure 1. OpenSky heatmap highlighting the maturity of EVRs in the EU and UK.

These findings led to Phase II of the research, which focused on three goals: first, to publicise the results of Phase I; second, to design a gold standard for a EVR common architecture; and, third, to conduct an in-depth analysis of the systems used in northern European countries.

For the third goal, we decided to concentrate on countries that obtained at least 85 per cent in Phase I. There were nine that qualified: Denmark, Finland, The Netherlands, England, Sweden, Wales, Ireland, Scotland and Northern Ireland. Including all UK countries posed a risk of redundancy so we selected one UK country and chose Scotland. The final list was Denmark, Finland, The Netherlands, Sweden, Ireland and Scotland.

We conducted a series of interviews with subject-matter experts and identified a set of data variables to create a benchmark for a successful common architecture for EVRs. Further, we identified the need to go beyond a simple benchmark and explored the idea of a gold standard. Analysing health systems against a gold standard allowed detailed vertical and horizontal analysis of the system, giving us the ability to identify similarities and differences between various systems and their EVRs. In our interviews with our six countries' subject-matter experts, we were guided by our gold standard.

Some interviewees were keen to present their country's situation in a highly positive light, and we applied the necessary filters to not allow this point of view overly impact the interviews. For example, when we asked about a specific feature and the interviewee answered, 'I do not know exactly, but we have an excellent system, so it must be there', we left the answer as, 'I do not know.' With three exceptions, the interviewees were not in the position to give details on the technical aspects of EVR systems.

5. COUNTRY OUTLOOKS

DENMARK

Denmark had the best score in Phase I, and Phase II confirmed that it deserved to be first in our analysis.

Data structure and tracking

The Danish vaccination registry's data structure supports operational tasks well, and there are multiple data points to allow data-driven policy analysis. However, the data does not capture delivery mechanisms such as the place where the vaccine was administered. As the system does not record the place of vaccine delivery, we cannot draw accurate conclusions about best practice. This is a significant deficit of an otherwise excellent system.

Access to patient information and other health data

The EVR is part of the Danish electronic health record (EHR). However, because the health system has a number of different registers, not all of which are integrated into the same system, it is not easy to combine them in a single, all-encompassing EHR. Furthermore, each register is the responsibility of a different organisation. The Danish authorities are addressing this issue in line with current legislation. As a result, the information displayed within the portal is linked to the EHR but not necessarily connected with all the other registers. Each person's record is linked using a unique identifier, which is an ID number given at birth. There is a movement to make data more available to third parties, which is done in a step-by-step approach to ensure the integrity of the data.

Geographical cover

Denmark's systems have excellent geographical cover, right down to the municipal level. This is important for the decision-making process at the policy level.

Data use and analysis

The dataset is intuitive enough to manipulate and use, but there are difficulties in extracting the data, which is not delivered in the best, most helpful formats: for instance, it is easy to extract data, but it is difficult to reliably interpret it because it is delivered in so many different datasets that need to be combined. One cannot do a brief analysis to check if the programme is lagging in particular geographic regions. This makes it difficult to know from which regions to draw insights regarding best practice, a difficulty compounded by the lack of details regarding the system's metadata.

Data storage and security

All EVR data is securely stored in a single, centralised repository. The database is secure and has a maintenance plan, with access locked down to specified applications and clearly defined roles for use and access. There is a data-quality monitoring solution in place, with processes for the remediation of data-quality issues in operation. A data-protection impact assessment has been performed. The data-protection officer is aware of the database and the basis for data-processing. Consent is captured and stored within the dataset. There are mechanisms in place to support all GDPR subject access request obligations. There used to be some problems with GDPR, which have been quickly resolved.

System notifications and administrative capabilities

A patient/guardian portal capability is in place that sends reminders to patients (via SMS, email or the portal) before appointments. At this time (2023), the portal does not allow bookings for vaccination appointments to take place, but trials are under way to make this possible, starting with the seasonal flu vaccination.

At the moment, the system functions on the basis of patients' age only and not diagnosis or risk. In the case of an age-based or a risk-based vaccination programme, the system would not be able to decide whether the better choice was to lower the age threshold or to address potentially greater at-risk groups who do not fall into a typical 'elderly' age range. Sending appointment invitations based on age only and not conditions or comorbidities (such as immune system disorders and diabetes) could lead to a lower VCR for at-risk groups.

Vaccine information access

There is much highly relevant literature on vaccination information and safety in the Danish system; however, the portal does not yet allow external users to make general inquiries on vaccination-related follow-up queries such as vaccination schema (the number of shots and the interval between them), contraindications, side effects, incidence of potential adverse effects, coverage rates, etc. This functionality is currently being added to the system.

Consent monitoring

A dedicated consent law is in place, and the portal allows the patient/guardian to opt out of their consent information being recorded, rather than opting in to their consent information being recorded.

Applications and third-party access

The portal is accessible via PC, mobile phone and tablet, but only by patients and authorities. Third parties, such as vaccine producers and suppliers, researchers and media, do not have access to the portal via these methods. A portal for health-care workers is in place to support the vaccination programme, and this is accessible via PC. The vaccinator records the vaccination event data in as close to real time as possible. The solution enables the capture of vaccination event data in offline scenarios, and this captured data is uploaded automatically at a later time.

Adverse event tracking

The Danish EVR does not enable health-care workers to record adverse-event data, and it cannot accept real-time information from manufacturers (e.g., batch recalls). However, a separate but connected register captures details of adverse events. These are treated very seriously, and relevant experts are required to have immediate access to this information. The information must also be available to more people than those involved in the vaccination, so even though this information exists outside the EVR, it is still connected to it. Any adverse-event data is pushed to manufacturers in real time (provided that sufficient anonymisation or pseudonymisation routines have been executed) but not directly through the EVR. The patient's health records could be checked if needed, for example to see if they have specific conditions before immunisation.

Data use in campaign optimisation, awareness and monitoring

The solution integrates all the necessary data to enable the vaccination programme management team to plan vaccination campaigns at a regional or country level. However, it does not allow vaccination programme managers to schedule or optimise the activities of the workforce. It does not have functionality to enable the best use of resources, does not ensure that the campaign is as effective as possible, and does not contain marketing functionality to allow the programme management team to target patients, guardians and health-care workers with information on upcoming campaigns. These functionalities are in the experimental phase of development.
The solution does allow the programme management team to track the progress of a vaccination rollout in real time and to adjust the campaign to improve efficiencies and to plan follow-on campaigns. The solution does not have an integrated data feed to the supply chain/cold chain system, nor is it able to send relevant data to improve these functions. This functionality is at a trial stage.

For four years now, Danish authorities have been running different vaccination pilot projects with the hope of improving the system. The initiative is promising, but there are concerns that the PolyData structure used will not be able to assess a pilot programme's potential for advancement to full implementation.

Access to other registries

The EVR solution does not facilitate a direct integrated view with screening registries, nor does it enable a direct integrated view with disease registers to assess the impact on preventive diseases. The integration must be done on an ad-hoc basis, using the patients' ID number as the unique identifier. As a result, third parties, such as researchers, have no access to the data. If researchers or data analysts assisting policymakers or managers want to extract and combine data from various registers, e.g., for preventive actions or screening access, they need to request access, and the personal data must be blinded. For this reason, they will not receive individual data but data at the cohort level. Having individual data allows in-depth scrutiny for narrow topics, but no one is allowed to offer individual data for privacy reasons, as required by GDPR.
The solution indirectly provides an aggregated data feed to monitoring agencies about adverse events, vaccine batches and campaign data (e.g., cohort, location, etc.). This data feed is generally in real time although on occasion it may be delayed for a few days or for a maximum of one week.

The EVR provides a data feed to population-level policy units, giving detail such as coverage rate, cohort/denominator data, etc. The data provided aligns with industry-standard metadata, ensuring that it can be integrated with external data such as demographic and benchmark data.

Data anonymisation and pseudonymisation

The data undergoes sufficient anonymisation and pseudonymisation routines to align with data-protection obligations. The Danish EVR has a data-analysis hub opening at a future date, where anonymised data is stored for analysis purposes. This hub contains sophisticated data analytics, machine learning and AI (artificial intelligence) capabilities. For the time being, curated direct access can only be granted to third parties upon application and with an approved protocol about what they intend to do. Most probably, the EVR data-analysis hub will facilitate data exports to international bodies and to open-data projects, but this depends on the granularity of the data requested.

FINLAND

In Phase I of our research, Finland scored second-best out of all EU countries. Phase II showed that Denmark and Finland were very close and that one might outperform the other at any time as they are both constantly improving their EVRs. In the early stages of creating the Finnish system, the central problem was that there were no good taxonomy and coding systems in place at the time. Health-care professionals were using a number of different patient systems, vocabularies and methods to record data. This was addressed by providing rapid feedback to the data providers, for example lower-quality data as early as possible. There was a lot of interaction between the data providers, the patient recording system providers and the health-care providers.

Another challenge was misaligned end goals between health-care providers, who were concerned with outcomes such coverage rates, and the patient recording system owners, who were more concerned with profit and traditional business motives. However, the system owners consider that both parties' goals are actually reasonably aligned as long as they provide more value-added services to health-care providers by increasing the market share.

Data structure and tracking

In Finland, the data structure is sufficiently comprehensive to support operational tasks. Vaccination coverage reports are published frequently, as are many other reports not related to vaccination. System tools allow municipalities to follow the VCR and act accordingly. The unit observation goes down to the child level, and special attention is given to those who are entirely unvaccinated because this cohort is of great concern for Finnish vaccination programmes. There are boundaries and controls in place too (regarding data use law): for example, there are statistical disclosure limitations for children.

Finland uses unique and permanent personal IDs to collect data, thereby linking multiple registers. Using these personal IDs, they can perform safety analysis linking the exposure (vaccination) data to disease data from any available source. For this reason, they do not need to collect vaccination and adverse events information together but instead collect them separately and then link them using the ID number.

Finland uses Postgres, an industry-standard relational database management system. With more than 5,000 international vocabularies, deciding on a specific approach is challenging. For vaccination, it is crucial that the system can identify the vaccine quickly and accurately. From our interviews, it was clear that Finland has a good understanding of the gaps and the benefits of various data standards for identifying vaccines. Finland uses the Nordic Article Number (Vnr), a six-digit code for medicines that allows reliable identification of a single drug packet throughout all drug delivery phases. As well as the Vnr, Finland also uses the Anatomical Therapeutic Chemical (ATC) code, an identifier assigned to medicine according to the organ or system it works on and how it works. This classification system is maintained by the WHO and allows comparisons to be made at various levels. To track chemical substances, Finland uses the International Nonproprietary Name (INN). If INN names are not assigned, USANs (United States Adopted Names) or BANs (British Approved Names) are usually selected. Experts working for the Finnish regulatory bodies concluded that the use of the Vnr was also needed because the ATC code can only distinguish vaccines to the level of enemy they are against. For example, all COVID-19 vaccines have the same ATC code. If you want to differentiate between the various COVID-19 vaccine products, you need more information than the ATC provides.

The European Medicines Agency (EMA) and other international medicines agencies regard batch-level surveillance as very important for vaccine follow-up safety. The vaccine's barcode represents one source of information. However, it does not contain the lot number, which is very important for recording purposes. In Finland, they can identify by lot number, which allows them to trace back to any of the international standards for the purpose of safety surveillance.

Geographical cover

Historically, Finland had a scattered municipal system, and each municipality had a different way of handling problems. Extensive health-care reform grouped 250 municipalities into twenty areas. Now it is much easier to implement the integrated vaccination register.

Data use and analytics

The dataset is intuitive to use by health-care teams, and the metadata is based on international standards, the surveillance being made at the batch level, as requested by the EMA, using the Vnr. The EVR has a data-analysis hub, where anonymised data is stored, and this contains sophisticated data analytics and machine learning/AI capabilities. Curated access can be granted for specific periods, and this facilitates data exports to international bodies.

There are sufficient data points available to support data-driven policy analysis, such as a real-time influenza vaccine effectiveness estimation. Following the policy needs at the EU level, Finland started to offer such information to the ECDC. This real-time impact evaluation capacity was enhanced during the COVID-19 pandemic, allowing the system to monitor both effectiveness and safety of programmes. This functionality was notably used for tracking the safety of the COVID-19 vaccines.

It is highly relevant that Finland is doing this work in cooperation with other Nordic countries, especially Denmark. This aligns well with the scorecard results, where Denmark scored the highest and Finland the second highest.

Data storage and security

A single, centralised repository securely stores all EVR data at the country level. The database has a maintenance plan, and access is locked down to specified roles and applications. A data-quality auditing solution is in place, and there are processes for the remediation of data-quality issues in operation. The repository is based on several source data collections integrated into an analysis database. In this way, it is not like a classical register, as it goes beyond simply raw data: it is a curated entity that collates information from many sources. The population information system provides the denominator, while the Finnish Medicines Agency provides the lot-number data for the identification of vaccines.

For different statistical authorities, the Generic Statistical Business Process Model (GSBPM) is used for the architectural model. From the official adoption of GSBPM to the first experiments on Generic Statistical Information Model (GSIM), Finland used the United Nations Economic Commission for Europe (UNECE) standards. The GSBPM was introduced first, then the GSIM and the Common Statistical Production Architecture (CSPA) were added.

In terms of their system's data flow, the Finns use a model whose data architecture identifies different forms of data. An entry database flows into the register. From there, an analysis database allows modifications to the data, use of potential external sources for validation of the data and leverage of the population information system to determine the denominator of

the data and leverage of the population information system to determine the denominator of the data – all of which are accessible online. This is for a variety of reasons, such as tracking the movement of people across regions. The analysis database is updated continuously for vaccine coverage, impact, safety and effectiveness.

A data-protection impact assessment has been performed, and various roles are clearly defined. Staff spend a lot of time monitoring data quality to continuously improve the process. The crucial aspects are continuous feedback and connection to the data providers. The data-protection officer is aware of the database, and there are mechanisms in place to support all GDPR subject access request obligations. All these are statutory.

There is no portal capability in place for patients or guardians. This is due to Finnish legislation. A High Court decision stipulated that data collected for registry purposes, such as surveillance, impact, monitoring and defining the vaccination programme is to be used for those specific purposes only. This data is not for individuals' use or for taking decisions that relate to a specific person. For individuals, there is a separate system, namely the National Kanta Patient Archive, which offers various functionalities in this respect.

System notifications and administrative capabilities

The EVR does not allow bookings for vaccination appointments, does not send reminders in advance of appointments and does not enable the external user to make general inquiries or follow-up queries about vaccination. Citizens can use the dedicated portal to obtain information about their vaccination. The governance for this portal, which is a browsing mechanism (patient archive), is at the Kela Social Reimbursement Institute.

Vaccine information access and consent monitoring

The EVR does not contain educational literature pertaining to vaccines and vaccination and does not capture consent information.

Access to patient info and other health data

All information displayed within the EVR is linked to the EHR of the patient. The EU-level Digital COVID Certificate is built into the electronic patient archive, so data is accessible to that also. But the information they are using in the EVR for statutory purposes is different because it is a secondary use of the data, not the primary use. The primary source for data is the EHR. This principle of segregation between the primary and the secondary data sources is highly relevant in Finland.

Application and third-party access

There is no health-care worker portal to support the vaccination programme, accessible via PC, mobile phone or tablet. The solution does not assist the health-care worker in integrating the vaccination activities with their other workload activities. Health-care workers use the patient recording system at the site, not the EVR. This is due to the legislation that forbids the use of secondary registers for any decisions on individuals. So, for instance, if a site worker wanted to check whether a child has had a specific vaccine (to assess whether a vaccine should be administered or not), they would need to consult the on-site patient recording system.

Adverse-event tracking

Finland cooperates closely with other Nordic countries and with the ECDC, and there is a long tradition of Nordic countries identifying rare adverse events. The health-care worker/vaccinator can record the vaccination event data in real time and contribute adverse-event data – but not in the EVR. The Finnish Institute for Health and Welfare (THL, formerly KTL) used to maintain the vaccine adverse-event register, but the legislation for this process was changed around a decade ago. The register is now under the mandate of the Finnish Medicine Agency, and all adverse events are reported by health-care professionals or even by ordinary citizens to the medicine agency. The EVR cannot accept information directly from manufacturers. Instead, it is the medicine agency, not the EVR, that gathers adverse-event data.

It is THL's responsibility to monitor the safety of the vaccines, even if these are not recorded via the EVR. Therefore, there is passive surveillance for adverse-event reporting systems based on spontaneous reporting. This is a signal generation mechanism rather than a safety evaluation mechanism. We noted that these signals need refinement to confirm adverse effects and start medical treatment of the affected person.

The THL system has been designed for better differentiation between vaccine-related and disease-related adverse events: objective routine surveillance includes all cases whether associated with vaccines or not.

The vaccination register identifies the vaccines at a batch level. When THL suspect a potentially problematic batch of vaccines, they can immediately examine any potential adverse events within that batch. The mechanisms needed to allow this process have been implemented, whether the information regarding the batch in question has been received directly from the manufacturers or from the medicine agencies – typically the latter, which allows a buffer between the manufacturer and the register.

It should be noted that the THL does not act directly but instead informs other agencies or organisations to act. The operational responsibility belongs to the municipalities. For instance, if the Measles, Mumps, and Rubella (MMR) VCR is low in a particular region, THL provides this information to policy- and decision-makers to prompt action.

Data use in campaign optimisation, awareness and monitoring

The Finnish EVR does not integrate the necessary data to enable the vaccination programme management team to plan the vaccination campaigns at a regional/country level. And it does not allow managers to schedule or optimise the activities of the workforce or the use of resources so the campaign is as effective as possible. Furthermore, it does not contain marketing functionality to enable the programme management team to target patients, guardians and health-care workers with information about upcoming campaigns. Nor does it allow workers to track the progress of a vaccination rollout in real time, to adjust the campaign to improve efficiencies, or to integrate data into the supply chain/cold chain system.

Access to other registries

The Finnish EVR is not directly integrated with the EHR. This is because in Finland they have two data pipes: one for primary use and the other for secondary use. As the primary data source, the EHR includes vaccination information, but the EVR, a secondary data source, cannot be directly integrated with it. Doing so would be against the law. The EVR is used to assess the impact on preventive diseases and facilitates an integrated view of disease registries (e.g., cancer

registries). It provides an aggregated data feed to monitoring agencies and population-level policy units about adverse events, vaccine batches and campaign data. And it provides real-time details of coverage rates and cohort/denominator data in line with industry-standard and best-practice protocols. This data aligns with industry-standard metadata, ensuring that data can be easily integrated with external data such as demographic and benchmark data.

Data anonymisation and pseudonymisation

All data in the system undergoes anonymisation and pseudonymisation to align with data-protection obligations.

THE NETHERLANDS

There is no EHR per se in the Netherlands, despite long-term plans and efforts like AORTA (Architectures, Design, Realisation, Testing of quality, Acceptance). General practitioners (GPs) and other health-care specialists use different systems for different purposes, as we will see below. The Netherlands' EVR and the COVID register are very similar but are different systems.

Data structure and tracking

The National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, or RIVM) is the only organisation in the Netherlands using an EVR (called Præventis). The data structure of this EVR is sufficiently comprehensive to support operational tasks, there are ample data points to support data-driven policy analysis to increase VCR, and the dataset is intuitive to use for health-care teams.

Information about the National Immunisation Programme (NIP) is held in a centralised system while information about COVID-19 vaccinations is stored on a different centralised system. Those who administer other types of vaccines (such as travel vaccinations and other adult vaccinations) must register the vaccination in their systems in line with current legislation. There is no common repository for these other kinds of vaccinations.

Geographical cover

The RIVM reports annually on the integrated vaccination uptake at the municipal level. Each municipality is required to register vaccinations and holds its own data. However, for more complex interpretations, for example to see whether a person is completely vaccinated, their age, which vaccine, etc., they typically address inquiries to the RIVM. Above these municipal and country levels, the RIVM reports to the WHO and the ECDC using the WHO system and The European Surveillance System (TESSy), respectively.

Data use and analytics

The data in the EVR is useful at multiple levels of research for the RIVM. Their goal is to guide their broader health-care policies to reach a higher VCR. For instance, much of the information related to gaps and delays in vaccination administration is crucial for enacting catch-up campaigns.

System notifications and administrative capabilities

The system can send invitations and reminders for vaccinations.

Consent monitoring

The system allows and records end-user consent for analytical purposes. This is the fundamental precondition for a proper estimation of the VCR because in the absence of informed consent no information can be provided regarding the person's vaccination status. Informed consent is actively provided by patients and stored in the system. This functionality has been in place since the beginning of 2022 and has demonstrated a possibility of generating problems down the line. There is no patient/guardian portal capability in place.

Access to patient info and other health data

Health-care workers directly involved in the NIP have access to the system, and those directly involved in COVID-19 vaccination have access to a system dedicated to this purpose. As indicated above, other vaccines received at adult age are not in a centralised system, but this could change soon.

Application and third-party access

Citizens have no direct access to the system by any means, and neither do researchers. A request must be made, and a committee will review the request and may provide the data required.

Adverse-event tracking

For adverse-event reports, an independently monitored register called Lareb gathers information from the EVR to determine whether a person has been vaccinated or not. Vaccine batches are registered in the EVR, but there is no direct link with the manufacturers. It is considered necessary that manufacturers have no direct access to the EVR whatsoever.

Access to other registries

The EVR does not facilitate a direct integrated view with other registries.

Data anonymisation and pseudonymisation

The data in the system undergoes sufficient pseudonymisation routines to align with data-protection obligations. In specific cases, an anonymisation routine is applicable.

SWEDEN

Data structure and tracking

In Sweden, a single, centralised repository headed by the public-health agency holds all EVR data at the country level. Health-care workers use a different system that integrates with the EVR. All information, whether captured in a journal at a school or at a well-baby clinic, is automatically transferred into the EVR. The Swedes can even link the vaccine batch number in the system to the patient's personal ID. The EVR's data structure is sufficiently comprehensive to support operational tasks, there are enough data points to support data-driven policy analysis, and the dataset is intuitive to health-care teams.

Geographical cover

In general, Swedish vaccine-related data is recorded in the EVR. However, if you are vaccinated privately, such as for travel-related vaccinations, the information will not be recorded in the system, as there is no joint registry for private vaccines. The Swedish ministry of health is aware of the need for such a system, and efforts are under way to find the best solution for comprehensive reporting on vaccination.

Data use and analytics

If required, the EVR can provide monitoring agencies with a real-time data feed of adverse events, vaccine batches and campaign data. In addition, population-level policy units can be provided detail such as coverage rate and cohort/denominator data. The system incorporates a data-analysis hub that stores anonymised data. This has sophisticated capabilities in data analytics, machine learning and (probably) AI.

Data storage and security

Data is securely stored, and the database has a maintenance plan, with access locked down to specified roles and applications. A data-quality auditing solution is in place, and a data-protection impact assessment has been performed, with clearly defined roles. The data-protection officer is aware of the database. The basis for processing consent is clearly captured and stored within the dataset, with mechanisms supporting all GDPR subject access request obligations.

System notifications and administrative capabilities

The Swedish NIP is highly structured, and citizens are asked to attend regular vaccination appointments. In fact, there is no need for a booking to be made, which is a direct contributor to their 97–99 per cent coverage of the DTaP vaccinations recommended in infancy by the NIP. There is no need for a portal with appointment functionality because a health-care worker will always initiate it. Reminders for regular vaccination appointments are automated, with the information going through the school nurse or a health-care worker at the well-baby clinic. The EVR system allows vaccination bookings for COVID-19 and for all vaccines included in the Swedish NIP. Follow-ups, reminders and first vaccination appointments are not a feature of the direct EVR.

Consent monitoring

Patient consent is captured in a separate but related solution and not in the EVR. There is no patient/guardian portal capability, but a solution is in progress that will be implemented at a later date.

Access to patient info and other health data

The EVR integrates with the patient-accessible electronic health records (PAEHRs). Each person has a unique personal identification number by which every health action, including vaccination, is tracked.

One task assigned by the Swedish ministry of health to the eHälsomyndigheten (e-health agency) is to have a nationwide vaccination registry that does not depend on whether a vaccination occurs under a NIP or is privately administered. The current proposal is that people could log in with their secure ID through an app on their phone and access all their personal health data. Swedish health authorities are trying to find the best way to integrate their standard COVID-19 vaccination card into this proposed system and then to update the registry regarding other vaccinations. The intention is that this system will be a single path for all screening, screening results and blood test results.

Application and third-party access

The EVR data-analysis hub facilitates data exports to international bodies and open-data projects. Curated access can be granted for specific periods to enable research partners to enhance their research projects without compromising system security. Since only aggregated data can be extracted, no personal data can be accessed.

The system integrates all the data required to allow the vaccination programme management team to plan vaccination campaigns at a regional and country level. However, in Sweden there are very few vaccination campaigns because the VCR is so high. These campaigns are more for health workers, preparing them to go to parents, for example, with information about colds and flu.

Adverse-event tracking

The EVR allows health-care workers to log adverse-event data and can accept incoming information regarding batch recalls, albeit not directly from the manufacturers. In the same way, adverse-event data are pushed to the manufacturers in real time but not directly from the EVR. For example, in the case of a recalled batch, the personal IDs linked to the batch are identified and the relevant health-care workers notified. Subsequently, they contact patients who were given the vaccine in that batch.

Data use in campaign optimisation, awareness and monitoring

The Swedish EVR system enables vaccination programme managers to optimise their activities and gives them insights for planning follow-on (e.g., catch-up) campaigns. It can be used to ensure the campaign is as effective as possible in terms of the optimal use of resources. Its marketing functionality enables programme management teams to target patients, guardians and health-care workers with information about upcoming campaigns. In addition, it allows the tracking of the progress of a vaccination rollout in real time and for adjustments to be made that improve efficiency.

The EVR does not have an integrated supply chain or cold chain system data feed. Suppliers have a system through which they receive vaccine orders, but this is not linked to the EVR.

Access to other registries

The Swedish EVR solution provides an integrated view with screening and disease registries to assess the impact on preventive diseases. For instance, the National Cancer Registry is linked with the vaccination registry for HPV, so they can find any information relating the vaccination status of a person diagnosed with cancer. The system also assists health-care workers in integrating vaccination with their other activities. It allows vaccination event data to be recorded in as close to real time as possible, and enables the capture of vaccination event data in offline scenarios. (Offline data is uploaded automatically at a later stage.)

Data anonymisation and pseudonymisation

Data undergoes sufficient anonymisation or pseudonymisation routines to align with data-protection obligations.

IRELAND

Ireland has a specific approach to VCRs, with its Schools Immunisation System (SIS) a central solution in the system.

Data structure and tracking

The SIS data structure is sufficiently comprehensive to support operational tasks. There are enough data points to support data-driven policy analysis, and the dataset is intuitive to health-care teams. Primary data – information on the school, the patients, vaccination and consent – is captured in Excel spreadsheets which are then imported into SIS. The SIS data is kept in a relational database with one of the tables dedicated to vaccines, vaccine types, consent and patient information. This allows the operational tasks to be adequately prepared. The data can be accessed through the application, the T-SQL (Transact Structured Query Language) or reports. Health-care workers interact easily with the EVR.

The metadata in SIS is not based on an international standard. The approach for creating the database architecture is specific, using cloud facilities, application programming interfaces (APIs), inputs and endpoints and retaining the Personal Public Service Number (PPSN) and the Individual Health Identifier (IHI) number. The SIS records vaccines, batches and expiry dates exist as a dictionary list, with no direct impact on the supply chain. There is no notification on schools or stocks, so vaccines are not ordered on the basis of the data in SIS.

Several possible improvements to the system have been identified. For example, a change to the number of HPV vaccines required is needed. There is also a need to expand the scope of SIS to include preschool vaccinations, five to six additional vaccinations, and new validation rules and nationality data. This will increase the number of system users and connect more stakeholders. To review duplicate patient entries side by side and select which data to retain in a merged single entry, a de-duplication functionality via the front end is needed. A series of APIs is expected, too, to integrate SIS with the IHI, Eircode (the Irish postal code system), and the Department of Social Protection for PPSN in an auto-upload functionality via the front end for annual PCR/IHI/denominator data uploads.

Data use and analytics

Currently, the EVR provides extracts from reports. No API or similar system exists, so there is no analysis hub. The solution provides a data feed to monitoring agencies, which gives an aggregated view of adverse events, vaccine batches and campaign data such as cohort and location, and to population-level policy units (coverage rate, cohort/denominator), in real time if required.

Data storage and security

There is no single centralised repository for EVR data at the country level. SIS is part of a greater encompassing architecture that uses several systems. The vaccination data captured in other systems are imported into SIS from time to time, which allows for better analysis and reports. Most probably for security reasons, the information regarding the general structure of the systems in which SIS links and performs its functions is not publicly available.

The data is stored using SQL Server. The database is secure and has a maintenance plan, with access locked down to specified roles and applications and processes for remediation of data-quality issues in operation. There are mechanisms in place to support all GDPR subject access request obligations. Roles such as data controller and data processor have been clearly

defined. The data-protection officer is aware of the database and the basis for data-processing. Consent is captured and stored within the dataset. These systems are highly secured, with the management on the HSE side owning the servers and all the network infrastructure, using specific standards.

System notifications and administrative capabilities

The invitation for vaccination is not done in SIS. The system only receives data after the vaccination event.

Consent monitoring

There is no patient or guardian portal capability in place.

Access to patient info and other health data

Health-care workers use a dedicated module that integrates with the EVR. The system enables them to record vaccination event data in as close to real time as possible and to capture vaccination event data in offline scenarios, with a later (semi-)automated upload of data.

Application and third-party access

Curated access can be granted for specific periods to enable research partners to enhance their research projects without compromising system security. The reports facilities are used to export data to international bodies.

Adverse-event tracking

The system allows health-care workers to record adverse-event data, and, in the case of an adverse event, it can capture information and comments about the change in the patient's health status. The health-care worker must confirm that the adverse event has been reported to the Irish Medicines Board. The EVR cannot accept information from manufacturers and does not push adverse-event data to them.

Data use in campaign optimisation, awareness and monitoring

Vaccination programme management teams can use SIS to plan campaigns at a regional or country level, but they cannot use it to schedule the workforce's activities or to optimise the use of resources and materials so that the campaign is as effective as possible. SIS does allow them to track a rollout's progress in real time and to adjust the campaign to improve efficiencies, but it cannot assist in planning follow-on campaigns. The EVR contains limited marketing functionality to target patients, guardians and health-care workers with information about upcoming campaigns.

Access to other registries

There are plans for a EHR in Ireland, but, to date, this has not yet been established. Existing cancer and cancer-screening registries are not integrated with SIS, despite them using the IHI number. Integration between SIS and the IHI system is done manually by an external team, usually once a year.

Data anonymisation and pseudonymisation

For internal issues like QA access, the data will have undergone sufficient anonymisation or pseudonymisation to align with data-protection obligations.

SCOTLAND

Scotland is an excellent example of how the COVID-19 pandemic catalysed improvements to their EVR. About a year before the pandemic, plans for the National Digital Platform were already advanced. This was a central clinical data repository that used the openEHR data model. The idea was that over the course of ten years Scotland would decommission local and regional data stores and migrate the data into this repository. This would have started with screening vaccinations and other health programmes and then progressed towards more localised services. The urgency of the pandemic led to faster implementation than would have been possible in different circumstances. The system developed for COVID-19 vaccinations will gradually integrate all vaccines.

Once the COVID-19 emergency was somewhat settled, the team returned to its core objective. Over the next two years, they will replicate the systems integration between the data repository and all the GP and primary-care systems. Using the international patients' summary standard, they will be equipped to administer and track vaccinations, allergies, a wide range of tests and detailed patient information (such as risk factors and comorbidities). This new approach envisions using large groups of volunteers to roll out vaccination campaigns.

To support this change, Scotland is slowly moving all vaccine records onto a unified platform: the GP Records Systems Data Scheme. This will be expanded to cover additional data items for different types of vaccination using SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) as a modelling language.

For various historical reasons, some UK countries are very reluctant to support the creation of a single personal identity or administration that governs multiple independent countries. While this tendency allows them their own sovereignty, it does come at the cost of being able to deliver effective, cross-country public-health services as well as they might otherwise be able to.

Data structure and tracking

In Scotland, forty-nine different systems make up the equivalent of one EHR. GPs, hospitals, community pharmacies, etc., all have their own dedicated systems. A complex web of integrations exists between them to present a single portal where the clinicians can access most of the records. Sometimes, people have portal views that access multiple systems at once. There is no central repository or structured database, and the current structure contains many legacy systems. FHIR messaging and other tools are used to send data between systems as and when needed.

The Community Health Index (CHI) is a population register used in Scotland for health-care purposes. Each CHI number identifies a person on the index. Using all GPs and hospital records in the country, an aggregated record has been created for each patient for booking, attendance, messaging and notifications around vaccines. On the clinical side, the on-site tool reviews the patient record ahead of the vaccination and then updates the record after the vaccine has been administered. When arriving at the place of vaccination, the patient provides their name and date of birth to the health-care worker who finds their CHI number through a web app or portal. The great advantage of this web-based tool is that it can be deployed as needed, for example in the GP's clinic, in primary-care offices and in mobile units.

Physicians use a patient list for the standard vaccines delegated to the primary-care level. They also have their own localised GP record system. They use a dedidated identifier against each person, allowing the creation of a general vaccine record held locally for each region. Still, it is difficult to aggregate these records at the country level.

Geographical cover

The public-health agency Public Health Scotland (PHS) has access to the system to allow surveillance and pandemic control in order to understand the level of vaccination in a region and act accordingly. PHS has working agreements with municipalities to offer information and cooperate on vaccination. The municipalities cannot directly access the data themselves.

Data use and analytics

The Scottish system accommodates various users. All access is role-based, with different tiers of staff having different access and rights. The programme management team uses parts of the system in the vaccination rollout. The National Vaccine Store is connected to a Power BI Management Information Dashboard that shows patients' flow, the number of people invited for an appointment and a variety of clinical audits, service planning, reporting and briefings for government ministers.

System notifications and administrative capabilities

For a COVID-19 vaccination, the patient receives a letter with their appointment details. If they want to change the date or the time of this appointment, they can do that through an online portal. For travel vaccines, patients contact their GP directly. For the flu, seniors over a certain age receive a letter stating that their flu jab is ready; they then need to contact their GP for an appointment. Alternatively, flu vaccines can be booked privately outside of the health service through an online portal used by pharmacies.

Consent monitoring

The Scottish EVR has a dedicated software application for clinicians to record patient consent regarding vaccination. The new system has a patient/guardian portal that allows citizens to see their records and download documents regarding vaccine status.

Access to patient info and other health data

Scotland's Digital Health and Care Innovation Centre works explicitly with patients' health records, for example, for the COVID-19 vaccine certificate, which is represented as a QR code or a printable document. Companies like Sitekit are also in operation. Sitekit provides a product called eRedbook, which is an immunisation record that allows people to move their vaccine data between community care groups, the NHS, municipalities and other groups.

However, some flaws were clear from Scotland's COVID-19 registration and tracking programme. Their programmes only initiated identification processes and verification work after two-thirds of the country had received their vaccination, which meant that the integrity and authority of the certificate they held were limited. This did not turn out to be a major concern in the end, but it could have been had travel been restricted more substantively or if people were not able to visit their loved ones in care homes because of it. The lesson is that if you do not design a coherent displayed identification mechanism into your EVR or vaccination administration system, everything downstream will be lower-trust, and it will be more difficult to coordinate multi-agency responses.

Despite the obvious complexity of Scotland's multi-system infrastructure, in the next five years there is expected to be a single data repository that patients can access via their phones that allows them to hold a localised version of their immunisation record so that if they need to they can provide it to different agencies for different purposes, including for travel.

Application and third-party access

Manufacturers are not connected with the Scottish EVR in any way. That does not mean they are completely outside the overall data ecosystem. Using a data-analysis hub, they can obtain data like any other third party with no specific rights. In certain conditions, an anonymised set of data can be copied into the so-called Data Safe Haven – a specialised university–NHS collaborative data space. To use the hub, researchers have to be physically on-site. They cannot take the data away. Scotland is very privacy-conscious, so all systems are designed to preserve this. There is no access to the vaccination database, either through marketing calls or communication with any private commercial entity.

Adverse-event tracking

A separate system, on Datex, is used by health-care professionals to record adverse events.

Data use in campaign optimisation, awareness and monitoring

The information governance arrangements are exact and for vaccine administration only. We do not know whether Scottish health-care workers use bespoke vaccine tools for that kind of data reporting or generic reporting tools. What is very clear is that the secondary use of the vaccine data is minimal.

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Contact Details:

Cristinela Velicu
Director Global Policy Strategy HPV
MSD
Email: cristinela.velicu@merck.com

Tudor Pitulac
Prof, PhD, PMP; RD&I Head
OpenSky Data Systems
Email: tpitulac@openskydata.com