Immunisation Information Systems at the cornerstone of improved vaccination policies in a digital Europe

Vaccination is one of the most cost-effective public health interventions ever implemented, significantly decreasing the incidence of numerous deadly diseases and associated mortality. However, it still doesn't reach its full potential. Europe is facing an increased burden or resurgence of vaccine-preventable infectious diseases, especially measles and influenza, creating a real and potentially severe public health risk for European citizens and for people traveling to/from Europe.

In a time where Europe is facing mobility of citizens, vaccination policies need to utilize technological advancements to increased access to records within Member States and across Europe. Health systems are (slowly) moving towards e-Health, (i.e. tools and services using information and communication technologies). The increasing digitalisation will allow for improved prevention, diagnosis, treatment, monitoring and management of health and wellbeing[1].

Immunisation Information Systems (IIS) have been acknowledged since 2014 as an 'integral part of well-functioning health systems'[2,3,4]. IIS will directly contribute to the three priorities for EU actions identified in the Digital Single Market (DSM):

1. Enable citizen's secure access to and use of health data across-borders
2. Support a cross-border data infrastructure to advance research and personalised medicine
3. Facilitate feedback and interaction between patients and health care providers, supporting citizen empowerment[5].

As currently defined, a IIS is a confidential, population-based, computerized database that records all immunisation doses administered by participating providers to citizens living in a given geopolitical area. Using this data, IIS could help close the gaps in immunisation coverage at all ages in life, by facilitating (1) clinical decision support, (2) patient engagement & citizen empowerment, (3) vaccination coverage assessment, (4) outbreak control & emergency preparedness, (5) vaccine safety and effectiveness assessment.

IIS connected with enhanced surveillance networks on infectious disease epidemiology, will allow tracking of the real-life impact of vaccination on disease burdens and will also flag trends in Vaccine Preventable Disease (VPD) evolution. Availability of these data is critical for continuous and reliable assessments to support the implementation and/or adaptation of National immunisation strategies and programmes across Europe in order to better protect all citizens.

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[1] European Commission (2017). *eHealth.* Available at:
https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/2017/05/30/eHealth (Accessed: 14th December 2017)
[2] WHO (2014) *European Vaccine Action Plan 2015-2020.* Available at: http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/2014/european-vaccine-action-plan-20152020-2014 (Accessed: 3rd December 2017)
[3] Council of the European Union (2011). *Council conclusions on Childhood immunisation: successes and challenges of European childhood immunisation and the way forward.* Available at:
http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/122391.pdf (Accessed: 10th December 2017)
[4] Council of the European Union (2014). *Council conclusions on vaccinations as an effective tool in public health*.
Available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145973.pdf (Accessed: 15th December 2017)
[5] Council of the European Union (2017) *Draft Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health*. Available at: http://data.consilium.europa.eu/doc/document/ST-14078-2017-INIT/en/pdf (Accessed: 5th January 2018

IIS Capabilities

As part of the implementation of the Council of the European Union Conclusions on vaccination from both 2011 and 2014 and the World Health Organisation's European Vaccine Action Plan 2015–2020, IIS are currently being operated, updated or piloted by some Member States across Europe at a national and/or sub-national level, while several European countries still do not have any IIS at all (See Table 1 in appendix). The European Centre for Disease Prevention and Control (ECDC) published an extensive report based on a survey performed in EU Member States showing that systems differ in their scope, definition and use of outputs[6] (Appendix: Table 1).

Well-designed IIS can deliver a range of benefits to healthcare systems, healthcare providers and to the populations they serve:

At the point of clinical care, IIS can support practitioners to identify patients at high risk for VPD, ensure appropriate individual vaccination, and adhere to applicable recommendations. With frequent changes in immunisation schedules and scattered immunisation records across multiple providers, assessing the need for immunisation at the provider level has become increasingly difficult. By compiling individual immunisation records into a single source, IIS supports the clear definition of corresponding dose to age, background, and immunisation schedule.

At a programme level, IIS can help monitor vaccination coverage rates, forecast and purchase vaccines and monitor supply, target interventions and resources efficiently and create life-long immunisation registers. By providing timely access to data on the effectiveness of vaccines programmes (level of VCR), IIS can inform on the need to run proactive immunisation campaigns.

At population level, IIS can provide aggregate data on vaccinations to:

- Support disease surveillance
- Inform immunisation programme operations
- Assess safety and effectiveness of vaccines
- Increase our understanding of vaccine hesitancy
- Provide evidence to guide public health policy[7]

IIS have the capability to promote patient engagement and citizen empowerment through the use of automotive reminders, provider assessments, and online access to official immunisation records. By providing vaccine recipients with a level of ownership over their records and health care decision-making, adherence to the National Immunisation Programmes can be positively influenced. Such systems can also be used as educational tools by incorporating easily accessible platforms that provide clear information and visualization of data (e.g. dashboards).

Citizen's right to have access to their own health data should be a core principle of IIS. From a citizen perspective, IIS should represent the electronic version of the paper booklet, providing information and rationale for being vaccinated, and a reminder system and opportunity to record adverse reaction to feed into the pharmacovigilance system.

IIS designed in such a way would contribute to increased health literacy on immunisation, reduce vaccine hesitancy, and increased adherence to immunisation programmes. By ensuring better adherence to immunisation programmes, IIS should contribute to more efficient use of healthcare resources and better targeted more integrated and safer healthcare. Information sharing between healthcare professionals leads to improved patient's safety, reduced number of avoidable vaccine preventable diseases and better adherence of patients with underlying diseases.

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[6] ECDC (2017). *Immunisation information systems in the EU and EEA.* (Available at:
https://ecdc.europa.eu/sites/portal/files/documents/immunisation-systems.pdf (Accessed: 12th December 2017)
[7] Peabody, R. (2012) Vaccine registers – experiences from Europe and elsewhere. *Eurosurveillance.* Vol 17 (17): 1.
Available at: http://www.eurosurveillance.org/content/10.2807/ese.17.17.20159-en (Accessed: 20th December 2017).

Current challenges with IIS and proposed way forward

Despite progress in the European region, significant challenges persist, which impede the potential of IIS to improve performance of vaccination programmes. These include:

- The wide variety and fragmentation of IIS at a national and sub-national level, and even at an institutional level
- A lack of consistency in data collection and data entry standards across IIS
- The inability for seamless interface (interoperability) between different IIS, at both an individual and population level
- A lack of technical capabilities and resources within public institutions to design, develop and implement IIS
- Concerns about data protection and privacy when collecting and combining data from different systems.

Vaccines Europe supports the ECDC's view, which provides considerations for ensuring IIS are valuable and useful tools, including:

- Having reliable and complete information on the denominator population (e.g. linking to birth registries)
- Using unique individual identifiers
- Ensuring reliable data on vaccines by limiting manual entry
- Increasing interoperability with other health databases (e.g. on health outcomes) to enable studies on vaccinations in areas such as effectiveness and safety

Important features of IIS should also include the ability to:

- Provide outputs for immunisation program managers such as reminders and recording of adverse events following immunisation
- Record adverse events following immunisation
- Identify individuals during an outbreak
- Record reasons for vaccine refusal

In addition to considerations identified by the ECDC, Vaccines Europe recommends, as a minimum, that IIS also:

- Cover the entire population of each country across the life span
- Incorporate disease surveillance
- Are populated with data from all vaccine providers – both public and private
- Provide information on all recommended vaccinations administered by health authorities regardless of funding (e.g. including travel vaccinations which are often out of pocket, or for private purchase only).

Vaccines Europe proposals:

- **IIS can track VPD burden, vaccine effectiveness and safety data**. Strengthen Member States' infrastructure for data collection to track infectious disease patterns and the real-life impact of vaccines (effectiveness and safety) to support the delivery of immunisation programmes across an individual's life span. Data collection at Member State level could be coordinated by the ECDC who should play a more active role in providing guidelines to Member States to ensure consistent data collection to inform future national immunisation policies.
- **IIS are digital to improve management, delivery and surveillance.** Establish/Strengthen vaccine electronic registries that can be used both as a management tool to deliver Member States' immunisation programmes (e.g. using electronic reminders), and for surveillance purposes to monitor national immunisation programmes.

Data from such systems can guide public health action and enable national authorities to enhance targeted communication efforts with the public if data show relatively low vaccine coverage and uptake[8].

- **IIS allow for EU vaccine-related research project implementation**. Provide inputs to the Digital Market Strategy by promoting public-private partnerships that could help fostering the roll out of targeted IIS. For example, Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)[9], IMI project that ends in September 2018, establishes a framework capable of rapidly delivering reliable data on the benefits and risks of vaccines that are on the market. Such framework could contribute to the basis of a well-designed IIS to help both regulators and public health authorities to make decisions on vaccination strategies, and help maintain public confidence in immunisation as an effective public health tool to control infectious diseases.

- **IIS should be harmonised / standardized across Europe.** Recommend that the European Commission, through the DSM strategy, empower the ECDC to lead the harmonised advancement of IIS in Europe, starting with the development and dissemination of minimal functional requirements, standardised terminology, and minimal datasets and uniform standards, leveraging lessons learnt from countries having/piloting IIS. This could be enhanced with the implementation of the Falsified Medicines Directive by linking the 2D bar code with patients' adherence programmes.

- **IIS should benefit from the implementation of the Falsified Medicines Directive by linking the 2D bar code with patients' adherence programmes**. Vaccines Europe members look forward to being engaged in the work of the ECDC and actively contributing to information technology and data management, knowledge and expertise. In particular, a consultation on system design should include industry to guarantee that the use of 2D bar code information could be used to automate data entry in IIS.

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[8] ECDC (2017). *Immunisation information systems in the EU and EEA.* (Available at: https://ecdc.europa.eu/sites/portal/files/documents/immunisation-systems.pdf (Accessed: 12th December 2017)
[9] IMI (2017). *Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE).* Available at: http://www.imi.europa.eu/projects-results/project-factsheets/advance (Accessed: 13th December 2017)

APPENDIX

Many countries in Europe have advanced IIS that have been in place for many years, whilst others are in the planning stages. There are also a number of countries that are currently reviewing and/or updating their systems. A substantial number of countries operate more than one sub-national system.

Innovative IIS, such as "mesVaccins.net" in France[10], which enable citizen empowerment and access to personalised recommendation for vaccination, should be favoured as a new way to prevent vaccine hesitancy at a large scale and thereby increase vaccination uptake.

Good practice sharing should be performed between EU Member States with existing systems to align their technology and services to the citizen and healthcare professionals and also in order to avoid further fragmentation of healthcare systems in Europe.

For the countries that have already invested in specific technologies, past investment should be protected and existing IIS should be upgraded to offer services allowed by the new technologies (IT, Digital, etc.).

Table 1 summarises the current state of IIS across Europe.

Table 1 (ECDC, 2017)

Countries with an IIS	Counties piloting an IIS	Countries with no IIS
Denmark, Finland, Iceland, Malta, the Netherlands, Norway, Romania and Ireland as per the US CDC definition	Greece, Hungary, Latvia and Slovakia are piloting a national system	Croatia, Cyprus, Czech Republic, Estonia, Luxembourg and Slovenia
Germany and Sweden have an IIS that does not fully meet the US CDC definition; their systems have no ability to consolidate immunisation histories for use at points of clinical care and only provided aggregated population level data		
Five countries have more than one subnational IIS: Austria, Belgium, Portugal, Spain and UK; the systems in Belgium, Portugal and Spain fulfil the US CDC definition, as do parts of the UK system	France is piloting subnational systems; Bulgaria is piloting one subnational system	

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[10] www.Mesvaccins.net (Accessed: 21st December 2017).