

Digital Health Society Summit 5th October 2022

Immunisation Information Systems: Making interoperable data systems for vaccination a reality in Europe building on COVID experience – Round Table 5

Panel Signposting

- Introduction to the Panel & Calls to Action
- Open Sky Data Systems Presentation: State of the Art in Electronic Vaccination Registries in Europe & UK
- Summary of the Recommendations of Round Table 5
- Observations from Cristinela Velicu & William Flanagan
- Panel Discussion and Q&A



Calls to Action on Health Data Ecosystems

RECOMMENDATIONS FROM
MULTI-STAKEHOLDER ROUND TABLES

Multi-stakeholder consensus recommendations

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 big health data opportunity

- Growing need for large scale access to health data
 - from conventional healthcare sources (e.g. detailed EHRs), patient and citizen generated, medical devices and non-health sources such as pollution
 - for this to be fine grained, individual level (not only aggregated), close to real time
 - for this to be longitudinal, reflecting health, wellness, disease trajectories and outcomes
- Growth of large scale data resources that offer these opportunities
 - a mixture of regional, national and EU data initiatives
 - a mixture of eHealth services and research infrastructures
 - a mixture of centralised and federated architectures

Need for alignment

- The growing European data infrastructures are set up quite differently
 - different kinds of data offerings
 - adopting different data standards
 - different permitted uses and users
 - different access terms
 - different approaches to GDPR compliance
- Europe is revealing variable interpretations of GDPR compliance when it comes to health data use and reuse e.g. legal basis, pseudonymisation safeguards
- COVID-19 has highlighted the value of sharing intelligence across countries, but introduced approaches that might only be temporarily acceptable e.g. location tracking
- Multiple public attitude surveys are generating mixed messages (not all surveys are framed well), perhaps confusing public opinion, and with mixed findings

The catalysts for alignment

- Four valuable European levers for alignment
 - The GDPR (General Data Protection Regulation)
 - The EEHRxF (European Electronic Health Record Format)
 - The Pandemic
 - Research competitiveness
- A new focal point for that alignment: the European Health Data Space (EHDS)
 - an opportunity to inform the design and governance of the EHDS
 - an opportunity to use the EHDS as a catalyst
- Increasing awareness amongst stakeholders that they need to collaborate

Our stakeholder engagements

- Four Round Tables, held in 2020 & 2021
 - Round Table 1 Acceptance criteria for societal trust in the use of health data
 - Round Table 2 A recipe for trustworthy digital health: standards, architecture and value
 - Round Table 3 Proposing a common basis for health data across Europe
 - Round Table 4 Scaling up the availability and reusability of big health data
- Developed and run by DHS and i~HD - neutral and independent
- Sponsored by Johnson & Johnson, Microsoft & MSD
- Each Round Table was attended by between 20 and 35 invited participants from industry, academia, health systems, healthcare professionals, patient representatives and regulators
- 3 new Round Tables in 2022 including RT 5 on Immunisation Information Systems

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Round Table 5 Recommendations

Nine Recommendations were made:

1. Immunisation should be a focus for the European Commission One Health mission, which will require that many of the prerequisites and success factors (core data set, interoperability, data quality etc.) detailed earlier in this report will need to be addressed.

This was the top priority over-arching recommendation from the Round Table.

Round Table 5 Other High Priority Recommendations

2. 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.

3. 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).

Round Table 5 Other High Priority Recommendations

4. 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.
5. 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.

Round Table 5 Other Important Recommendations

6. 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 European Health Data Space
7. 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.
8. 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.
9. 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 needed to implement the recommendations

The Round Table participants recognised that the recommendations 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
- European Centre for Disease Prevention and control
- European Commission
- Patient, civil society & HCP organisations
- Healthcare Semantic experts

Key Success Factors

A total of twelve success factors were identified and the four most strongly endorsed were:

- 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.

Observations from Cristinela Velicu MSD

Observations from William Flanagan (OpenSky Data Systems)



Panel Discussion and Q&A

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