

Immunisation Information Systems: Making interoperable data systems for vaccination a reality in Europe

2022 RECOMMENDATIONS BASED ON
CALLS TO ACTION ON HEALTH DATA
ECOSYSTEMS



Round Table 5

Immunisation Information Systems: Making interoperable data systems for vaccination a reality in Europe, building on the COVID-19 experience

Round Table findings and recommendations based on Calls to Action on Health Data Ecosystems

This report presents the findings of two multi-stakeholder Round Table meetings that explored, and have proposed recommendations for how Europe and its Member States can advance effectively and rapidly towards having the most functionally suitable and interoperable information systems used to run, document, and evaluate immunisation programmes.

This report is a consensus of 28 invited expert stakeholders in vaccine research and development, immunisation programmes, public health, clinicians, vaccination registries, immunisation information systems, health informatics and policy-setting. The Round Tables were held on 23rd June and 7th July 2022.

The two Round Tables were scoped and convened by the Digital Health Society (DHS) and The European Institute for Innovation through Health Data (i~HD) neutrally and independently from the event sponsors Johnson & Johnson, Microsoft and MSD. This topic is part of a rolling programme of deeper dives drawing on 7 [Calls to Action on Health Data Ecosystems](#) that were published in 2020, taking an immunisation-specific focus in particular on the three Calls to Action on the right:

1 **Raise the digital literacy & skills of all stakeholders**

2 **Generate and value trustworthy Real World Evidence**

3 **Accelerate interoperability across Europe and globally**

4 **Demonstrate benefits to society from data access, use and reuse**

5 **Adopt a risk stratification approach**

6 **Build a trustworthy framework for data access and use**

7 **Adopt a transformational approach to health data**

The stimulus for this topic has to some extent been the COVID-19 pandemic which has shown the value of real time interoperable data systems across the EU in the field of healthcare, and immunisation in particular, including the value of cross-border co-operation on the EU Digital COVID Certificate. A recent investigation by OpenSky commissioned by MSD, a summary of which is [here](#), has highlighted the variation in the maturity and use made of immunisation information systems and electronic vaccination registries across Europe, and the prevention value gained from the mature country examples. The forthcoming European Health Data Space is another catalyst for European action in this area, providing the opportunity to collate and enable permitted cross-border access to citizen-level immunisation information and aggregated-data intelligence

on coverage, outbreaks and the effectiveness of prevention and containment strategies.

The recommendations in this report cover the spectrum from strengthening immunisation information and vaccination programme delivery to individuals through to national and multi-national co-operation on outbreak intelligence sharing and co-ordinated action.

We intend to promote, and elaborate on, the recommendations in this report and other topics arising from the Calls to Action, as future multi-stakeholder engagements during 2022-23. We will cooperate with OpenSky as they prepare a second follow on report later this year.

This report was published in November 2022. A Glossary is included on page 28 and a Contributors List on page 29.

Round Table recommendations



Immunisation should be a focus for the EC One Health mission, which will require that many of the prerequisites and success factors (core data set, interoperability, data quality etc.) detailed later in this report will need to be addressed. This was the top priority over-arching recommendation from this Round Table.

Other high priority recommendations



Although some country maturity exists (in the countries identified by a green colour in the OpenSky heat map of Figure 1), cross-Europe maturity seems still to be a long way off. Each Member State holding the EU Presidency should help to accelerate Europe-wide alignment on data sets and data standards, building on the cross-border momentum promoted by Portugal when it had the Presidency. Successive Presidencies, perhaps for the next 3 years, could be requested to include immunisation information systems as one of their priorities. Another example of how Presidencies are able to work together relates to FH (Familial Hypercholesterolaemia) when in 2021 the Slovenian Presidency held a high-level technical meeting resulting

in scientific and political consensus and recommendations followed by the Czech Presidency and the Prague Declaration in September 2022 on FH paediatric screening across Europe ([read here](#)).



Research, investigation and consultations with Member States is needed to determine what incentives might persuade countries in the amber or red zones of the OpenSky report to shift towards green. This could be through funding support, piloting support, expertise, mentoring from another country, some centralised computing power, sharing technology solutions (without needing to share their actual data).



Core data sets need to be defined with multi-stakeholder and cross-country involvement, recognising the data sets will be use case specific and might have vaccine specific elements. Interoperability standards and data quality standards are required for these data sets. The WHO should play a prominent role in these definitions, working in collaboration with informatics experts and standards development organisations.



Coordination across sectors and organisations will be required. Immunisation records might sometimes be part of a school record or occupation

record rather than a health record, requiring inter-agency and sector alignment within as well as between regions and countries.

Other important recommendations



European Commission actions to advance European coherence about immunisation systems, and to support the early adoption of an immunisation data space, need to be undertaken jointly between DG HEALTH and DG CONNECT utilising the momentum from the development of the EHDS.



DG HEALTH and DG CONNECT should convene further multi-stakeholder round tables in particular to gauge the extent of country alignment on the areas covered in this Round Table and also the investigation findings from OpenSky.



Regional health systems may at times play a leading role within countries if the health system is set up regionally. This is a topic to be explored within EUREGHA.



Large scale demonstrators should be funded for models and tools that

enable individuals to exercise control over their personal vaccination and immunisation data, as an implementation of self-sovereignty. Blockchain could play a valuable role in this.

Stakeholders to engage in taking these actions



It was recognised by Round Table participants that the recommendations above would largely need to be undertaken by multiple stakeholders working in collaboration, and were not the exclusive responsibility of a single stakeholder group. The stakeholders who are most important to engage in further elaborating a plan for each of these recommendations, and then putting them into action are:

- **Ministries of Health & Public Health for Policy**
- **WHO**
- **Clinical & Immunisation Experts**
- **Standard Development Organisations**
- **ECDC**
- **European Commission**
- **Patient, civil society & HCP organisations**
- **Healthcare Semantic experts**

Context

A pair of virtual Round Tables on 23rd June and 7th July brought together approximately 20 multi-stakeholder experts in vaccine development, immunisation programmes, public health, clinicians, immunisation information systems and informatics to explore how Europe and its Member States can advance effectively and rapidly towards having the most functionally suitable and interoperable information systems used to run, document, and evaluate immunisation programmes as well as improve disease surveillance and outbreak monitoring.

The meeting objectives were to formulate the actions that are needed to advance Europe's immunisation intelligence capability and programme effectiveness, at both Member State and the European level, catalysed by the European Health Data Space (EHDS) and the pandemic, and to define actions required by other stakeholders across Europe.

In July 2022 the European Parliament approved the Digital Services Act and the Digital Markets Act, which provide new opportunities and additional context along with the EHDS draft Regulation for collaborating at a European level on immunisation and disease information sharing and insights.

This Round Table topic is part of a series jointly organised by the Digital Health Society and the European Institute for Innovation through Health Data, sponsored by Microsoft, Johnson & Johnson and MSD. Following two Round Tables in 2020 which culminated with 7 Calls to Action on Health Data Ecosystems ([read here](#)), two further Round Tables were run in 2021 on Proposing a common basis for health data access across Europe ([read here](#)) and on Scaling up the availability and reusability of big health data ([read here](#)). This Round Table topic on immunisation information systems is part of the 2022 programme of topics.

1

Rationale for this Round Table topic

The COVID-19 crisis has shown the value of interoperable data systems across the EU in the field of healthcare and immunisation in particular. The European Centre for Disease Prevention and Control (ECDC) has played, and continues to play, a critical role in collecting all COVID-19 relevant data in a harmonized and timely manner in close collaboration with Member States and regions, with the view to informing decision-making at all levels. Such **coordination effort for effective pandemic monitoring has proven to be key in driving a harmonized response to health threats** with better informed decision-making as well as becoming a reference for monitoring of COVID-19 vaccination coverage rates. In parallel, **the Regulation enabling the EU COVID-19 Digital Certificate was adopted in record time to allow for free movement of people within the EU**, keeping safety and privacy by design in mind. The common certificate also required an accelerated technical architecture and infrastructure development in all Member States and regions. It has created the ICT infrastructure and legal framework on which further applications could emerge, such as a common vaccination card compatible with electronic immunisation information systems and recognised for use across borders (as men-

tioned in the EC Roadmap for the implementation of actions based on the Commission Communication ([read here](#)) and the Council Recommendation on Strengthening Cooperation against vaccine preventable diseases ([read here](#)).

There is a need for all health systems to put greater emphasis on prevention, for which vaccination is an important measure. Prevention is a cost-effective intervention for health systems and immunisation information offers an excellent case to demonstrate the importance of an EU integrated prevention strategy to improve decision-making, prevent outbreaks and prepare for the next pandemic. However, there is still a digital divide when it comes to the maturity and uses made of immunisation information systems across Europe.

Enabling effective, timely and interoperable information about all vaccine-preventable diseases, available at EU, country and regional levels would have many benefits including a) leading to a better assessment of vaccination campaigns b) helping to target resource allocation where it is most needed c) protecting more citizens against vaccine-preventable diseases and d) making an early contribution to the European Health Data Space and the European Health Union. As a concrete example, while the EU has set ambitious goals of eliminating HPV related cancers and improving Hepatitis B vaccination with specific targets to be reached by 2030, there is to date no possibility to track progress across the EU27 as data are not communicated in a comprehensive manner nor in a harmonised way, nor updated on a regular basis.

2

The ambition of these Round Tables

Rather like the ambition of the EHDS, **immunisation information systems should support the primary use of data to bring direct benefits to individuals, to optimise their immunity, and support secondary uses such as public health, service planning, policy making, research and innovation.**

High quality, interoperable and potentially linkable immunisation information systems that capture the operation of programmes, the details of vaccination administration to individuals, geographic coverage, and the concurrent incidence of diseases that the immunisations are intended to prevent, could deliver great value to health systems, public health agencies, national and European decision-makers and policy-makers, to vaccination and medicines development companies and to patient organisations. There will be a wide range of use cases for such information systems that these round tables have compiled, to help begin to formulate the ideal (gold standard) features of future immunisation information systems, their ideal operational adoption and co-operation models across Europe.

Recognising that Europe is presently in a heterogeneous situation with regard to the maturity of deployed information systems,

the meetings also sought to better understand the good practices and solutions in some countries from which others can learn, and to identify and prioritise any widely occurring gaps across Europe in system functionality and operational adoption when compared to the idealised gold standard.

The forthcoming European Health Data Space can play an important role in enabling the access to individual level and population level immunisation and relevant disease incidence and prevalence information for more evidence-based decision making. Immunisation information could potentially be an early use case for the EHDS. Although initially scoped on Europe, the invited experts included those from a beyond Europe perspective with the aim to learn from other countries' experiences, and since many of the finalised recommendations and calls to action would be globally applicable.

Open Sky Data Systems, an international enterprise automation specialist technology company, has recently investigated the maturity of vaccination registries across Europe and is preparing a report "State of the art in Electronic Vaccination Registries in the European Union and the UK". This report has been commissioned by MSD (one of the Round Table sponsors) and will be published in the coming months. OpenSky contributed to the Round Tables, presenting their high level findings and exploring with participants the extent of correlation between Electronic Vaccination Registries and Vaccine Coverage Rates. These findings contributed to Round Table discussions about the design considerations and success factors for immunisation in-

formation system, and the improvements that may need to be made across European countries to reach a gold standard target of functional capability and adoption maturity.

The OpenSky findings and expert input have contributed to the recommendations for advancing vaccination information interoperability and timely data gathering both at national and EU level, building on the COVID-19 experience. Leveraging infrastructure and policy framework recently set for the EU Digital COVID Certificate was the starting point of this discussion, adding to the extended mandate of the ECDC as part of the EU's Health Union package. The meeting learned about best practices from countries with most advanced information immunisation systems and electronic vaccination registries to illustrate what can be done and the advantages of such advanced systems for individuals and for public health decision-making. **The Round Table highlighted significant informatics gaps that need to be addressed as European priorities, and concluded by proposing policy recommendations and calls to action across stakeholders.**

3

Summary of the Round Table discussions

OpenSky Research findings

HPV vaccination was used as a case study in the favourable context of Europe's Beating Cancer Plan, to enable valid comparisons to be made across countries. 10 functional capabilities were used as variables to generate a scorecard and ranking of the surveyed countries, which was used to generate a "heat map" for Europe (Fig. 1).

The scorecard results of the electronic vaccination registry (EVR) analysis are very diverse across countries, corresponding to concrete action taken in terms of integrated national approaches instead of regional ones, continuity in programme implementation, and fighting inertia.

The OpenSky team identified a wide range of maturity across Europe of electronic vaccination registries (EVRs), or equivalent registry-like systems. Their investigation findings strongly emphasise a consistent correlation between the existence in a country of evolved Electronic Vaccination Records and higher Vaccine Coverage Rates.

The ten functional capabilities used as variables to generate the heat map (Figure 1) and scorecard (Figure 2)



The presence of a vaccine register or equivalent



Whether there is a cancer register



Whether HPV vaccination was included in the register



Whether vaccination related information was included in the cancer registry data set



The level of interest in using ICT (EHR systems etc.) within healthcare provider organisations



Whether there is an integrated national approach to managing vaccination information



The level of interest in developing registers



The extent to which best practices are being replicated



Whether there is a cancer screening register



The frequency with which reporting data is generated

Figure 1: OpenSky heatmap highlighting the correlation between Electronic Vaccination Registries and Vaccine Coverage Rates throughout Europe and the UK. Ten functional capabilities were used as variables to generate a scorecard and the ranking of the surveyed countries in the heat map in Figure 1. The ten capabilities are listed in Figure 2

Country	Weighted score
Denmark	99%
Finland	96%
Netherlands	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%
Lithuania	48%
Austria	44%
Czech Republic	40%
Croatia	38%
Greece	36%
Cyprus	36%
Poland	34%
Bulgaria	33%



Figure 2: Scorecard of EU & UK Countries taken from the OpenSky Report

Country/ Territory	Vaccine register	HPV vac- cination in the register	Vaccine related informa- tion on the Data set	Level of interest in using ICT in Health (EHR etc.)	Level of the register develop- ment	Cancer screening register	Cancer register	Inte- grated national approach	Relative replica- bility as a Best Practice	Country/ Territory	Country/ Territory
Denmark	1	1	1	3	4	1	2	2	9	5	99%
Finland	1	1	1	3	4	1	1	1	9	4	96%
Netherlands	1	1	1	3	4	1	1	1	9	3	94%
England	1	1	1	3	4	1	1	1	8	3	92%
Sweden	1	1	1	3	4	1	1	1	8	3	92%
Wales	1	1	1	3	4	3	1	1	8	4	90%
Ireland	1	1	1	3	3	1	1	1	8	2	86%
Scotland	1	1	2	3	4	1	1	1	8	2	86%
Northern Ireland	1	1	1	3	3	2	1	1	7	3	85%
Latvia	1	1	1	3	3	1	1	1	4	2	81%
Malta	1	1	1	3	3	1	1	1	6	1	81%
Slovenia	1	1	2	3	3	1	1	1	5	1	76%
Belgium	1	1	1	3	3	1	1	3	7	1	75%
Portugal	1	1	2	3	3	3	1	1	7	7	74%
France	2	1	1	3	1	2	1	1	8	2	73%
Spain	1	1	2	3	4	2	1	3	5	2	72%
Germany	1	1	2	3	3	2	1	3	8	1	70%
Romania	1	2	2	2	3	2	1	1	4	1	66%
Estonia	2	1	2	3	1	1	1	1	5	1	65%
Italy	1	2	1	3	1	2	1	2	5	3	64%
Hungary	1	2	2	2	1	1	1	1	3	1	60%
Slovakia	1	3	3	3	3	2	1	1	3	1	59%
Luxembourg	1	2	3	2	2	2	1	1	3	1	58%
Lithuania	1	3	3	2	1	3	1	1	3	3	48%
Austria	1	3	3	3	1	3	1	3	4	1	44%
Czech Republic	3	3	4	1	1	1	1	1	2	1	40%
Croatia	3	3	4	2	1	3	1	1	2	1	38%
Greece	3	3	2	1	2	3	1	3	3	1	36%
Cyprus	3	3	4	1	1	3	1	1	2	1	36%
Poland	3	3	3	2	1	1	1	2	2	1	34%
Bulgaria	3	3	4	1	1	2	1	2	2	2	33%

Vaccine Register	1 Yes 2 There is an equivalent 3 Not yet
Level of the Register Development	1 Incipient 2 Pilot 3 Functional 4 Advanced
Level of Interest in using ICT in Health (EHR etc.)	1 Low 2 Moderate 3 High
Cancer Register	1 Yes 2 Information not clear or available for the moment 3 No
Cancer Screening Register	1 Yes 2 Information not clear or available for the moment 3 No
Integrated National Approach	1 Yes 2 Information not clear or available for the moment 3 No
Vaccine-related Information on the Data Set	1 Yes 2 Most probably yes 3 Information not clear or available for the moment 4 No
Relative Replicability as a Best Practice	On a 1-10 scale, with 1 being least desirable and 10 most desirable
Reporting	1 Unavailability/unable to source or confirm 2 Data available at least annually (but with delays in reporting) 3 Data available at least annually and up-to-date 4 Data available quarterly and up-to-date 5 Access to reporting, up-to-date

Note: The scorecard does not reflect the ratio to an ideal model but to what we have identified as the State-of-the-Art. For example, the 99 points out of 100 obtained by Denmark do not mean that an absolute maximum has been reached there. It tells us that the Danish system is more or less advanced than those used in other countries.

The main take-aways from this Open Sky investigation are:

- Instant access to up-to-date information from the EVRs significantly impacts on vaccination coverage rates
- There is a need for an EVR template in Europe.
- Linkage of HPV vaccination (in females and males) to cervical cancer screening data and cancer registry information (including mortality rate) can enable more precise strategic decision making and better targeted campaigns
- There is a significant disparity between the north and the south of Europe and between the west and east of Europe in terms of immunisation information system maturity, with regard to HPV registries (or equivalent data sources) and the ways in which registry data are used to help maximise vaccination coverage rates.
- An important success factor is the capability to have near to real time information on vaccination coverage in order to know where and when to act swiftly to better promote uptake.
- All countries have a will to increase their vaccination rates.
- A common European approach would allow better interoperability, lead to greater sharing and larger scale evidence across Member States

A follow on second deeper dive phase of the Open Sky investigation, in selected countries, will be used to identify the key functions of a gold standard immunisation information system and a proposal for a common model. They expect to identify some of the most potent drivers and barriers to investing in and adopting high quality electronic vaccination registries. This work is intended to distil generalisable learning points that could be relevant to and used by all European countries. It will be followed advocacy efforts to help promote the importance of mature immunisation information systems and of European sharing and interoperability.

It was recognised during discussion of their presentation that the scorecard values might be slightly different between countries for different vaccinations, but the learning and implications would probably be very similar. COVID-19 vaccination information is handled quite differently in different countries, through dedicated systems that were set up specifically to handle the pandemic, and the information system maturity of that vaccination would not be representative of the overall maturity in each country.

Citizen access to their own vaccination record was considered an important information system function, along with the ability to manage individual level scheduling of vaccine administrations. It is not yet widely delivered across European Member States.

Information about the vaccination supply chain, stock management and distribution was another important function taken into account within the immunisation system. This should ideally be linked to the administration strategy (e.g., in

schools, clinics) and educational campaigns so that a) poor uptake areas can be identified and the reasons for this understood and b) success factors can be identified in successful vaccination campaigns

OpenSky found that the more mature countries were more publicly open and detailed in the information they made available about their immunisation operations, including the use of ICT systems.

Meeting participants were reminded that the OpenSky team remain willing to receive new inputs that supplement information they have already gathered from included countries, and to learn about countries that they have not yet included in their investigation.

The final summary report on phase 1 has been circulated to all meeting participants.

Use cases for immunisation information systems (incorporating vaccination registries)

The expert meeting next considered what use cases an ideal immunisation information system or network of connected information systems should enable, within the country and potentially across countries.

It is important to distinguish, but to deliver, on all of these levels:

- 1. Individual level vaccination administration and immunity status information** to people (and their families) so that they can track their prevention and enable continuity of care, possibly linked to disease screening programmes

- 2. Population level intelligence** within countries, regions or even local settings about vaccination uptake, programme adherence, and disease incidence and prevalence, that allows for strategic decision-making at different granularities of geography allowing discovery of low prevalence uptake areas, the impact of campaigns, and early detection and tracking of outbreaks

- 3. Multi-country intelligence sharing** that enables sufficient scale of data for knowledge discovery (for example in the case of new infections) and for comparing the effectiveness of different prevention and control strategies and co-operation on pandemic management

Following extensive discussion, nine use cases were identified, spanning from individual level data supporting empowerment and adherence to vaccination programmes, through to information to support the design of successful programmes, research, and innovation.

Participants were asked to rank these nine in priority order, as indicated above, imagining the case of a country starting from a low level

of present-day maturity, limited legacy information systems that could be built on, and now with a potentially limited budget. The country would therefore need to prioritise the areas of investment that should be undertaken first. It was recognised that every country will be at a different point and that this priority ranking would only be applicable to countries in a general sense.

Nine use cases for Immunisation Information Systems



1

Providing vaccination record access to individuals and families so that they can also ensure maintenance of their schedules in case they move and be aware of their protection status.



2

Enabling continuity of care including cross border continuity if vaccination administration records are interoperable.



3

Connecting vaccination administration to the occurrence in individuals and at population level to complications and adverse events, in the general population and in demographic or disease sub-populations.



4

Linking vaccination coverage to the disease prevalence burden, for example in unprotected or high risk groups.



5

Linking outbreaks to vaccination coverage gaps: geographic pockets of low coverage and/or demographic profiles of risk populations.

**6**

Linking health promotion and education campaigns to vaccination uptake, to assess the impact of these programmes.

**7**

Academic research into the diseases being prevented, vaccine effectiveness, safety, education, programmes, the design of campaigns etc.

**8**

Industry research into new or improved vaccines and other prevention measures.

**9**

Comparison of vaccination programmes and delivery models across regions and countries, and other public health research.

It was also recognised that a different way of approaching the prioritisation that was undertaken could have been to vote only on the top priority use case, to have participant discussion about their different rankings, then to move onto the second priority etc. That was not done on this occasion, for time reasons, but could be an interesting option for a future discussion of the use cases.

The top ranked use case was giving individuals access to their own immunisation status and vaccination schedule (use case 1). This was first ranked because it was generally assumed that unless there is good quality and reasonably complete individual level vaccine administra-

tion information then many of the other use cases would be difficult to achieve. Indeed, without public trust in the system, population buy-in and acceptability of shared data would be difficult. It was also noted that this is an area of public interest that has been strongly driven by the recent experience of COVID-19, in which apps to provide individuals with this kind of information have proved popular and well used. The population have seen the benefits of being able to present their vaccination history and immunity status when they travel around, and perhaps the public expectation and/or desire is that this will or should shortly be broadened to other vaccination programmes. Also, this use

case positively involves and engages citizens and demonstrates the real benefits of legally compliant data sharing helping to build trust in the wider use cases for health data sharing.

As a real life example, Portugal has been giving citizens their vaccination information and schedule, and vaccination or recovery certificates, via an app that has proved very popular with a high proportion of the population, including taking advantage of the ability to schedule their next vaccination. 70% of the population have downloaded the app. Their learning is that empowering citizens within information about their vaccination status and proposed next scheduled dose, alongside information about the disease, avoidance measures and about the vaccination itself, all contributed to a quick and effective public response to their vaccination programme.

Another strongly supported priority use case was the ability to support cross-border continuity of vaccination. This was seen to be an area on which Member States should cooperate, and which will require interoperability of vaccine administration and vaccination schedules. Interoperability with other related systems, such as contact tracing, should also be a transnational priority in line with the ongoing EU efforts on cross-border care continuity solutions such as MyHealth@EU. Portugal found that these areas of interoperability enabled

their country to implement effective measures during the pandemic.

An alternative prioritisation was discussed, in favour of the ability to gain population level insights and potentially even individual level insights, without the ability to provide data back to individuals (use cases 3, 4 and 5). Some countries may have existing vaccination programme administration systems and disease registries, for example an HPV vaccination system, a cervical cancer screening system and a cancer disease registry that could be linked at the individual level as an early win, allowing insights into the effectiveness of the programmes.

On the other hand, if these information systems are not in place, or have limited coverage, then targeting the delivery of information back to individuals about their vaccination administration and schedule might be a low hanging fruit because it would not require linkage across multiple information systems.

It was remarked that the priority use cases for a country might vary depending on which vaccination was being considered. Countries might construct a use case roadmap in order to impact on the success of particular vaccination programmes that they are most concerned about. In some situations, such as COVID-19, use cases focused on assessing the burden of disease and linking that to vaccination programme uptake might be a very important public health priority. In other conditions, such as yellow fever vaccination, cross-border continuity and recognition of immunisation status would be a high priority. Countries (including EU Member States) will therefore need to consider if they want

to focus attention on a small number of vaccination programmes, initially, and prioritise the use cases that are most pertinent to those, or proceed more generally across their entire vaccination portfolio. In the context of transnational priorities, the European Commission should consider whether it believes from the EC One Health it wishes to promote any priority use cases. In any event, vaccine specific information silos should be avoided.

In summary, there are several factors that a country will need to weigh up when determining its use case prioritisation. These include:

- **the current extent of information system maturity for vaccination scheduling and administration, immunisation certificates, disease screening programs, disease registries, electronic health records that might contain information about adverse reactions to vaccinations and disease prevalence, and the extent to which these might be linkable**
- **the particular vaccination or vaccination programmes that are the priority to improve uptake for, or to collect evidence about**
- **public health priorities regarding disease burden, vaccination uptake and vaccination effectiveness.**

Design considerations for future immunisation information systems

The spectrum of use cases that are agreed to be prioritised – by individual countries or across countries at a European level - will largely dictate the scope of the data and workflows that the ideal immunisation information system or systems will need to support.

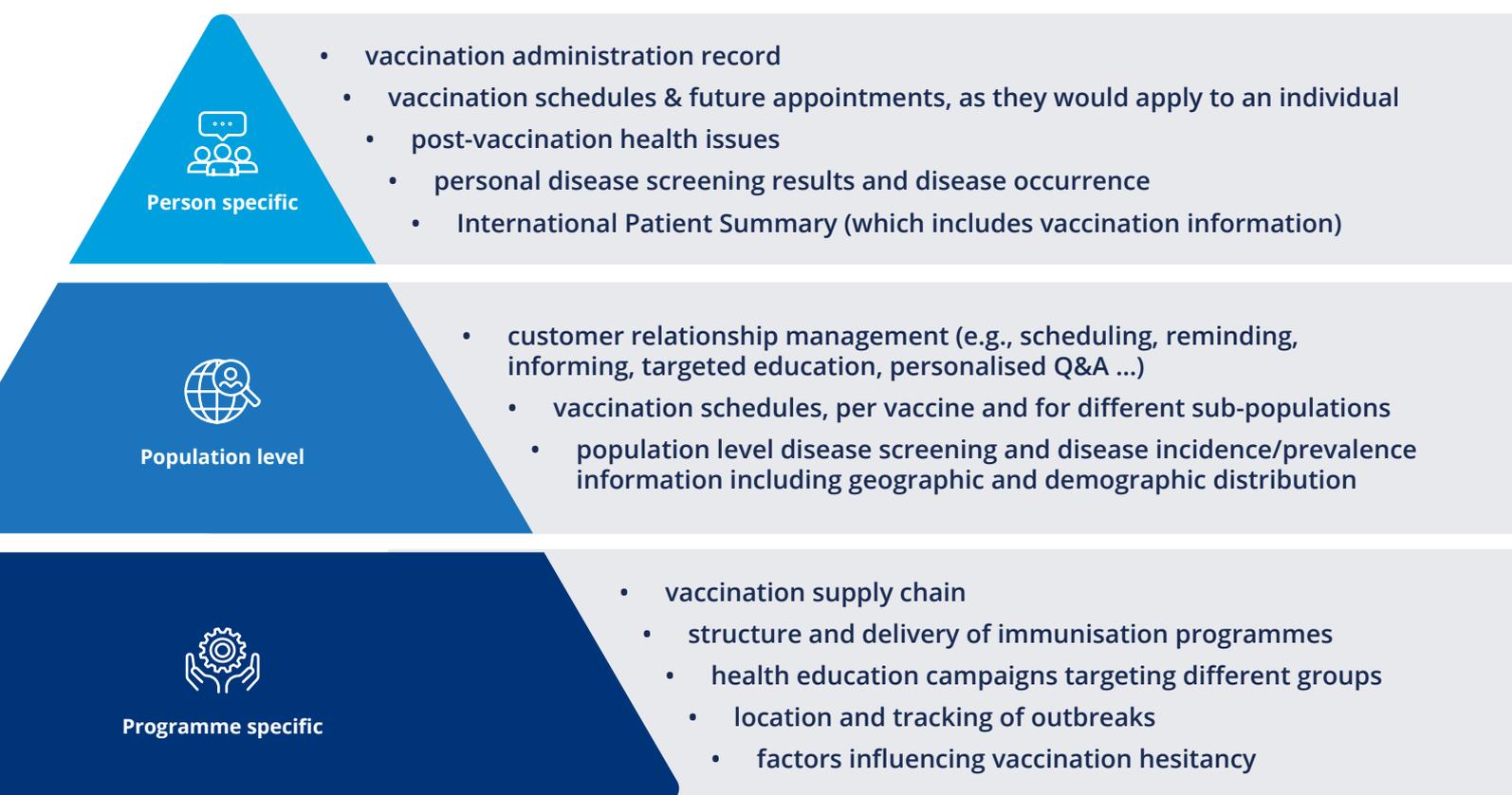
For example, these systems should ideally not be limited to vaccination administration records, but also include post-vaccination health issues, disease screening and disease incidence information, immune status of individuals if this is tested, vaccination supply chain, the structure and delivery of immunisation programmes, linkage to health education campaigns targeting different groups, and linkage to the location and tracking of outbreaks. Some data is more difficult to capture in a structured form, such as the factors influencing vaccination hesitancy and complementary risk reduction measures (e.g., mosquito net availability), but which are nevertheless important to take into account. Less feasible to capture at all in a digital form, but relevant to the interpretation of information from different countries, will be the culture of acceptance or mistrust in top-down health policies and programmes, and the level of engagement of healthcare professionals (especially primary care physicians) in vaccination programmes since they can often influence the perspectives of their patients.

If the systems that deal with the administration of vaccinations are closely coupled to the healthcare provider systems that care for the health of individuals, then it will be much more feasible to link vaccination history with clinical history, such as for the tracking of adverse events following vaccine administration and the protective effects of the immunisation achieved. This coupling applies to both the

information systems and the organisational systems and should include feedback loops. In addition to the healthcare delivery and public health systems, education and occupational health systems need to be part of this connected environment since they often hold immunisation records and may administer vaccinations.

Immunisation Categories & Functions

Categories of information and functions that an ideal immunisation information “system of systems” should support:



It was noted that there will be person specific workflows and population level workflows that are different and may require different information flows and systems.

Customer relationship management functions were considered very important by the roundtable participants, was regarded as an important feature to assess in the OpenSky investigation, and had been found to be a strong driver for the adoption in Portugal of the personal vaccination management app. In the context of immunisation information systems, this is intended to mean information about individuals, the vaccinations they have, the schedules they are meant to be following, the ability to set up new appointments or to modify them, appointment reminders and following up with non-responders or those who missed a mass vaccination event such as a school administration session, access to generic information that is relevant to each individual, and the ability for the individual or a parent or guardian to raise questions and to receive personal answers from a qualified individual if resources exist for that facility. These are the functions that would normally be incorporated into an app that provides vaccination schedule status information to individuals, which was the top-ranked use case. The availability of such functions was included as one of the criteria assessed by OpenSky. In the future AI bots could become part of such systems.

It was emphasised that information systems should adopt international interoperability standards, and European

aligned efforts should consider partnering international standards development organisations (SDOs) such as HL7 (e.g., through the adoption of the HL7 FHIR standard). In order to achieve the holistic information system linkage opportunities listed earlier, the interoperability standards used for immunisation information including vaccine administration need to be well aligned with the interoperability standards used for clinical information. **Work is needed to define a minimum core data set for each of these areas of interoperability.** It was not clear to the workshop participants who would drive the development of these core data sets, although one would expect that a multi-stakeholder expert group would be required to provide relevant inputs. The current specification for the International Patient Summary (IPS), a data set that is being ratified by ISO as an international standard and which has strong alignment with the European Patient Summary being implemented across Member States, now includes vaccination administration information and this could therefore be the interoperable means of enabling cross-border continuity of vaccination history information.

The IPS does not currently include a vaccination schedule (planned vaccinations), but this is important for continuity, especially across borders. The information about the vaccination schedule needs to be personalised to each individual in their personal record. This is because the next vaccination in a series might be timed according to the interval between vaccinations or might be timed according to the age and gender of the

individual, or an individual being in a high-risk population, or might be triggered by a clinical or lifestyle event such as intention to travel. Tracking this kind of information across populations would enable a programme operational team to determine the timeliness of vaccine administration across a population, not only simple coverage rates.

Immunisation information systems should include the details of the structure and schedule of a vaccination programme, for each vaccination provided within a country. These schedules are often modified over time, for example if there are changes to the epidemiological picture for a disease, or if there are outbreaks. Vaccination scheduling information and the way that programmes are structured and delivered should therefore be captured in a computable and standardised data format (even if the actual schedules vary between countries), to allow for the sharing and analysis of vaccination programmes as part of studying their effectiveness. The WHO publishes vaccination schedule recommendations that are adopted by many countries worldwide, which provides the content of a scheduling specification, but not in a computable form. Individual immunisation systems deployed within countries will have computable rules that are used when generating vaccination invitations, but these will usually be system specific. There does not appear to be a standard computable representation of this information, which might therefore be a gap to address. Cross country comparisons using such a standard could

help contribute to programme optimisation research. It was felt that interoperable vaccination programme information would probably not be a priority topic for a country unless its other systems are relatively advanced. However, it may be possible to start by focusing on a few vaccinations that a consensus of countries regard as the next priorities to improve on, following the experience of the COVID-19 pandemic.

Standardised analyses and reporting data formats will also be valuable for European and international collaboration and scale. It was recognised that not all countries will be in a position, or be willing, to share detailed immunisation data per person at a European level. Distributed (federated) querying should still allow for European level analysis, inferences, and comparisons to be made provided that there are standards for data analysis methods.

Data quality, especially completeness and reliability, is vital for trustworthy decision making. Data capture standards are therefore important. Good data quality and a willingness between countries to share their data for large-scale inferences will also enable the effective use of artificial intelligence in the future. In order to scale this up rapidly, it may prove acceptable to allow heterogeneous data or rather sparse data set to be contributed to **a common European immunisation data space**, provided the quality is adequate, in order to accelerate research.

Immunisation Information Standards

In summary the following areas of standardisation need to be ensured or developed:

- A minimum core data set for each of the areas of immunisation information system function
- Data capture standards
- Interoperability standards
- Data quality standards
- Vaccination (digital) card standards
- Federated analysis standards (e.g., APIs, query formats)
- Standardised analyses to allow for comparable metrics
- Standardised reporting data formats

It was also proposed, as a “nice to have” standard, to develop an interoperable representation for structure and scheduling of the immunisation programmes.

Key success factors

The following key success factors arose at different points in the discussion and are brought together here for ease of reference. It was not possible in the time available to rank these in a priority or importance order, except that the first four (marked below in bold) were most strongly endorsed as important during the meeting.

- **Respecting and maintaining public trust in immunisation systems as greater data sharing is enabled, for example GDPR compliance and transparency about data access. This trust in information flows is inevitably linked to trust in the vaccines themselves.**
- **Clearly defining and agreeing across stakeholders the scope and use cases that immunisation information systems should support. Critical to this will be engagement with citizens and patient groups.**
- **Defining a core set of immunisation information system functions that can allow Member States with limited existing infrastructure and funding to focus their resources most effectively.**
- **Agreeing an EU wide data sharing protocol so that Member State information about vaccination administration, programme design and effectiveness, screening programmes and their results, and disease incidence and prevalence can be compared and combined for maximum scale insights.**

- Agreeing a core dataset for each of the use cases, including a minimum that can be quickly achieved by most Member States and extended as a roadmap.
- All Member States agreeing on the adoption of international interoperability standards that align with those adopted for other kinds of clinical data, to better enable linkage of different data sources (e.g., within country registries) and for sharing across countries.
- Enabling individuals and families to have access to their own vaccination records, and to update their records (with appropriate quality checks).
- Promoting the importance of data quality across all kinds of immunisation information, especially importantly when dealing with the quality, safety, and continuity of care to individuals but also when analysing the data for strategic decision-making.
- Establishing a European level immunisation data space as an early implementation, potentially an early win, for the EHDS.
- Gathering and sharing evidence that can be used at a European scale to counter misinformation.
- All Member States striving for close to real-time access to information in order to allow for rapid and accurate public health decision-making, for safety and effectiveness monitoring of new vaccinations and to enable timely evidence-based responses to public concerns and misinformation situations.
- For countries lagging in infrastructure development, adequately using available EU funding (EU4Health and Recovery funds) to support the set-up, development or improvement of immunisation data systems' infrastructure and technical solutions.

The Round Table participants strongly ranked the success factors relating to trust as the most important. This includes trust in the vaccine itself (safety, effectiveness) and trust with their personal data in terms of data protection and trust in what authorities would do with the personal information they collect.

Trust in a vaccine is not only related to public confidence in its safety, but for people to know how important it is for them to have the vaccination. This could be described as vaccine literacy. It would be helpful if they were able to receive, for example on their vaccination app, information about disease prevalence and new incidence in their area, and perhaps also vaccination coverage rates. Safety data should also be provided to individuals, coming from trusted sources such as Ministries of Health to help balance the less evidenced information sources that they might be exposed to.

Trust in immunisation information systems would be strengthened if the public were able to benefit directly from the information they contribute and receive, to allow them to make informed decisions as well as to plan their future vaccination schedules and appointments.

It is also important that individuals know who has access to their personal data, how the data are being protected (GDPR compliance) and what will be done with it. A more complex topic is the extent to which citizens should have control over this data access, which would be challenging to deliver at scale today (across all ethnicities, educational and digital literacies) and would need to balance individual interests

with societal and public health interests. People need to be able to trust the institutions that are handling their data. There is an opportunity now to build on the population experience of COVID-19 immunisation apps and the EU Digital COVID certificate. Conversely, a low level of trust in the information systems or in the authorities running the information systems should not be allowed to jeopardise trust in the vaccines themselves. Public education about data protection and information security safeguards could help with building trust. Trust will be a cornerstone for EHDS so the work of EHDS could facilitate and build the necessary vaccine trust especially if an immunisation information system becomes an early use case for the EHDS.

Such information could allow people to weigh up their concerns about the safety of a vaccination against their concerns about contracting the disease. Electronic Vaccination Registries and other linked information systems, with good quality data, are important in order to be able to generate this evidence to be communicated back with transparency to the population.

Having Europe-wide data sharing protocols and agreements was also ranked highly as a key success factor. Minimum core data sets for sharing intelligence need to be as easy as possible for countries to generate so that almost every country can quickly contribute, even if their vaccination registry and patient level information systems are not yet very mature. Countries will be more willing to share their data if they are clear about the

purposes for which data will be used. For example, countries are usually willing to share aggregate data relating to outbreaks with the WHO. European Member States are committed to common targets and goals regarding vaccination coverage rates, and also share this information. Admittedly, the data is not always of high quality.

However, there is very limited sharing of individual level data to enable continuity of care, nor the reuse of (anonymised) individual level data for research. Both need to scale up, across Europe to being benefits to travelling or migrating people and to innovators such as vaccine developers. The opportunities for real world data access not only include registries but vaccination management apps that patients are increasingly using.

Immunisation data space

There was discussion about what would make countries willing or reluctant to share immunisation data within a European health data space if immunisation was nominated as an early adoption topic.

One concern that has generally been voiced by countries is sharing information for secondary uses that might be problematic to anonymise, such as genetic information. However, a core immunisation data set should be more straightforward to anonymise or pseudonymise. Member State confidence in sharing data across Europe might be easier to gain if it starts with coarse-grained (e.g. national level) aggregate data, and progresses to fine-grained aggregate data as confidence grows.

It was recognised that the EHDS is providing a secondary use environment that is intended to cover a broad range of secondary uses including strategic decision-making by public health and policymakers, research and education. Decisions about data access requests, for example by a public health agency in another country, will be made by national data access bodies, who will also work together at a European level. When countries contribute aggregate or anonymised data for wider reuse, they should be able to rely upon these bodies (who will be acting according to the EHDS Regulation) to govern data access across Member States by different (public and private) data user organisations.

For primary use purposes, at individual level for continuity of care, one advantage with launching the EHDS with immunisation data is that it

involves nearly every citizen. There is also now some public familiarity with sharing immunisation status, through the EU Digital COVID Certificates which are shown to many different organisations and personnel. Also, the EU Digital COVID Certificates have provided demonstrable benefits to citizens such as travel and entry to various facilities.

The Round Table suggested that priority vaccines to include should be in the following order (although this could vary between countries):

- **HPV**
- **Meningococcal/Pneumococcal**
- **Measles**
- **Flu**
- **Hepatitis**

In August 2022 and after this Round Table was held the European Commission published a Study called [“Provision of options and recommendations for an EU citizen’s vaccination card”](#). The Study is focused on Citizen’s Vaccination Cards not immunisation information systems which is the subject of this Round Table report. The proposal for a EU citizens vaccination card is a reasonable development building on the EU Digital COVID certificate.

Glossary

API	Application Programme Interface
DHS	The Digital Health Society
EC	European Commission
ECDC	The European Centre for Disease Prevention and Control
EHDS	The European Health Data Space
EVR	Electronic Vaccination Registries
EU	European Union
HCP	Health Care Professional
HL7	Health Level 7 refers to a set of international standards for the transfer of health and administrative data.
HPV	Human Papillomavirus Infection
I~HD	The European Institute for Innovation through Health Data
Immunisation	* A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation
Immunity	* Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.
IPS	International Patient Summary
OpenSky	OpenSky Data Systems
SDO	Standard Development Organisations
Vaccination	* The act of introducing a vaccine into the body to produce protection from a specific disease
Vaccine	* A preparation that is used to stimulate the body's immune response against diseases
Vaccines	* A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.
WHO	World Health Organisation

* Centres for Disease Control and Prevention definitions

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ON HEALTH DATA ECOSYSTEMS

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