TECHNICAL REPORT

Immunisation information systems in the EU and EEA

Results of a survey on implementation and system characteristics

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This report was commissioned by the European Centre for Disease Prevention and Control (ECDC) and coordinated by Tarik Derrough.

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Abbreviations

AEFI	Adverse Events Following Immunisation
AIRA	American Immunization Register Association
CHIS	Child health information system
IIS	Immunisation information system
IT	Information technology
EEA	European Economic Area
EU	European Union
HPV	Human papillomavirus
VPD	Vaccine-preventable diseases
NFP	National Focal Points
NUTS	Nomenclature of Territorial Units for Statistics
US CDC	US Centers for Disease Prevention and Control

Country codes

AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czech Republic
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
GR	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

Executive summary

Background

Immunisation information systems (IIS) are defined as confidential, population-based, computerised databases that record all immunisation doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, they support practitioner decision-making in ensuring appropriate individual vaccination and adherence to applicable policies. At population level, IIS provide aggregate data on vaccinations for use in surveillance and programme operations, and in guiding public health action to improve vaccination rates and reduce vaccine-preventable diseases [1].

The European Council conclusions on vaccinations from both 2011 and 2014 recommend the adoption of such systems and the World Health Organization's European Vaccine Action Plan 2015–2020 recognises IIS as 'an integral part of well-functioning health systems´[2-4]. IIS have the potential to improve performance of vaccination programmes and to increase vaccine uptake, but the design, development and implementation of such systems can be challenging for national programme managers. The European Centre for Disease Prevention and Control (ECDC) is currently running activities to support the Member States in establishing IIS. One important initial activity was to gather information about the implementation level and the functionalities of existing immunisation information systems in European Union/European Economic Area (EU/EEA) countries. To do this, ECDC, in close collaboration with subject-matter experts, developed surveys on IIS status and functionalities in EU/EEA countries.

Methods

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

Results

The country response to both surveys was 90% (27/30 EU/EEA countries). Among the responders there were two countries that did not respond to either of the two surveys but answered the set of five basic questions. Out of the 27 countries that completed the surveys or answered the brief questions, 52% (14/27) of countries had a national system in place or were piloting a national system, 26% (7/27) had a subnational system(s) in place or were piloting one, whereas 22% (6/27) had no IIS currently in operation. The different sections of the more comprehensive survey that explored the functionalities of the IIS were analysed for each country.

Conclusions and next steps

The surveys provide information on the status of IIS implementation in EU/EEA countries and a detailed examination of how the systems have been set up and how the different systems function. The more comprehensive survey explored similarities between the various existing IISs and the challenges the countries faced during the development and early use of the IIS. Many countries have quite advanced systems that have been functioning for many years, whilst others are in the planning stages. There are a number of countries that are updating their current systems. To ensure that an IIS is a valuable and useful tool for monitoring immunisation programmes there are a number of important system characteristics to consider. These include having reliable and complete information on the denominator population, 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. Other important features include

providing outputs for immunisation programme managers such as reminders, recording of adverse events following immunisation, identifying individuals during an outbreak and being able to record reasons for refusal.

The detailed information included in this survey report is especially important for those countries who have no system, who are in the initial stages of implementation or are updating their systems. The survey results can potentially help to build minimal functional requirements for an IIS and can be used to guide standardised terminology, a minimal dataset and uniform standards for an IIS.

1. Background

In May 2016, the vaccine-preventable diseases programme (VPD) at the European Centre for Disease Prevention and Control (ECDC) launched a cross-sectional web-based survey evaluating the level of implementation of immunisation information systems (IIS) in the European Union/European Economic Area (EU/EEA) Member States and the main features of such systems.

Immunisation information systems (IIS) are defined as confidential, population-based, computerised databases that record all immunisation doses administered by participating providers to persons residing within a given geopolitical area [1]. At the point of clinical care, they support practitioner decision-making in ensuring appropriate individual vaccination and adherence to applicable policies. At population level, IIS provide aggregate data on vaccinations for use in surveillance and programme operations, and in guiding public health action to improve vaccination rates and reduce VPDs.

Following the introduction of a vaccine, its uptake and benefit-risk profile requires continuous assessment in order to monitor the performance of vaccination programmes [5,6] and to respond to national and international public health monitoring requirements (e.g. reporting on vaccination coverage, responding to vaccine post-licensure requirements, investigation of safety signals). One of the key performance indicators of a well-functioning immunisation programme is vaccination coverage – the proportion of the population eligible for vaccination that has been immunised. It is an indirect measurement of population immunity and determines the level of herd protection against VPDs. Historically, coverage assessment in EU Member States has been performed through regular surveys (e.g. telephone-based, at school-entry), review of claims and social security databases or analysis of data from paper-based registries [7-13]. IIS can be a key tool for monitoring vaccination coverage. They can also facilitate evaluation of the safety and effectiveness of vaccines by linking individual vaccination data with other records on health outcomes [14-17]. The functionalities of such systems, including electronic patient records in the framework of e-Health initiatives, are developing rapidly and they should be able to provide useful information to public health authorities, vaccine providers and vaccine recipients.

For an IIS to fully support vaccination programmes, there are various features that are considered important:

- Complete and accurate denominator populations from different sources.
- Secure vaccine recipient and record identification through uniform unique identifiers (UID).
- Complete, timely and correct vaccination records with real-time electronic access to the IIS.
- Recording of vaccinations given to the recipient and vaccine details (batch and vial ID etc.) facilitated by pre-entered information, selection menus and reading of barcodes.
- Production of automated outputs.
- The facility to offer services that are useful to all parties including vaccine recipients, parents and vaccine providers. For example, recall functions, trusted medical information, and the possibility for parents and vaccine recipients to request certified records of immunisation history.

The European Council conclusions on childhood immunisation in 2011 and on vaccinations as an effective tool in public health in 2014 both recommend the adoption of such systems and the World Health Organisation European Vaccine Action Plan 2015–2020 recognises IIS as 'an integral part of well-functioning health systems' [2-4].

This report presents the findings of a survey conducted by ECDC across EU/EEA countries that assessed the level of implementation of IIS and their functionalities, as well as the challenges encountered during the design and implementation. The aim of the survey was to share knowledge about IIS in the EU/EEA in order to build consensus on the characteristics of an optimal system and to describe differences in core functionalities and standards across countries.

2. Materials and methods

2.1. Survey population

In May 2016, 28 EU countries plus two EEA countries (Norway and Iceland) were invited to participate in the survey. Respondents were identified through the ECDC National Focal Points (NFPs) for VPD.

2.2. Survey development

Following a review of the literature, two surveys were developed in consultation with subject-matter experts [18,19]. The first, more comprehensive survey which included 100 questions, targeted countries with an IIS in operation or being piloted (see Appendix 1). The second, briefer survey with nine questions, targeted countries with no IIS or those at a very early stage of IIS implementation (see Appendix 2). Respondents decided on the survey they would like to answer based on their national or subnational situation regarding IIS implementation status. The surveys were then piloted for feasibility and clarity with subject-matter experts in the field of IIS. Those countries that could not complete either of the two surveys were asked to complete a basic set of five questions.

2.3. Survey tool

EU Survey [20], the online survey tool, was used to administer the surveys. The comprehensive survey was divided into 11 sections and included 53 multiple-choice and 47 open-ended questions. The majority of multiple-choice questions had either 'yes' or 'no' options with only one answer permitted. There were a certain number of multiple-choice questions that allowed for more than one answer and several questions were followed by the box 'If other, please specify'.

The United States Centers for Disease Prevention and Control (US CDC) definition of an IIS was used as a reference in this survey [1]:

> *IIS are confidential, population-based, computerized databases that record all immunisation doses administered by participating providers to persons residing within a given geopolitical area.*
>
> - *At the point of clinical care, an IIS can provide consolidated immunisation histories for use by a vaccination provider in determining appropriate client vaccinations.*
> - *At the population level, an IIS provides aggregated data on vaccinations for use in surveillance and programme operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable diseases.*

Comprehensive survey

Each section of the comprehensive survey covered a specific area of the IIS, as outlined below:

Section one – Background information

Respondents were asked to provide their contact information and country details.

Section two – General information

This section explored the current status of IIS implementation. Respondents were asked to specify if the IIS was currently operating or being piloted, and if it was a national, subnational or a multiple subnational system. If more than one subnational IIS was currently operating in a country, the answers relating to the IIS that covered the largest population were reported. Those countries with subnational systems were asked to specify if the systems have similar or different structures and if the systems can share information. The respondents were asked about the size of the population living in the covered areas and to specify which geographical areas are covered using the nomenclature of territorial units for statistics (NUTS) [21] classification. Furthermore, the eHealth strategy of the country and whether the IIS was outlined in this strategy, was questioned.

Section three – Description of the IIS

This section looked at the national IIS or, in case of more than one subnational system, the largest population covered by the IIS. Respondents were asked about the IIS name; which year it was established; if the US CDC IIS definition is used to describe the IIS established in the country; which institution held the governance; the financial resources and if there were any regulations in place for the recording of private or public vaccinations.

Section four – Characteristics of the system

In this section respondents were asked details about the population covered by the IIS and how individuals included in the register were identified. There were questions about the methods used for vaccine identification in the IIS, the minimal data set required and if historical vaccination data or vaccines administered in foreign countries could be entered in the IIS.

Section five – Technical aspects of IIS

Section five looked at the various technical issues related to the information technology (IT) solution used for IIS.

Section six – Input, access and linkage

This section explored the type of information that was fed into the IIS, how a record was set up and if consent was required. The respondents were asked about access rights for different 'actors' within the IIS and about data validation and time between vaccination and data input. This section also explored in detail which links were established between the IIS and other registries, including civil registries and other health-related registries.

Section seven – Outputs

This section looked at the outputs generated from the IIS such as the ability to obtain an individual immunisation history, the smallest administrative area that aggregated vaccination uptake could be computed on, and a question about the sources of denominator data that were used for the IIS.

Section eight – Planning of immunisation activities

In this section respondents were asked about the ways that the IIS is used in planning immunisation activities. The questions explored whether systems automatically send out reminders to vaccine recipients, if the IIS is able to identify unvaccinated individuals in an outbreak and if the IIS can record reasons for refusal or hesitancy.

Section nine – Support to the immunisation programme

In section nine the survey explored how the system is used to support the management of the vaccination programme, such as the ability for the IIS to record adverse events following immunisation (AEFI) and which organisations have the authority to use IIS data for research.

Section ten – Challenges and barriers

In this section respondents were asked to specify the challenges and barriers faced at various stages of the implementation of the IIS.

Section eleven – Comments

The final section asked respondents if there was any area related to IIS where ECDC could potentially provide technical guidance. Respondents were also asked to provide any further comments or information such as websites or articles relating to IIS in their country.

Brief survey

The brief survey was divided into three sections with a total of nine questions (three multiple-choice and six open-ended questions). The multiple choice questions had either 'yes' or 'no' options with only one answer permitted.

Each section covered a specific area of the IIS, as explained below:

Section one – Background information

Respondents were asked to provide their contact information and country.

Section two – General information

This section explored the current status of IIS implementation. Respondents were asked to specify if an IIS was currently operating or being piloted, or if there was no IIS at this time. There was a question about the eHealth strategy in the country and if the IIS was outlined in this strategy.

Section three – Barriers and plans for the future

In this section, respondents were asked to outline the challenges and barriers faced in planning or trying to implement an IIS. Respondents were asked if there was a plan to develop an IIS in the next five years and how ECDC could provide technical support with IIS implementation in the country.

2.4. Data collection and validation process

Each participant was sent an email explaining the aim of the survey, the invitation to complete it and information on the ECDC contact point. The survey opened on 1 May 2016 and closed on 20 May 2016. The survey could be revisited several times before being submitted. There was no automatic reminder system, but each late responder was contacted personally by email from ECDC.

In August 2016, as part of the validating process, a preliminary survey report, that included a summary of results and analysis, was sent to the nominee from each country. Each was offered the opportunity to check and validate the survey analysis and report back with comments or corrections. In October 2016, the draft survey report was then sent to VPD NFPs asking them to review the report and validate the results.

2.5. Data analysis

The data were analysed using MS Excel software. Frequencies of all variables were produced.

3. Results

3.1. Participation in the different surveys and response rate

In May 2016, the 28 EU countries plus two EEA countries (Norway and Iceland) were invited to participate in the survey. Respondents were identified through the VPD NFPs. Out of those 30 countries, ECDC received 26 nominations from the NFPs naming a respondent to answer the survey.

For those countries that could not complete the survey, a basic set of five questions related to the status of IIS implementation in their country was disseminated after the May 2016 deadline.

Information was received from 27 countries out of the 30 contacted, with a response rate of 90%. Out of the 27, 16 countries answered the full comprehensive survey, nine countries answered the brief survey and two countries (Luxembourg and Slovakia) replied to the basic set of five questions and not to either of the two surveys.

For Belgium, Portugal, Spain and the United Kingdom, the survey describes the systems in operation in Flanders, mainland Portugal, Andalusia and England, respectively.

There was no response to either of the two surveys or the basic set of five questions from three countries: Italy, Lithuania and Poland.

The list of responding institutions and which survey they completed is shown in Table 1. The respondents were staff from public institutions at national or subnational level with responsibility for the national vaccination programme or IIS managers.

Table 1. Institutions in EU/EEA countries that participated in ECDC surveys on IIS implementation, 2016 (n = 27 countries/institutions)

	Countries with respective institutions responding to the comprehensive survey (n=16)
Belgium	Ministry of Social Affairs, Pubic Health and Environment, Scientific Institute for Public Health
Denmark	Statens Serum Institut, Department of Epidemiology Research
Finland	National Institute for Health and Welfare, Department of Vaccination and Immune Protection
Germany	Robert Koch Institute, Infectious Disease Epidemiology
Hungary	National Center for Epidemiology, Department of Communicable Diseases Epidemiology
Iceland	Centre for Health Security and Communicable Disease Control, Directorate of Health
Ireland	National Immunisation Office, National Immunisation and Child Health Information System
Latvia	Centre for Disease Prevention and Control, Infectious Diseases Risk Analysis and Prevention Department
Malta	Ministry for Health, Department for Health Regulation – Health Promotion and Disease Prevention
Netherlands	National Institute for Public Health and the Environment, Centre for Infectious Disease Control
Norway	Public Health Institute, Norwegian Immunisation Registry
Portugal	Department of Disease prevention and Health Promotion, Directorate General for Health
Romania	National Institute of Public Health, National Centre for Communicable Diseases Surveillance and Control
Spain	Ministry of Health, Social Services and Equality, Immunisation Programme
Sweden	Public Health Agency, Unit for Vaccination Programs
UK	Public Health England, Department of Immunisation, Hepatitis & Blood Safety
	Countries with respective institutions responding to the brief survey (n=9)
Austria	Austrian Federal Ministry of Health, Vaccines Department
Bulgaria	Ministry of Health, National Centre of Infectious and Parasitic Diseases
Croatia	Croatian Institute of Public Health, Immunisation Department
Cyprus	Cyprus Ministry of Health, Directorate of Medical and Public Health Services
Czech Republic	National Institute of Public Health, Department of Infectious Disease Epidemiology
Estonia	Public Health Administration, Health Protection Inspectorate
France	French National Public Health Agency, Institute for Public Health Surveillance
Greece	Hellenic Centre for Disease Control and Prevention, Department for Surveillance and Intervention
Slovenia	National Institute of Public Health, Centre for Communicable Diseases
	Countries with respective institutions responding to the basic set of five questions after the survey deadline (n=2)
Luxembourg	Ministry of Health, Directorate of Health
Slovakia	Public Health Authority, Department of Epidemiology

3.2. Implementation status

The status of implementation of IIS in the 27 countries is as follows (Figure 1):

Countries with IIS in place

- Eight countries have a national system currently operating that meets the US CDC definition of an IIS: Denmark, Finland, Iceland, Malta, the Netherlands, Norway, Romania and Ireland. In Finland the IIS includes more features than specified in the US CDC definition of an IIS.
- Two countries (Germany and Sweden) have national systems in place that do not fully meet the US CDC definition of an IIS. Their systems have no ability to consolidate immunisation histories for use at point of clinical care and only provide aggregated data on vaccinations at population level.
- Five countries have more than one subnational IIS: Austria (number not specified), Belgium (Flanders, covering parts of Brussels, and the Walloon region also covering parts of Brussels), Portugal (mainland and Madeira), Spain (Andalusia, Balearic Islands, Catalonia, Valencia region, Castilla-León, Galicia, Madrid region and Murcia region) and the United Kingdom (England, Northern Ireland, Scotland and Wales). For Belgium, Portugal, Spain and the United Kingdom, the survey describes the systems in operation in Flanders, mainland Portugal, Andalusia and England respectively. The systems in Belgium, Portugal and Spain fulfil the criteria of the US CDC IIS definition. In the UK some of the subnational systems meet the US CDC definition of an IIS system while others do not. This information was not available for Austria as they completed the short version of the survey where this question was not included.

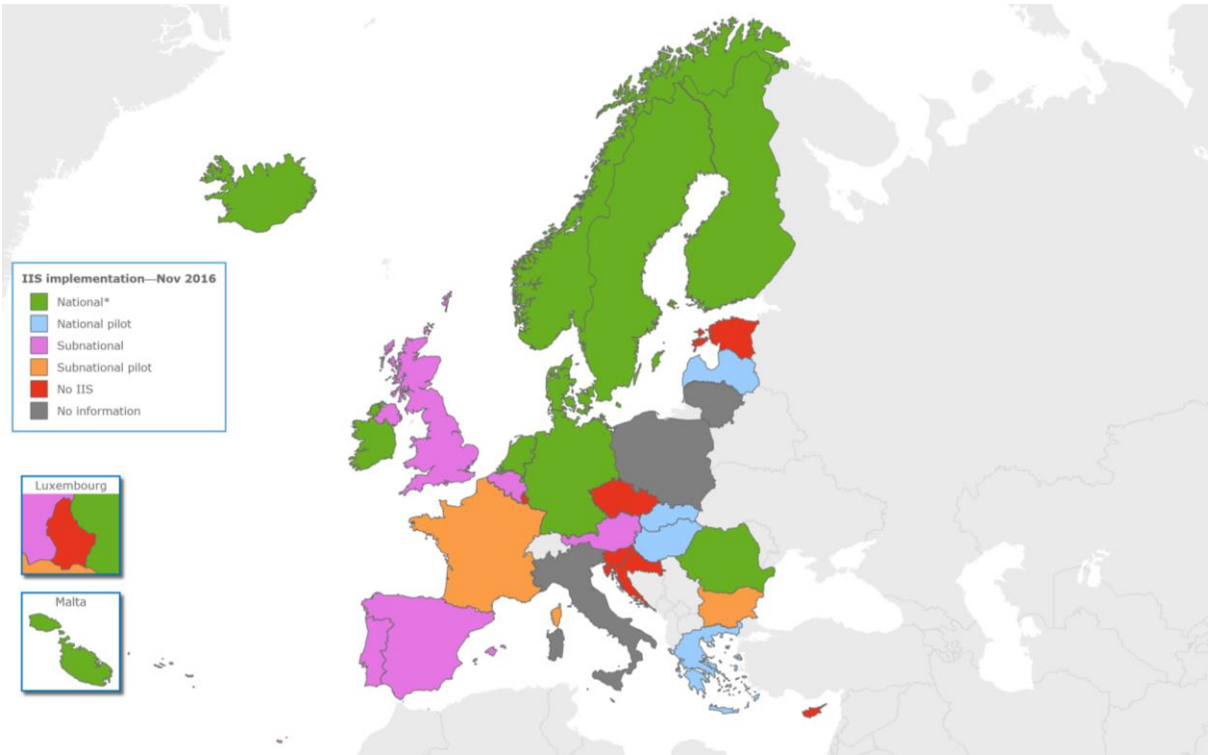
Countries piloting IIS

- Four countries, Greece, Hungary, Latvia and Slovakia are piloting a national system. Latvia had planned to pilot its system in 2017.
- France is piloting more than one subnational IIS.
- Bulgaria is piloting one subnational IIS.
- Among the countries piloting an IIS, whether at sub-national or national level, how the IIS was defined was only provided by Hungary and Latvia, as these two countries participated in the comprehensive survey. Both countries had an IIS fitting the US CDC IIS definition.

Countries with no IIS

- Six countries have no IIS in operation or being piloted: Croatia, Cyprus, Czech Republic, Estonia, Luxembourg and Slovenia.

Figure 1. Status of implementation of Immunisation Information Systems in EU/EEA countries, 2016 (n = 27)



** Germany and Sweden have national systems that do not have the ability to consolidate immunisation histories for use at point of clinical care. Their systems only provide aggregated data on vaccinations at population level.*

Additional comments from respondents that enable a better understanding of the IIS in countries with a national system are as follows:

- Finland: IIS covers the national immunisation programme provided through the public health service.
- Ireland: has a national school IIS and eight individual primary childhood IIS at local level. A project has been initiated to implement a combined National Immunisation and Child Health Information System (CHIS) which will replace the existing separate child health systems. It is intended that the new system will link to other relevant health information systems to facilitate appropriate levels of information sharing. There is currently no interoperability between the current individual primary childhood systems. The new system will essentially be a module of the planned national electronic health register. Work is currently taking place to define the system requirements.
- The Netherlands: IIS is also used for the registration and invitation for the heel-prick test for newborns and antenatal blood test in pregnancy (for HIV, hepatitis B, Rh blood group and syphilis).
- Romania: has national IIS that has been operational since 2011. The system has been improved annually and at present there are plans to pilot a new improved version in 2017. There are some electronic health systems in place, however these systems are not yet correlated.

Additional comments from respondents that enable a better understanding of the IIS in countries that are piloting a national system are as follows:

- Greece: is preparing to set up a national health system creating an electronic immunisation record for every child. Currently there is only electronic prescription of vaccines for children who have been vaccinated.
- Latvia: has a national IIS that is currently under development and testing. The piloting phase is planned for 2017. Replies to the survey apply to the system that is being developed and tested.
- Slovakia: has an eHealth project in place with a goal of creating the national health information system to incorporate electronic data about the vaccination status of patients. This project is currently being piloted nationally and is divided into several phases that will be initiated over the coming years.

Additional comments from respondents that enable a better understanding of the IIS in countries with subnational systems:

- Belgium: has two systems in place - one in Flanders (with the system also covering parts of Brussels): Vaccinnet and one in the Walloon Region (with the system also covering parts of Brussels): e-Vax. The IIS covering the highest population is in Flanders (approximately seven million people of all ages). The structure of the two systems are identical and, although there is no exchange of data, they are completely compatible. In the future, exchange of data between the databases is foreseen with the use of hubs (common data source).
- Portugal: has two systems in place - one on the mainland covering 9.5 million people and one on Madeira (autonomous region) covering 267 000. A new IIS is being piloted on mainland Portugal and it will have all the features (and more) of the one that is currently in place.
- Spain: has at least eight systems currently operating. The IIS that covers the largest population is in Andalusia and is at regional and local levels.
- United Kingdom: England is the largest of four countries in the UK, the other three countries (Scotland, Wales and Northern Ireland) have their own national CHIS in operation which are not covered in this survey. England has five main suppliers of CHIS with just under 150 local databases which record vaccination status at a local level. This heterogeneity and the decentralisation make it difficult to develop a national register. There is a new system in place called the Children and Young People Health Services Data Set [22] that aims to create a national, individual level register which is starting to be populated, but currently is not in use.

In relation to interoperability between the subnational systems, Belgium and the United Kingdom (England) both have subnational IIS that have the ability to share data. However, this varies between systems in the United Kingdom (England), with some having electronic interoperability and others only allowing for manual data sharing. In Portugal (mainland) and Spain (Andalusia), systems have different structures, characteristics or data elements and data sharing between the systems is not possible.

Additional comments from respondents that enable a better understanding of the IIS in countries piloting subnational systems:

- Bulgaria: since November 2014, Bulgaria has engaged the Project Grant Contract under the Programme BG 07 'Public Health Initiatives' based on the financial support of the Norway financial mechanism 2009-2014 and the financial mechanism of the European Economic Area 2009-2014. The project is named 'Improving

the surveillance of vaccine-preventable diseases: Development of a model of a web-based immunisation registry.' The project aims to contribute to the improvement of governance in healthcare and the quality of national immunisation programmes through a web-based immunisation register. The web-based immunisation register model aims to ensure the quality of national immunisation programmes and VPD surveillance and control by achieving a number of specific tasks:

- increasing vaccine data quality and completeness by reducing vaccine providers' paperwork;
- detection of non-immunised and insufficiently immunised (unprotected /under protected) people;
- effective monitoring of vaccination status of moving or mobile children;
- dissemination of the information concerning introduction of new vaccines or changes in the immunisation schedule as well as current vaccine recommendations;
- improvement of AEFI surveillance.

The duration of the project is November 2014 to April 2017 and it is being piloted in one region of Bulgaria.

- France: is currently piloting an IIS in some regions. The system is based on individual electronic vaccination records, shared by patients with their treating physician, which feeds a unique database. The main issue is currently the interoperability with other vaccination providers' software (which is not standardised). It is hoped that this issue will be solved through the results of the pilot projects, allowing a large scale deployment in the near future. The remaining challenge is how this tool will be utilised by both the health professionals and the general public as it will continue to be based on personal choice. Of note, the National Healthcare Reimbursement Database has been used by the French national public health agency for several years to provide estimates of vaccine coverage. It covers the entire French population and includes those vaccines integrated into the immunisation schedule and reimbursed. Only a small proportion of all vaccines administered are not registered, such as those provided for free in public vaccination centres. Although this database includes the vaccination status of more than 60 million individuals, it has not been considered, for the present survey, to match the definition of an IIS, in so far as the information entered is not made available at the point of care for use by vaccine providers.

Additional comments from respondents that enable a better understanding of the situation where there is no IIS in operation:

- Cyprus: most paediatricians working in the private sector who deal with paediatric immunisations can record immunisations electronically for each child. However, more than half of all children are immunised in the public sector by health visitors where there is no electronic recording of immunisations. Cyprus is currently preparing to set up a national health system. In this health system, electronic immunisation records of every child or adult will be considered and formulated. It is hoped that an IIS will be implemented in the context of the national health system.
- Estonia: currently has no IIS in place or being piloted. According to national legislation, all immunisations should be registered in several documents, including an immunisation passport (paper). Multiple inputs of immunisation data make it difficult for medical staff, and patients often lose their immunisation passports. There is an ongoing project which will be finalised in 2017, the result of which will be an immunisation module (electronic immunisation passport) as part of an eHealth system. Personal immunisation data will be electronically available for doctors and patients. The owner of the software is the Ministry of Social Affairs and the software is being developed by the Estonian eHealth Foundation.
- Slovenia: vaccine providers in Slovenia have their own records on vaccinations (paper or electronic). There is a plan to develop an IIS in the next five years by establishing an electronic registry of all vaccinations carried out in the country - eRCO. The registry will include data from their central population registry about the targeted population (all persons less than 18 years). This information will allow for the completeness and timeliness of vaccination against a particular infectious disease to be calculated, as well as vaccination coverage for all the vaccines in the vaccination schedule. Reporting of AEFIs from all healthcare providers will also be a part of the same system.

eHealth strategy and IIS

Table 2 shows countries that currently have an eHealth strategy in place and whether IIS is outlined in this eHealth strategy (with the hyperlink attached if applicable).

Table 2. eHealth strategies and IIS in 27 EU/EEA countries

Country	National eHealth strategy in place	IIS outlined in eHealth strategy	Hyperlink or reference to eHealth strategy if applicable
Austria	Yes	No	http://www.elga.gv.at/index.html
Belgium (Flanders)	Yes	Yes	Decree of 21 November 2003 concerning the preventive health policy Ministerial Decree of 29 January 2015 to determine the vaccination scheme for Flanders
Bulgaria	Yes	*NA*	-
Croatia	Yes	No	-
Cyprus	No	-	-
Czech Republic	Yes	No	http://www.mzcr.cz/dokumenty/narodni-strategie-elektronickeho-zdravotnictvi_9813_3216_1.html
Denmark	Yes	Yes	http://sundhedsdatastyrelsen.dk/da
Estonia	Yes	Yes	https://www.riigiteataja.ee/akt/108032016011
Finland	Yes	NA	http://www.kanta.fi/en
France	No	-	-
Germany	Yes	No	-
Greece	Yes	Yes	www.idika.gr
Hungary	Yes	Yes	-
Iceland	No	-	-
Ireland	Yes	No	http://health.gov.ie/wp-content/uploads/2014/03/Ireland_eHealth_Strategy.pdf
Latvia	Yes	Yes	http://polsis.mk.gov.lv/documents/1829 (strategy) https://www.vestnesis.lv/index.php?menu=doc&id=264943 (legislation)
Luxembourg	Yes	Yes	-
Malta	Yes	Yes	-
Netherlands	No	-	-
Norway	Yes	Yes	-
Portugal (mainland)	Yes	Yes	http://dre.pt/application/file/75542041
Romania	Yes	Yes	http://www.ms.ro/2016/10/04/8008/
Slovenia	Yes	Yes	http://www.ezdrav.si/ezdravje/ http://www.ezdrav.si/category/projekti/
Slovakia	Yes	Yes	http://www.ezdravotnictvo.sk/en/eHealth_Programme/Pages/default.aspx
Spain (Andalusia)	Yes	No	-
Sweden	Yes	No	-
UK (England)	Yes	Yes	https://www.england.nhs.uk/digitaltechnology/info-revolution/digital-primary-care/child-health/

NA – no answer

Out of the 27 countries who responded, there were 23 (85%) who have an outlined strategy for eHealth in place. Four countries have no current eHealth strategy in place.

The use of IIS is described in the eHealth strategy for 14 (67%) of 21 countries. There was no information provided by Bulgaria or Finland for this question. The seven countries that have an eHealth strategy in place but do not outline IIS in their plan are Austria, Croatia, Czech Republic, Germany, Ireland, Spain (Andalusia) and Sweden.

3.3. Description of the IIS

Among the 27 countries who responded to the survey and the short set of questions, 17 provided information on the IIS currently in operation. Table 3 outlines the descriptions of these systems.

Table 3. Overall descriptions of the IIS in 17 EU/EEA countries

Country	Name of the IIS	Year established	National (N)/ Subnational (S)	IIS governance	Financial resources	Is there a legislation that governs the use of IIS?
Belgium (Flanders)	Vaccinnet	2005	S	RHA	RG	Yes [23]
Denmark	The Danish Vaccination Register (DDV)	2013	N	NIPH	NG	Yes [24]
Finland	The National Vaccination Registry	2011	N	NIPH	NG	No
Germany	'KV-Impfsurveillance' ['Associations of Statutory Health Insurance Physicians (ASHIP) vaccination monitoring']	2011	N	NIPH	NG	No
Hungary	Országos Szakmai Információs Rendszer (OSZIR) Védőoltási és oltóanyag logisztikai alrendszer	2014 piloting	N	NIPH	NG	No
Iceland	Central Immunisation Register	2007	N	NIPH	NG	Yes [25]
Ireland	School Immunisation System (SIS)	2011	N	MoH	NG	No
Latvia	National e-health System	2016*	N	NHS	NG and EU funds	Yes [26]
Malta	National Immunisation Electronic Database	2009	N	MoH and PHC	NG	No
Netherlands	Praeventis	2005	N	NIPH	NG	No
Norway	SYSVAK - Norwegian Immunisation Registry	1995	N	NIPH	NG	Yes [27] [28]
Portugal (mainland)	Vacinas	2016 piloting	S	NIPH and MoH	NG	NA
Romania	National Electronic Registry of Immunisation	2011	N	NIPH and MoH	NG	Yes [29]
Slovakia	National Health Information System	Unknown, piloting	N	NHIC	NG and EU funds	Yes [30]
Spain (Andalusia)	Módulo de vacunas DIRAYA	2016	S	RHA	RG	No
Sweden	National Vaccination Registry	2013	N	NIPH	NIPH	Yes
UK (England)	Child Health Information System	Late 1980s	S	RHA	NG	No

** IIS is developed but is not in use yet. Pilot programme is expected in 2017*
RHA Regional Health Authority
NIPH National Institute of Public Health
MoH Ministry of Health
NHS National Health Service (subordinated to MoH)
PHC Primary Health Care
NHIC National Health Information Centre
RG Regional Government
NG National Government

The following was further specified by respondents:

- Denmark: a voluntary system was established in 2013 and became compulsory in 2015.
- Germany: the IIS started in 2011 with retrospective use of data back to 2004.

- Norway: established a piloting system in 1976 in several counties, then developed a national IIS in 1995.
- Portugal (mainland): the Vacinas system is being piloted and implementation is planned in 2017. An IIS called SINUS has been in place since 2003.
- Slovakia: the IIS is funded through the national government and the European Regional Development Fund through Operation Programme 'informatisation of society' (OPIS).
- Sweden: there is an additional IIS used in half of the counties called Svevac. Since 2014, Svevac has been operated by the Swedish Association of Local Authorities and Regions. Counties using Svevac electronically feed immunisation data to the national vaccination registry.

Governance and financial support

Among the 27 countries who responded to the survey, 17 provided information on governance and financial support. In the survey, governance was defined as 'the body at national or regional level that is in charge of the day-to-day management of the IIS and of the data contained in the system'. There are thirteen countries who have a national system and four with subnational systems. For eight of them, governance of the IIS is the sole responsibility of the national institute of public health. For Ireland, governance is held by the Ministry of Health, in Malta it is held by the Ministry of Health and primary healthcare, for Latvia it is held by the national health service, in Portugal (mainland) and Romania it is held by both the national institute of public health and Ministry of Health, and in Slovakia it is held by the national health information centre. For Belgium (Flanders), Spain (Andalusia) and the United Kingdom (England) governance is held by regional health authorities (see Table 3).

Financial support for the IIS comes from the national government for thirteen countries. In Latvia and Slovakia the IIS is funded by the national government and EU funds. The regional government provides the finances for Belgium (Flanders) and Spain (Andalucia) (see Table 2).

Legislation

There is specific legislation governing the use of the IIS in eight countries out of the 16 (50%) that provided information for this question. There was no information provided for this question by Portugal (mainland). The hyperlink or reference to the legal act is provided if applicable (see Table 3).

Characteristics of IIS

The results discussed in the following sections are based on questions only included in the comprehensive survey, hence only the 16 countries that responded to this survey (Table 1) are included in the sections below.

IIS definition

For 13 countries out of 16 (81%), Belgium, Denmark, Finland, Hungary, Iceland, Ireland, Latvia, Malta, the Netherlands, Norway, Portugal (mainland), Romania and Spain (Andalusia), the description of their IIS fits the US CDC definition of an IIS [1]. In Finland the definition exceeds the US CDC definition in that the system is also used at individual level to provide immunisation information for use in surveillance, vaccine efficacy and impact studies.

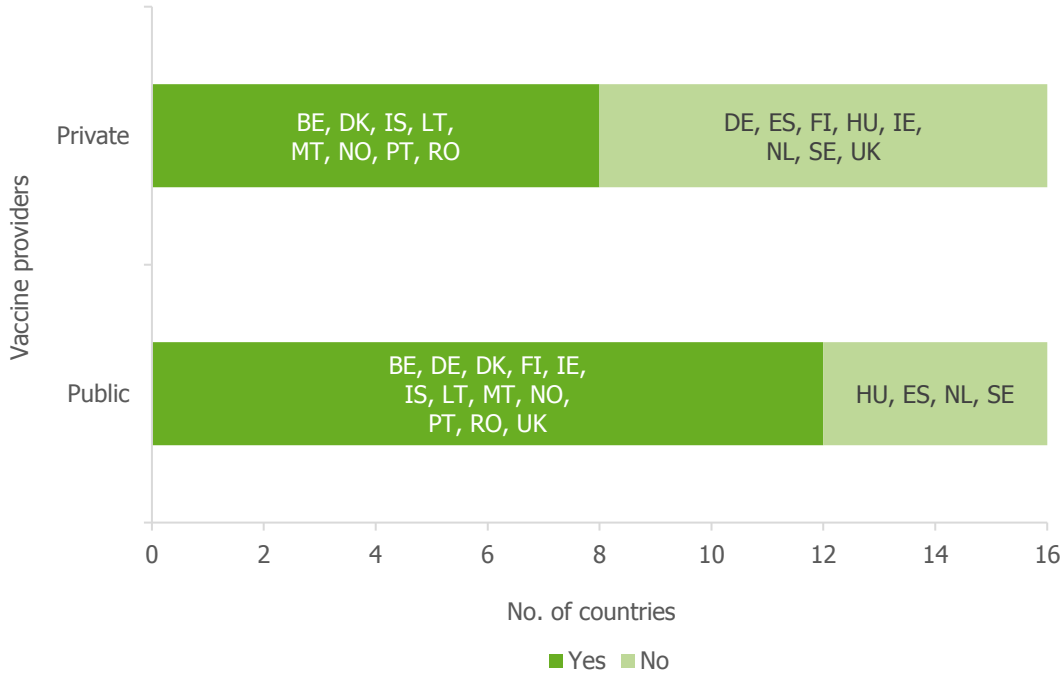
IIS in two countries (Germany and Sweden) do not fulfil the criteria of the US CDC definition of an IIS. The subnational systems in the UK are varied, with some fulfilling the US CDC definition and others not.

- Germany: the Robert Koch Institute receives insurance claims data from all physicians providing medical services to the statutory health insured population in Germany (~85% of the total population; the remainder is mainly privately insured). The claims data are generated by the physicians for the purpose of reimbursement of medical services and include the administration of vaccinations, i.e. all nationally recommended vaccinations as these costs can be claimed. At the point of clinical care, physicians or vaccination providers do not have access to this database. At the population level, the data can be used for longitudinal and national analyses to guide public health action and also regional analyses at district level to allow for regional or local interventions.
- Sweden: the national vaccination register cannot provide consolidated immunisation histories for use by a vaccination provider in determining appropriate client vaccinations due to restrictions in data laws. The objective of the current national vaccination register is to improve monitoring of the national vaccination programmes.
- United Kingdom (England): vaccination history at point of clinical care is variable. In primary care, it is dependent on the supplier of the local doctor's IT system and the local CHIS. In secondary care, it is not available.

Legislation to record vaccinations in the IIS

Figure 2 displays the number of countries out of 16 that lawfully require vaccine providers to record vaccinations in the IIS.

Figure 2. Providers required by law to record vaccinations in the IIS (n=16)



In 12 countries (75%) there is a law that requires public vaccination providers to record individual vaccinations in the IIS. For eight of the countries (50%) private vaccination providers are also required by law to record data in the IIS. For the four countries that answered 'no' to both public and private (Hungary, the Netherlands, Spain (Andalusia) and Sweden) there is an indication that there is no legal requirement for providers to record vaccination information in the system, however this is planned in the future for both Hungary and the Netherlands.

Further comments from country respondents:

- Finland: data are collected through national health data collections which are not regulated for the private sector. The national immunisation programme is carried out by public vaccination providers, with few exceptions. Vaccination recording in patient data systems is regulated and covers all providers.
- Germany: public vaccination providers are required to claim administered vaccinations. However, this is not performed for the IIS but for billing purposes. The primary data are then only subsequently used for secondary analyses in the IIS.
- Malta: private vaccination providers are required by law to report vaccinations to the national immunisation service. These reports are then recorded in the national immunisation database. However, this law is not enforced and unreported vaccinations have occurred.
- Portugal (mainland): private vaccination providers included in the national immunisation programme have to register or inform the national health service of their data. In the future, private vaccination providers will register in the IIS. Since they receive vaccines from the national health service, their information is provided back to the health service.

3.4. Characteristics of the system

This section of the survey explored the population that was covered by the IIS, how individuals were identified and the minimum data set required in the IIS. Table 4 shows which population groups are covered in the IIS and how information about the population groups and vaccinations are recorded.

Table 4. Population covered and identified in the IIS and recording of vaccinations (n=16)

Country	Does the IIS record life-course vaccination data?	Each immunised individual is recorded with a unique identifier?	How is the unique personal identifier generated?	Can vaccinations administered in the past be recorded?	Can vaccinations administered in foreign countries be recorded?	How is vaccination data entered in the IIS?
Belgium	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list • Upload from electronic medical files by webservice
Denmark	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list
Finland	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list • Manually • Linking to product database
Germany	Yes	Yes	Specific for the IIS	No	No	• Selecting from list
Hungary	No	Yes	Specific for the IIS	Yes	Yes	• Manually • Linking to product database
Iceland	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list
Ireland	No	Yes	Specific for the IIS	Yes	No	• Selecting from list • Manually
Latvia	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list • Manually
Malta	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list
Netherlands	No	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list • Manually
Norway	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list
Portugal (mainland)	Yes	Yes	Uses number given for healthcare services	Yes	Yes	• Selecting from list • Manually
Romania	No	Yes	Specific for the IIS	Yes	Yes	• Selecting from list
Spain (Andalusia)	Yes	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list • Bar code reader
Sweden	No	Yes	Uses number given at birth or immigration	No	No	• Selecting from list
UK (England)	No	Yes	Uses number given at birth or immigration	Yes	Yes	• Selecting from list

Life-course vaccinations

The systems in ten countries (63%) can record vaccinations provided at any age.

The national IIS in Ireland records only vaccinations included in the recommended school-based vaccination programme. Hungary, the Netherlands, Romania, Sweden and the United Kingdom (England) do not include vaccination data of persons over 18 years in their systems.

Further comments from country respondents:

- Germany: only vaccinations that are recommended at national level (and are reimbursed by health insurances) are recorded in the IIS.
- United Kingdom (England): most vaccinations are delivered in general practice and recorded in local doctors' IT systems, which then feed into the CHIS. For school-delivered vaccines, data are collected manually from schools and entered in the local IIS. For adult vaccines Public Health England separately commissions an external company (ImmForm) that centralises data from 95% of all local healthcare IT suppliers.

Use of a personal ID

All 16 systems used a unique personal identifier for each immunised individual recorded in the IIS. In eleven countries (69%) the unique identifier used in the IIS is an ID given to citizens at birth or immigration. For four countries (25%) the unique identifier is specific to the IIS. In Portugal (mainland) the IIS uses the unique identifier applicable for healthcare services.

Further comments from country respondents:

- Ireland: all local IIS use a system-generated patient identifier, however the same identifiers are not used at national level. A national Individual Health Identifier project has commenced in Ireland and when implemented will be used in all the systems.
- Germany: administered vaccinations can be linked via a unique ID at individual level so all vaccinations given at any point in time can be identified. However, this personal identifier cannot be used for re-identification of the individual outside the system.
- Denmark: asylum seekers are not assigned a unique identifier so it is not possible to register their vaccinations in the IIS.

Recording of historical data

Fourteen country systems (88%) could record vaccinations that have been given in the past. This is not possible for the systems in Germany and Sweden.

Recording of data administered in another country

Vaccinations administered in another country can be recorded in 13 countries (81%). This is not possible in Ireland, Germany and Sweden. In four countries with subnational systems (Belgium, Portugal (mainland), Spain (Andalusia) and the United Kingdom (England)), vaccinations administered in other regions can be recorded in the IIS.

Further comment from country respondent:

- Belgium: people living in other parts of the country are not included in the IIS, however through a request to the federal government it is possible to add them. The population database is updated twice a week (additions, deletions and changes).

Identification of the vaccine administered

In eight countries (50%) the data that identified the vaccine were *solely* selected from a list of vaccines included in the IIS. In four countries (Ireland, Latvia, the Netherlands and Portugal (mainland)), the vaccine information could be either selected from a list or entered manually. In Belgium, vaccination data are selected from a list and uploaded from electronic medical files by web service. In Finland, administered vaccines can be recorded in the IIS either by selecting them from a list, entering them manually or linking to a product database. In Hungary, data can be manually entered or linked to a product database. In Spain (Andalusia) vaccines can be selected from a list and data can also be identified electronically with the help of a barcode reader.

Further comments from country respondents:

- Latvia: has developed different classifications to facilitate manual recording.

- Sweden: Läkemedelsverket (the Swedish Medical Products Agency) provides a monthly list of all vaccine batches released. The list is entered into the IIS and the vaccine name and batch is entered by selecting from the list.

Table 5 shows the minimal set of data variables required for a record to be considered valid in the IIS.

Table 5. Minimal set of data variables for a record to be valid (n=16)

Country	Unique ID	Name	Date of birth	Sex	Residence	Vaccine info	Batch number	Expiry date	Date of vaccination	Name of vaccine provider	Name of healthcare facility
Belgium	X					X	X		X	X	X
Denmark	X					X	X		X		
Finland	X					X	X		X		
Germany	X		X		X	X			X		
Hungary	X	X	X	X	X	X	X	X	X	X	X
Iceland	X	X	X	X	X	X			X	X	X
Ireland	X	X	X		X						
Latvia	X					X	X		X	X	X
Malta	X					X	X	X	X		
Netherlands	X	X	X			X			X		
Norway	X	X	X	X		X			X		X
Portugal (mainland)	X	X	X	X			X	X~	X	X*	X*
Romania	X	X	X		X	X	X	X	X		
Spain (Andalusia)	X					X	X	X		X	X
Sweden	X				X	X	X		X	X	
UK (England)	X	X	X	X	X	X	X		X	X	X

** Automatic at log-in*
~ Prefilled back-office

All countries recorded a unique ID for the vaccine recipient, 14 countries (88%) recorded vaccine information (type and brand) and 14 countries (88%) recorded date of vaccination as essential elements to make a record valid.

Additional information required by countries to ensure that a record is valid:

- Denmark: for vaccinations administered in the past, a batch number is not necessary.
- Germany: a valid vaccination claim code is required.
- Hungary: an insurance number is required.
- Ireland: the school and academic year needs to be recorded.
- Latvia: it is mandatory to record the volume of vaccine administered, route of administration of the vaccine, type of syringe used (e.g. pre-filled syringe) and who finances the vaccination (e.g. state budget).
- Malta: the dose number is recorded.
- Norway: the type of ID document used (from a list of 12 options) must be recorded.

Other variables that are included, but their completion not mandatory, are:

- Portugal (mainland): residence and vaccine information included but not part of minimal data;
- Romania: place of birth, mother's name, healthcare provider name, recommended age of vaccination and AEFI.

Further comments from country respondents:

- The Netherlands: it was possible to record vaccinations for undocumented children that could not provide a date of birth, name or address.
- United Kingdom (England): recording of batch number is dependent on the system and completeness is not 100%.

3.5. IIS software

Table 6 shows the range of technical characteristics related to the IT solution used for an IIS. This includes the owner of the IIS, the developer of the software and the type of software used.

Table 6. Technical aspects of the IIS (n=16)

Country	Does the government authority own the IIS software?	Who developed the IIS software source code?	What type of software is used for the IIS?
Belgium	Yes	Government	NA
Denmark	Yes	Government and private	Commercial
Finland	Yes	Government	Open source (no license)
Germany	Yes	Government	Commercial and open
Hungary	Yes	NA	NA
Iceland	Yes	Government and private	Commercial
Ireland	Yes	Private	Commercial
Latvia	Yes	Private	Commercial and open
Malta	Yes	Private	Open source (no license)
Netherlands	Yes	Private	Commercial
Norway	Yes	Government	Commercial
Portugal (mainland)	Yes	Government	Ministry of Health software
Romania	Yes	Private	Free to use (license needed)
Spain (Andalusia)	Yes	Private	Commercial and open
Sweden	Yes	Government	Commercial
UK (England)	No (private suppliers)	Private	Commercial

NA – no answer

IIS software ownership

In 15 countries (94%), the government authority (including national, regional, district local health unit or vaccination centre) is the owner of the IIS software. In the United Kingdom (England) there are five main private sector software suppliers.

Software source code development

Fifteen out of 16 countries provided information on software source code development. This information was missing for Hungary. Seven countries (47%) use a private company and six countries (40%) use programmers from the government authority. Systems for two countries (13%) were developed by both private and government programmers.

Type of software used

In seven of 14 countries (50%) commercial software was used for the IIS. Information was missing for Belgium and Hungary for this question. In three countries (21%) - Germany, Latvia and Spain (Andalusia) the software is partially open and partially commercial source. In Finland and Malta, the software is open source with no licensing requirement, but in Romania the software is free-to-use, although a licence is necessary. In Portugal (mainland) Ministry of Health software is used.

Further comments from country respondents:

- Belgium: software was developed by the IT team of Child and Family, the Flemish agency organising well-baby clinics. It was built on their existing vaccination database for babies (generally used since 1999 for well-baby clinics only).
- Finland: the software consists of database, extract, transform, load, analysis, reporting and publishing software.
- Germany: the software for documentation at local doctor level is owned by the physician. These data are then forwarded to the Association of Statutory Health Insurance Physicians (ASHIP). The ASHIP database is used for extracting, anonymizing and formatting the data. It is programmed and owned by Robert Koch Institute and has been designed for the IIS. Further software for data analyses has been purchased from Robert Koch Institute.
- Latvia: the software developed for IIS is the property of the national health service of Latvia. Healthcare institutions can use it for free without modifying it and consultations regarding electronic data exchange are available
- Sweden: the software was developed in-house with use of commercially available programs.

3.6. Linkage, input and access

Table 7 provides information about the registries the IIS can link with, how a record is set up in the system and whether consent is required to record information in the IIS.

Table 7. Linkage with population registries, set up and consent (n=16)

Country	Is the IIS fed by any population registry?	Is an individual vaccination record set up automatically at registration of a live birth (or a certain time later)?	Is an individual vaccination record set up automatically at the time of immigration (or a certain time later)?	Is formal consent (oral or written) required from the vaccine recipient for record set up?
Belgium	Civil	Yes	Yes	No
Denmark	Civil, healthcare	Yes	Yes	No
Finland	Patient data system records	No	No	No
Germany	No	No	No	No
Hungary	Healthcare	No	No	No
Iceland	Civil, healthcare	Yes	Yes	No
Ireland	No	No	No	No
Latvia	Civil	Yes	No	No
Malta	Civil	Yes	No	No
Netherlands	Civil	Yes	Yes	Yes*
Norway	Civil	No	No	No
Portugal (mainland)	Healthcare	Yes	Yes	No
Romania	No	No	No	No
Spain (Andalusia)	Healthcare	Yes	Yes	No
Sweden	Civil	Yes	Yes	No
UK (England)	Civil	Yes	No	No

** to enter the data in IIS (from 2018)*

Population registry information

Thirteen countries (81%) have information fed into the IIS from a population registry. Out of these 13 countries, seven countries have their IIS from the civil population registry, three from the healthcare registries and those in Denmark and Iceland are fed by both the civil and the healthcare registries. In Finland data are entered by extraction from patient data system records. For three countries (Germany, Ireland and Romania) data are entered manually only at the time of patient encounter for immunisation.

Automatic record set up at birth and immigration

Ten countries (63%) reported that an individual vaccination record was set up automatically at the time of the registration of a live birth (or a time later). Seven countries (44%) have a vaccination record set up automatically at the time of immigration.

Consent

Only the Netherlands reported that formal consent will be required to enter data in the IIS in 2018.

Access rights to the IIS

Table 8 shows the access rights that various stakeholders have to the IIS.

Table 8. Access rights to the IIS (n=16)

Country	Vaccine recipients able to view own individual records	Who has full access (ability to create, read, write and delete) vaccination records?							
		Public healthcare providers	Private healthcare providers	Vaccine recipient's regular healthcare provider not involved in vaccination delivery	Other healthcare professionals not involved in vaccine delivery	The national public health institute (appointed staff)	School immunisation programme (appointed staff)	The national health insurance organisation (appointed staff)	Private insurance organisation (appointed staff)
Belgium	No	No[1]	No[1]	No[1]	No	No	No[1]	No	No
Denmark	Yes[1]	Yes	Yes	Yes	N/A	Yes	N/A	No	No
Finland	N/A	N/A	N/A	N/A	N/A	No[2]	N/A	N/A	N/A
Germany	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
Hungary	No*	Yes	Yes	NA	NA	No[2]	Yes	N/A	N/A
Iceland	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No
Ireland	No	No[2]	No	No	No	No	Yes	No	No
Latvia	Yes	Yes	Yes	Yes	Yes	No[2]	N/A	No[2]	No
Malta	No[2]	No[1]	No	No	No	Yes	No[1]	N/A	No
Netherlands	No	No[1]	No[1]	NA	No	Yes	N/A	No	No
Norway	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Portugal (mainland)	No[2]	Yes	No[1]	No[2]	No[2]	No[2]	N/A	No	No
Romania	No	No[1]	No[1]	N/A	N/A	Yes	No	No	No
Spain (Andalusia)	No	Yes	No	No[2]	No	No	No	No	No
Sweden	No	No[1]	No[1]	No[1]	No[2]	Yes	No[2]	No	No
UK (England)	No	No	No	No	No	No	No	No	No

[1] Able to enter and view records
[2] Able to only view records

** In the pilot phase, planning to introduce this in future*
N/A – not applicable
NA – no answer

Access for vaccine recipients

Four countries (25%) allowed vaccine recipients to view their own records in the IIS. In Denmark recipients are also able to enter their records in the system.

Access for public healthcare professionals providing vaccinations

Eight countries (50%) allowed public healthcare providers (including doctors, nurses, vaccination services staff, school health services) to have full access to records in the IIS. Public healthcare providers can only enter and view data in five countries (Belgium, the Netherlands, Portugal (mainland), Romania and Sweden). In Ireland, access rights for public healthcare professionals are limited to viewing only.

Access for private healthcare professionals providing vaccinations

Five countries (31%) allow full access to the IIS for private healthcare professionals (Denmark, Hungary, Iceland, Latvia and Norway). Four countries allow private healthcare providers to enter and view records.

Access for the vaccine recipients' first line healthcare providers (doctor, nurses, family paediatrician) even if they do not play a role in vaccination delivery

Four countries out of 14 (29%) allow full access to regular healthcare providers. There was no information from Hungary and the Netherlands for this question. For two countries (Belgium and Sweden) providers can enter and view records. In Spain (Andalusia) and Portugal (mainland) providers can only view records.

Access to other healthcare professionals even if they do not play a role in vaccination delivery

Three countries out of 15 (20%) gave full access to other healthcare professionals. There was no information provided by Hungary for this question. In Sweden and Portugal (mainland) other healthcare professionals can only view records.

National public health institute (appointed staff)

Seven countries (44%) provided full access to the IIS for national public health institute appointed staff. Four countries allowed staff to only view records.

School immunisation programme (appointed staff)

Four countries (25%) allowed school immunisation programme staff full access. In Belgium and Malta staff can enter and view records and in Sweden staff are only able to view the records.

National health insurance organisation

Only one country (Latvia) allowed the national health insurance organisation the ability to view records.

Private insurance organisation

No countries allowed private insurance organisations access to the IIS.

Other actors

For other actors involved in the IIS, respondents were asked to specify them and indicate what access rights they had:

- Belgium: changes can only be made by the medical managers of the system. Data from the IIS are available for consultation in a platform for visualising medical data (Vitalink). These data can be viewed by vaccinees and other healthcare providers if the vaccinee allows it. All vaccinators that have access to Vaccinnet can add AEFIs to a vaccination record, even if they were not the vaccinator.
- Denmark: non-authorised healthcare professionals at regional level or in private nursing homes who handle a resident's medication have view-only rights.
- Finland: data entry and queries are made within patient data systems by healthcare professionals.
- The Netherlands: anonymous data can be viewed by researchers after permission is granted.
- United Kingdom (England): only child health records department staff have full access. Specific public health staff at the local level have access to individual level data, whereas national level only have access to aggregated data.

Table 9 details the validation procedure for data captured in the IIS and the estimated time between vaccination and the information being entered into the IIS.

Table 9. Validation of IIS data and time of information entry (n=16)

Country	How is the data captured in the IIS validated?	What is the estimated time between vaccination and the information being entered into the IIS?
Belgium	Automatically	Within 1 day
Denmark	Automatically	Real-time
Finland	Automatically	Within 1 week
Germany	Automatically, IIS management team	6 months
Hungary	Automatically	NA
Iceland	IIS management team	Real-time
Ireland	Local regional administrators	Within 1 month
Latvia	Automatically	No defined period
Malta	No checks, all data are considered valid	Real-time
Netherlands	Automatically	Within 2 weeks
Norway	Automatically	Real-time
Portugal (mainland)	Automatically, IIS management team	Real-time
Romania	Automatically for some data and manually by public health administration	No defined period
Spain (Andalusia)	No checks, all data are considered valid	Real-time
Sweden	Automatically for some variables. System has come validity checks	Real-time
UK (England)	Local teams at entry level, national teams before reporting data	Varies from real-time to weeks

NA – no answer

Data validation

Seven countries (44%) reported that data in the IIS were validated automatically only by the system through preset rules and similar.

For the remaining nine countries:

- Germany: there is a combination of automatic data quality control and manual checks by the IIS management team at Robert Koch Institute. Data collected at Robert Koch Institute has been pre-checked to some degree at the Associations of Statutory Health Insurance Physicians level, however not directly for the IIS.
- Iceland: the IIS management team validate data.
- Ireland: validation of data is designated to local regional system administrators.
- Portugal (mainland): data are validated both automatically and by the IIS management team.
- Romania: there are monthly validations by the public health administration, but for some data there is automatic validation by the system through preset rules or similar.
- Sweden: the system has some validity checks (i.e. only valid batches, personal identifier, date of immunisation and selected vaccine).
- Spain (Andalusia) and Malta: no-one validates the data as all entries are considered valid.
- United Kingdom (England): there are several levels of validation: local teams validate when data are entered, and the national team carries out a quality assurance process when the data are submitted for publication of national statistics.

Time between vaccination and data entry

Seven countries out of 15 (47%) responded that data are entered into the IIS at the time of vaccine administration (real-time). There was no information from Hungary for this question. In Belgium there is one day delay, for Finland there is a lag of one week. In Germany it can take up to six months, Ireland up to one month and in the Netherlands it can take up to two weeks.

Further comments from country respondents:

- Germany: data are entered into the physician's system at the time of vaccine administration. Data are transferred from the physician to ASHIP at the end of each quarter. Data are then transferred from ASHIP to Robert Koch Institute quarterly with a six-month delay.
- Latvia: there is no defined time period, data are included as soon as possible.
- Romania: at maternity level there is a five-day gap or at discharge, for local doctors there is no time frame, they usually record vaccination data on the date of vaccination or at the end of the month.
- United Kingdom (England): it varies from near real-time to weeks in areas where the primary care data are manually entered into the CHIS.

Table 10 shows IIS linkage with health outcome registers.

Table 10. Linkage of IIS records with health outcome registers (n=16)

Country	Ability to link with other health outcome registers				
	Patient record systems/ databases	Hospital discharge diagnosis register/ database	Notifiable communicable diseases database (national/ regional)	Pharmaco-vigilance (vaccine safety) registries	Other health outcome registers different from the ones mentioned
Belgium	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes
Denmark	Yes, systems are integrated	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	No
Finland	Yes, linkage routinely done	Yes, linkage routinely done	Yes, linkage routinely done	Yes, link for specific purposes	No
Germany	No	No	No	No	Yes
Hungary	NA	NA	NA	NA	NA
Iceland	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	No
Ireland	No	No	No	No	No
Latvia	Yes, systems are integrated	Yes, system is integrated	Yes, link for specific purposes	Yes, system is integrated	No

Country	Ability to link with other health outcome registers				
	Patient record systems/ databases	Hospital discharge diagnosis register/ database	Notifiable communicable diseases database (national/ regional)	Pharmaco-vigilance (vaccine safety) registries	Other health outcome registers different from the ones mentioned
Belgium	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes
Malta	No	No	No	No	No
Netherlands	Yes, link for specific purposes	Yes, link for specific purposes	Yes, linkage routinely done	Yes, linkage routinely done	Yes
Norway	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes
Portugal (mainland)	Yes, systems are integrated	Yes, link for specific purposes	Yes, link for specific purposes	No	No
Romania	No	No	No	No	No
Spain (Andalusia)	Yes, systems are integrated	Yes, linkage routinely done	Yes, linkage routinely done	Yes, linkage routinely done	No
Sweden	Yes, systems are integrated	Yes, link for specific purposes	Yes, link for specific purposes	Yes, link for specific purposes	Yes
UK (England)	No	No	No	No	No

NA – no answer

Eleven out of 15 IIS (67%) can be linked with health outcome registers. There was no information provided from Hungary for this question. Three countries (England, Ireland and Romania) are unable to link any systems with the IIS.

Link with patient record systems

Ten countries out of 15 (67%) can in some way link patient record systems with the IIS. For Denmark, Latvia, Portugal (mainland), Spain (Andalusia) and Sweden these systems are integrated and appointed staff can navigate from one to the other register with the same login. In Finland the systems are separate but the linkage of data is routinely done, whereas in Belgium, Iceland, the Netherlands and Norway the systems are separate and the link is possible only for specific purposes (e.g. research project).

Link with hospital discharge diagnosis registries

Ten countries out of 15 (67%) can link hospital discharge diagnosis registries with the IIS. In Finland and Spain (Andalusia) the linkage is routinely done, and for Belgium, Denmark, Iceland, Latvia, the Netherlands, Norway, Portugal (mainland) and Sweden linkage is possible for specific purposes.

Link with notifiable diseases database

Ten countries out of 15 (67%) can link IIS with the notifiable communicable diseases database. This is routinely done in Finland, the Netherlands and Spain (Andalusia). For the remaining seven countries the database is only linked for specific purposes.

Link with pharmacovigilance registries

As regards to the pharmacovigilance registries, nine countries out of 15 (60%) can link them with the IIS. In Latvia these registries are integrated with their IIS. In the Netherlands and Spain (Andalusia) linkage is routinely done, whereas for Belgium, Denmark, Finland, Iceland, Norway and Sweden the vaccine safety registry is only linked for specific purposes.

In five countries, the following health outcome registers can also be linked with the IIS:

- Belgium: if systems use the same identifier (national number), then the data can be linked.
- Germany: IIS data on administered vaccines can be linked to doctors' claims data on the diagnosis and treatment of selected VPDs at individual level. Furthermore, International Classification of Diseases, tenth revision (ICD-10) codes for selected VPDs are transferred and analysed by using the same personal identifier. The addition of vaccine safety data (further selected ICD-10 codes) is currently in preparation.
- The Netherlands: work to link the IIS to cancer registration (for human papillomavirus - HPV) is in progress.

- Norway: electronic patient record systems can be electronically linked to the IIS on an individual basis and the IIS can be linked to all registries based on the unique ID given to all citizens.
- Sweden: the IIS can be linked to various disease specific registers.

Further comments from country respondents:

- Romania has a pilot project planned for 2017 that will link the IIS with the notifiable communicable diseases database.
- United Kingdom (England): the future Children and Young Persons Health Services dataset will allow linking of vaccination status to clinical episodes and other sources of data such as the Child Protection Register.

3.7. Outputs

This section of the survey explored the outputs that can be generated from the IIS. Table 11 shows the public access to the IIS, whether it is possible for vaccine recipients (or their guardians) to obtain an individual immunisation history that is accepted as an official immunisation record, the smallest administrative area to compute aggregated vaccination uptake and the sources of denominator data for the IIS.

Table 11. Outputs generated from the IIS (n=16)

Country	Is there public access to the IIS (for those vaccinated and guardian)?	Is it possible for vaccine recipients to obtain an official immunisation record from the IIS?	Sources of denominator data	Smallest administrative area to compute aggregated vaccination uptake
Belgium	No	Yes, through the exchange platform	Civil population registries	Postal code
Denmark	Yes	Yes	Civil population registries	Municipality
Finland	No	No	Civil population registries	Health care centre
Germany	No	No	Healthcare population registry	NUTS 3
Hungary	NA	No*	Healthcare population registry	NUTS 1
Iceland	Yes	Yes	Civil population registries	Postal code
Ireland	No	No	School level census	NUTS 3
Latvia	Yes	Yes	NA	NUTS 3
Malta	No	By request through the IIS	Civil population registries	NUTS 3
Netherlands	No	By request through the IIS	Civil population registries	Postal code
Norway	Yes	Yes	Civil population registries	NUTS 3
Portugal (mainland)	Yes	Yes, through exchange platform	Healthcare population registries	Municipality, health unit, local doctor
Romania	No	By request through health provider	New-born hospital registry	NUTS 3
Spain (Andalusia)	No	Yes, but not official record	Healthcare population registry	NUTS 3
Sweden	No	By request through health provider	Civil population registries	Municipality
UK (England)	No	No	Civil population registries	NUTS 3

** In the pilot phase, planning to introduce this in future*
NA – no answer

Access to personal vaccination history

Five countries out of 15 (33%) (Denmark, Iceland, Latvia, Norway and Portugal (mainland)) gave vaccine recipients public access to the IIS. There was no information from Hungary for this question.

Official immunisation record

Six countries out of 16 (38%) provided vaccine recipients with the ability to independently log in to the IIS or exchange platform and obtain an individual immunisation history that is accepted as an official immunisation record.

For five countries, immunisation records can be obtained through the following:

- Malta: recipients can send a request and the official record is sent by email or printed out and provided to the recipient.
- The Netherlands: the vaccine recipient can send a request through the IIS for an immunisation history.
- Spain (Andalusia): vaccine recipients can obtain a vaccination history but it cannot be used as an official immunisation record.
- Romania and Sweden: individuals can request an immunisation record through their health provider.

Further comments from country respondents:

- Belgium: data from Vaccinnet are transferred (daily actualised) to the platform Vitalink where people can login with their eID-card and check and print their vaccination record from there.
- Portugal (mainland): recipients can access their records anytime by logging in into the health data platform.

Five countries did not give vaccine recipients the option to obtain an official immunisation record from the IIS.

Assessment of vaccination coverage

With regard to estimating vaccination coverage, nine countries out of 15 (60%) use civil population registries as the denominator data for the IIS. There was no information for Latvia for this question. Four countries (Germany, Hungary, Portugal (mainland) and Spain (Andalusia)) use healthcare population registries as the denominator. In Ireland, the number is manually obtained from school level census and Romania uses the number of newborn children from maternity hospitals.

Additional comment from country respondent:

- Germany: for paediatric and adolescent vaccinations, cohorts are established which resemble the denominator and which can then be used to calculate vaccine uptake. For adults, statistics are based on the numbers of people insured under the statutory health scheme.

Computing vaccination uptake

In order to compute aggregated vaccination uptake by the smallest administrative area, half of the countries use NUTS 3. Hungary computes uptake at the NUTS 1 level. Seven countries have the ability to calculate coverage on a smaller geographical area. Sweden and Denmark can compute data at municipality level; Belgium, Iceland and the Netherlands at postal code level, and Finland and Portugal (mainland) can go as low as healthcare centres' level.

Additional comment from country respondent:

- United Kingdom (England): vaccine coverage is estimated by manually aggregating data from around 150 local databases.

3.8. Use of IIS in practice

This section of the survey explored the ways in which the IIS was used to plan for immunisation activities. Table 12 shows information about automated reminder or recall; built-in decision support system availability, identifying unvaccinated individuals during an outbreak and whether the IIS can be used to record reasons for vaccine refusal or hesitancy.

Table 12. IIS use in planning for immunisation activities (n=16)

Country	Automatic reminders sent to vaccine recipients	Automatic reminders to the vaccine provider to call a patient for the next vaccination?	Built-in decision support system / decision tree?	Identify unvaccinated individuals in an outbreak?	Record clinical or lifestyle risk factors	Communicates updated information?	Identify individuals incompletely vaccinated according to age?	Record reasons for refusal or hesitancy to vaccination?
Belgium	No	No	No	Yes	No	Yes	Yes	No
Denmark	No	No	Yes	No	No	No	No	No
Finland	No	No	No	Yes	No	No	Yes	No
Germany	No	No	No	No	Yes	No	No	No
Hungary	No	No	No	No	No	No	No	Yes
Iceland	No	No	Yes	Yes	No	No	Yes	Yes
Ireland	No	No	No	No	No	No	Yes	Yes
Latvia	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Malta	Yes	No	No	Yes	No	No	Yes	Yes
Netherlands	Yes	No	Yes	Yes	No	No	Yes	No
Norway	No	No	No	Yes	No	No	Yes	Yes
Portugal (mainland)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Romania~	No	No	No	Yes	No	No	Yes	Yes
Spain (Andalusia)	No	Yes	Yes	No	Yes	Yes	Yes	Yes
Sweden	No	No	No	No	No	No	Yes	No
UK (England)	Yes*	Yes	No	Yes	No	No	Yes	Yes

** Varies between systems*
~ Plan to include a number of these outputs in the new IIS

Automatic reminders for vaccinations that are due

Four countries (25%), Latvia, Portugal (mainland), the Netherlands and the United Kingdom (England), had automated systems that could send reminders to people who are due for a vaccination. Four systems (25%), in Latvia, Portugal (Mainland), Spain (Andalusia) and the United Kingdom (England), could send automatic reminders to the vaccine provider to call a patient for their next vaccination.

Further comments from country respondents:

- Denmark: since 2014, the National Institute for Public Health (Statens Serum Institut) has been sending out written reminders concerning childhood vaccination to parents of children who turn 2 years, 6½ years and 14 years, provided that the children lack a minimum of one of the vaccinations recommended under the Danish childhood vaccination programme. The reminders are based on the information gathered from the Danish vaccination register.
- Germany: the IIS does not have a personal identifier for re-identification of the patient, therefore it is not possible to send out personal reminders or to build up a recall system.

Built-in decision support systems

Five countries (31%), Denmark, Iceland, the Netherlands, Portugal (mainland) and Spain (Andalusia), had a built-in decision support system that supported the vaccine providers by identifying which vaccines to give the recipient based on age, previous vaccination, allergies, travel and risk factors.

Outbreak support

In the event of a disease outbreak related to a VPD, ten countries (63%) could identify unvaccinated individuals in an outbreak.

Record clinical or lifestyle risk factors

Four systems (25%), in Germany, Latvia, Portugal (mainland) and Spain (Andalusia) could record clinical or lifestyle risk factors for VPD in relation to the immunised person.

Further comment from country respondent:

- Germany plans to add variables for the identification of selected clinical risk groups in the future.

Updated information on new vaccines

Three countries (19%), Belgium, Portugal (mainland) and Spain (Andalusia), were able to use the IIS to communicate updated information on new vaccines, updated policies, safety concerns or out-of-stock situations to the vaccine provider.

Further comment from country respondent:

- Finland: communication with vaccination providers is handled in alignment with, but outside of, the IIS.

Identify individuals

Thirteen countries (81%) had systems that have a function to identify individuals who were incompletely vaccinated according to age.

Further comment from country respondent:

- Belgium: the recommended vaccination schedule is shown in the online version so the vaccine provider can see gaps in vaccination or registration.

Vaccine hesitancy

Ten countries (63%) had systems that could be used to record reasons for refusal or hesitancy to vaccinate.

Further comment from respondent:

- Norway: vaccine refusal and hesitancy is limited to 'medical' or 'other causes'.

3.9. Vaccination programme management

This section explored the ways in which the IIS is used to support the management of a vaccination programme. Table 13 displays the use of the IIS to record AEFI, IIS support with vaccine ordering and who has access rights to data for research purposes.

Table 13. Surveillance of AEFI, programme management and research rights to IIS data (n=16)

Country	Is the IIS used to record AEFI?	Is the IIS used for routine passive reporting of AEFIs to national/ regional health authorities?	Does the IIS have a vaccine inventory function to facilitate vaccine ordering?	Which organisations can use IIS immunisation data for research?	Other organisations that have access to IIS data for research
Belgium	Yes	No	Yes	RHA	No
Denmark	No	No	No	NIPH	No
Finland	No	No	No	NIPH; MPA; AI	MPA; AI
Germany	No	No	No	NIPH	No
Hungary	No	No	Yes	NIPH	No
Iceland	No	No	No	NIPH; RIPH; MoH; RHA; MPA; AI	No
Ireland	No	Yes	No	NA	No
Latvia	Yes	Yes	Yes	Not yet defined	Not yet defined
Malta	No	No	Yes	NIPH; MoH	No
Netherlands	No	No	No	NIPH	No

Country	Is the IIS used to record AEFI?	Is the IIS used for routine passive reporting of AEFIs to national/ regional health authorities?	Does the IIS have a vaccine inventory function to facilitate vaccine ordering?	Which organisations can use IIS immunisation data for research?	Other organisations that have access to IIS data for research
Norway	No	No	No	NIPH; RIPH; MoH; RHA; MPA; AI	All researchers with an approved application.
Portugal (mainland)	Yes	No	No	NIPH; RIPH; MoH; RHA	No
Romania	Yes	No	No	NIPH	No
Spain (Andalusia)	Yes	No	Yes	NA	NA
Sweden	No	No	No	NIPH; RIPH; AI	Health officers with responsibility for school and/or child health at municipal or county levels after ethical and formal approval by the public health agency
UK (England)	No	No	No	All investigators require ethics approval	No

RHA – Regional Health Authority
MPA – Medical Products Agency
RIPH – Regional Institute of Public Health
NA – no answer
NIPH – National Institute of Public Health
AI – Academic Institutions
MoH - Ministry of Health

Recording of AEFI

Five countries (31%) used their systems to record AEFI.

Further comment from country respondent:

- Germany plans to add variables to record AEFI.

Passive recording of AEFI

Two countries (13%), Ireland and Latvia, use their IIS for routine passive reporting of AEFIs to health authorities.

Further comment from country respondent:

- Belgium: AEFI can be added and are marked in colour, so they can be seen online by the provider at the time of future vaccinations.

Vaccine ordering

Regarding programme management, five (31%) - Belgium, Hungary, Latvia, Malta and Spain (Andalusia) - had systems that included a vaccine inventory function to facilitate vaccine ordering.

Further comment from country respondent:

- The Netherlands: the system can check if the period between vaccinations is too short, if the vaccine is out of date and also has recall procedures in place.

Use of IIS data for research

Out of the fourteen countries who responded to this question, twelve allowed the national institute for public health to use IIS data for research, such as in vaccine effectiveness studies and safety studies. In the United Kingdom (England) when there is research that requires data from the IIS, the investigators can request a specific dataset, but this needs to go through prior ethics approval. There was no information from Ireland and Spain (Andalusia) for this question and Latvia has still not defined this.

Countries also gave IIS data access for research to the following bodies:

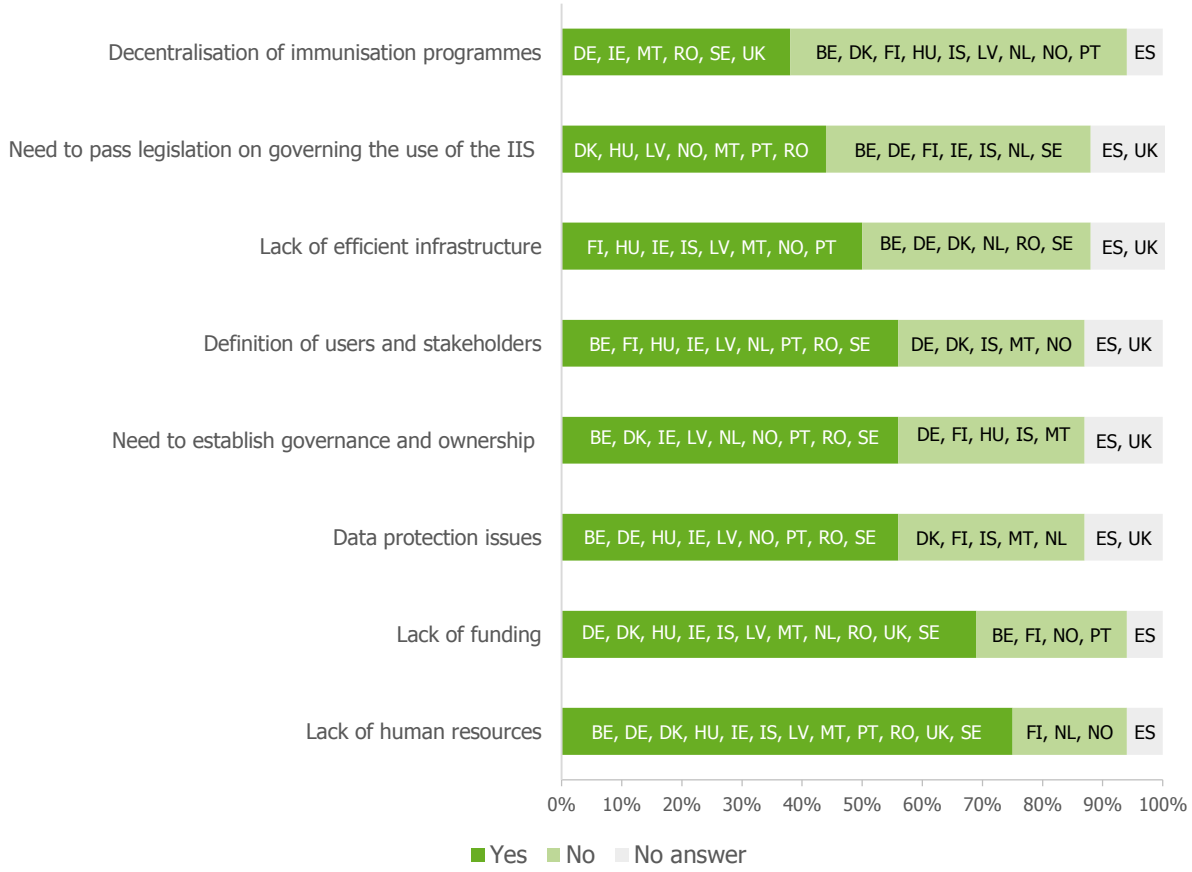
- Belgium: other non-public health organisations could have access to IIS data for research, only if properly justified and in agreement with external parties.

- Finland, Iceland and Norway: the medical products agency and academic institutions have access to IIS data for research purposes.
- Latvia: the Centre for Disease Prevention and Control and the Health Inspectorate have access to IIS.
- Norway: all researchers with an approved application have access to data.
- Sweden: health officers who are responsible for school and child health at municipal or county levels and academic institutions can gain access to IIS data after ethical and formal approval by the Public Health Agency.
- United Kingdom (England): access by public health organisations has to be requested, it is not automatic.

3.10. Challenges and barriers

This section explored challenges that countries may have faced through the various stages of IIS implementation - before a decision was made to set up an IIS, design and early use. Figure 3 details the challenges that countries faced before a decision was made to set up an IIS.

Figure 3. Challenges to overcome before a decision was taken to set up the IIS (n=16)



As shown above in Figure 3, the most common challenges faced before a decision to set up an IIS included a lack of human resources (12/15; 80%) and a lack of funding (11/15; 73%), with no answer from Spain (Andalusia) in either case. The next most common challenges relate to data protection (9/14; 64%), with no response from United Kingdom (England) and Spain (Andalusia). The majority of countries did not find that decentralisation of immunisation programmes or a need to pass legislation were issues during this period.

Further challenges that countries found during this stage included:

- Finland: having a national IIS required bringing together the decentralised healthcare system which was an issue to overcome.
- Ireland: linkage of the IIS to all other relevant health systems was a challenge. A system containing data only on immunisation does not fit with the objective to implement a national central eHealth or electronic health record. The IIS needs to be linked to other health systems in order to add benefit to patients and clinicians.
- The Netherlands: the diversity of having nine regional IIS was a challenge.

Figure 4. Challenges to overcome during the design phase of the IIS (n=16)

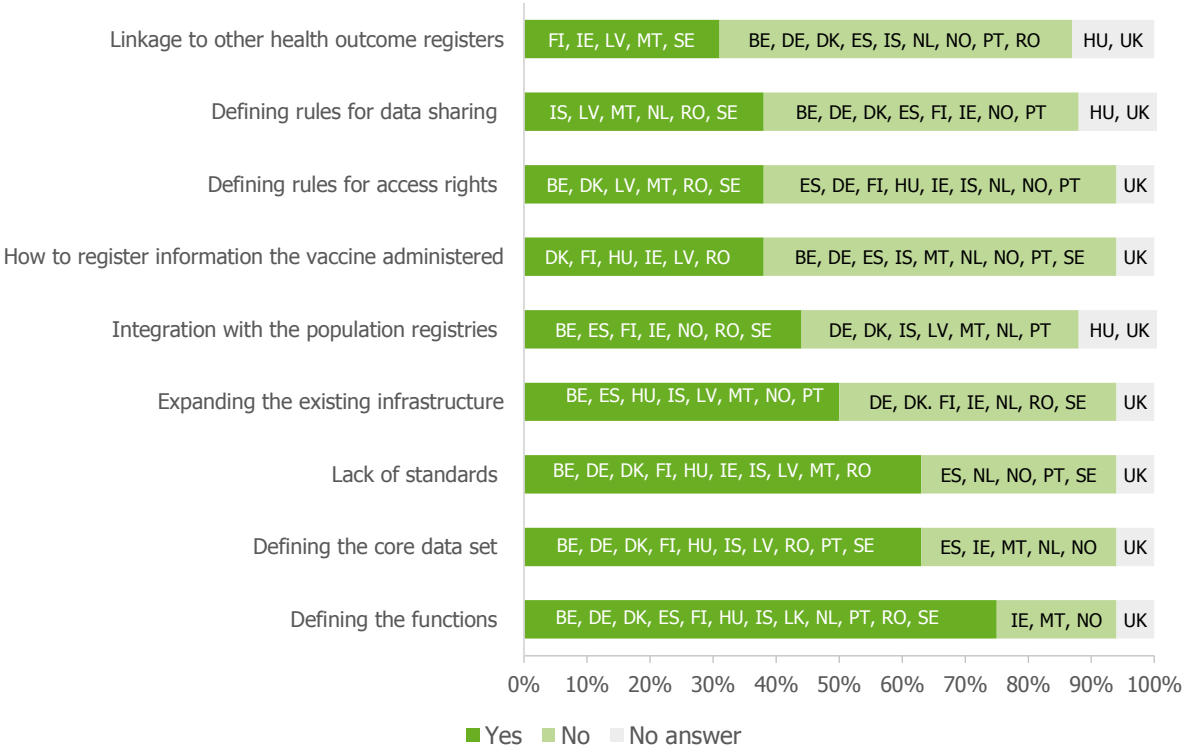
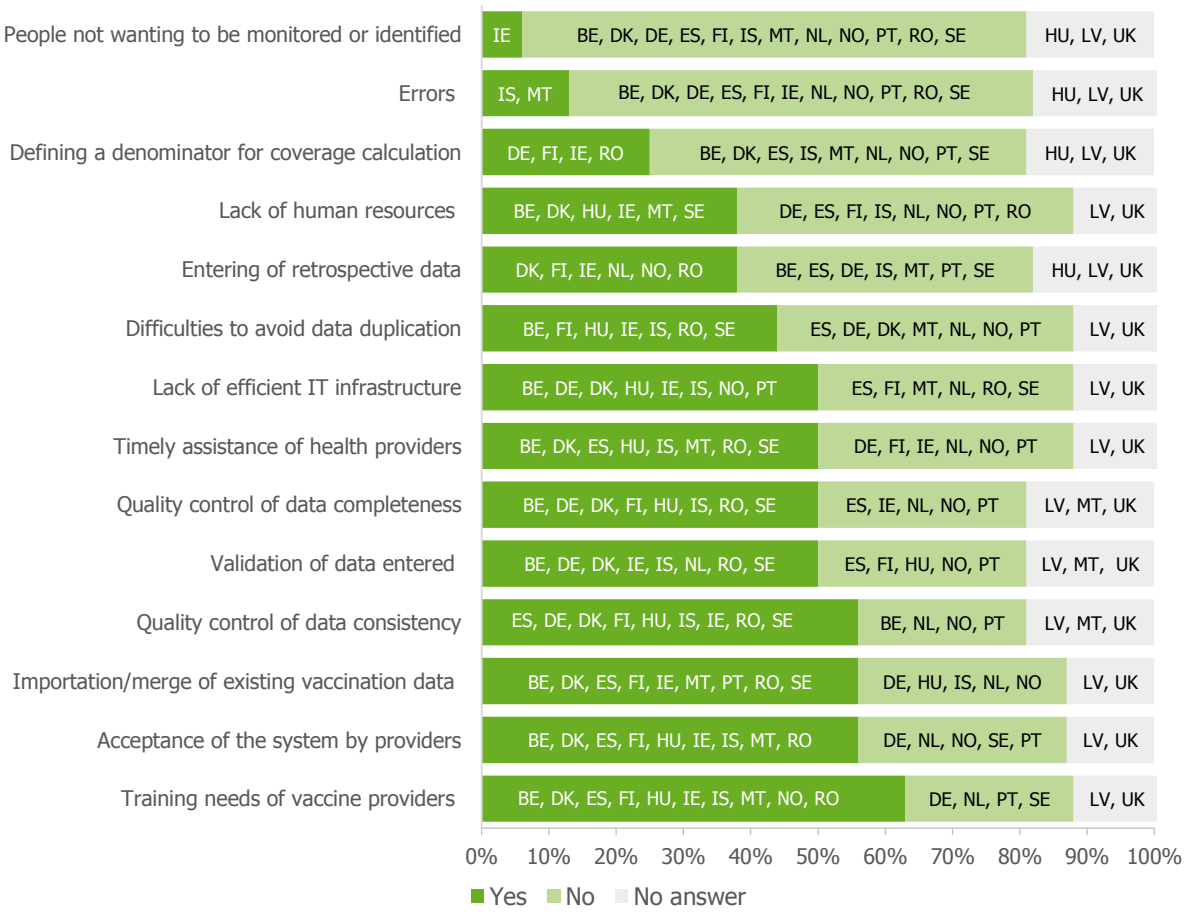


Figure 5. Challenges to overcome during the early use of the IIS (n=16)



As shown in Figure 4, during the design phase, the challenges faced by most countries included defining the functions required by the system (12/15; 80%), and a lack of standards to provide a point of reference for developing the system (10/15; 67%), with no response from United Kingdom (England) in either case. Defining the core data set of information to be collected (10/15; 67%) was also a challenge, although there was no answer from United Kingdom (England).

Further challenges faced by countries:

- The Netherlands: with all the regional differences between the health systems it was an issue to reach one decision on how a national IIS should be designed so that it would take into account all their differences.

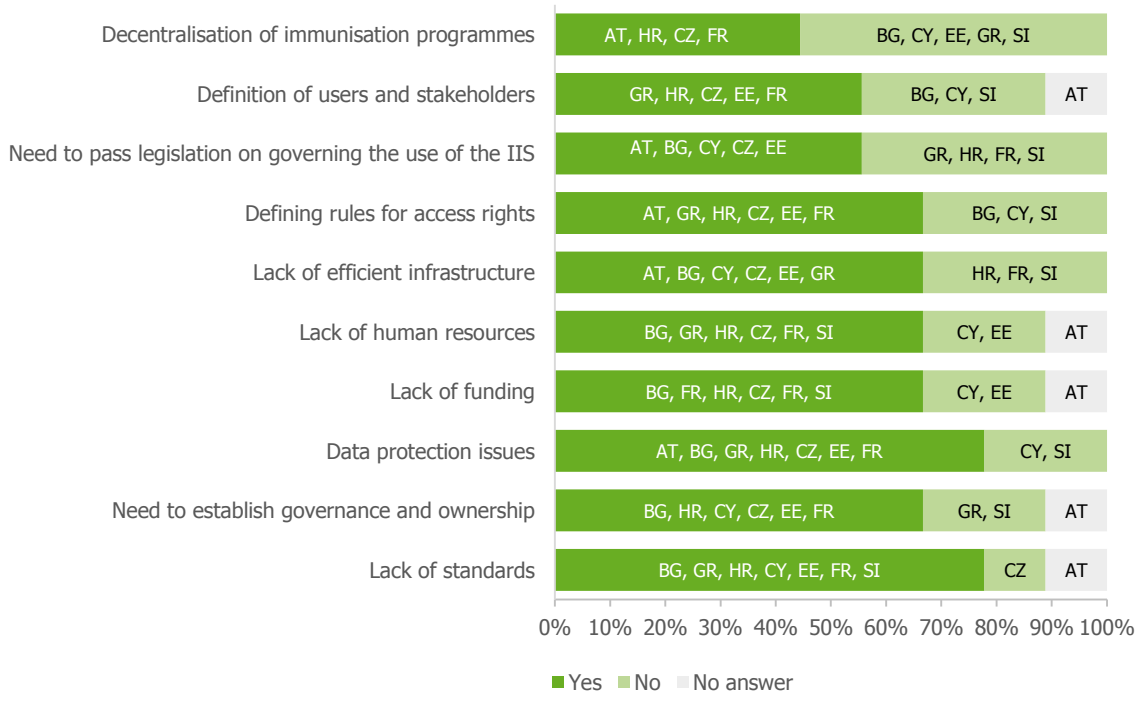
As shown in Figure 5, during the early use phase (those countries that were piloting IIS were asked to leave this section blank), the main issues encountered included training vaccine providers to use the system (10/14; 71%), with Latvia piloting the system and no answer from the United Kingdom (England). Further issues were validation of data entered by different users (9/13; 69%) and quality control of data completeness (9/13; 69%), with Latvia piloting and no answer from Malta and the United Kingdom (England) in both cases. Ireland reported that privacy concerns of people not wanting to be monitored or identified were an issue. Iceland and Malta found that errors, such as sending invitations to non-targeted individuals, were an issue during this stage.

Further challenges met during the early use of the IIS mentioned by country respondents:

- Belgium: one of the important issues was double registrations in the electronic medical file by the local doctors or paediatricians vaccinating, and in Vaccinnet. Currently the uploads from the electronic medical file to Vaccinnet are more automated.
- Netherlands: the conversion of electronic data from the previous system into the new system and the continuity between this old data and the new data.

Figure 6 displays results obtained from the short version of the survey directed to countries with no IIS.

Figure 6. Challenges to planning or implementing the IIS for countries without IIS (n=9)



For the nine countries with no IIS in place or in the initial stages of implementation who answered the brief survey, the main challenges were a lack of standards (7/8; 88% - no answer from Austria), data protection issues (7/9; 78%) and issues relating to governance and ownership of the system (6/8; 75% - no answer from Austria).

The majority of countries did not find that decentralisation of immunisation programmes, passing legislation or lack of efficient infrastructure were issues during this period.

3.11. Comments

In the comments section, countries were asked if there was any area of IIS where ECDC could provide technical guidance or other support.

Comments included:

- Cyprus: provide support to the key stakeholders, in particular in the preparation stage or when purchasing the informatics system.
- Czech Republic: a general basic guideline for an IIS implementation would be helpful.
- Finland: a vaccine code-set would be helpful.
- Greece: advice on the different steps of IIS implementation and basic guidelines.
- Malta: guidance on data validation.
- The Netherlands: a standardised terminology and minimal dataset for IIS in Europe.
- Portugal (mainland): guidelines for an IIS.
- Slovenia: ECDC could prepare a uniform set of core variables as a standard, and a repository of all the well-functioning IIS in the EU/EEA Member States.

Countries were asked to add any additional information or links to references or websites to further describe their IIS in their country. The results are shown in Table 14.

Table 14. Additional information or links provided by countries for further information on IISs

Country	Additional information or links to references or websites
Belgium	Cookbooks can be obtained for exchange of data from electronic medical files
Denmark	Danish Vaccination Register homepage: http://sundhedsdatastyrelsen.dk/vaccinationsregister Article on the Danish Vaccination Register: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20155
Germany	Articles on the German Immunisation Registry: http://europepmc.org/articles/PMC4185903 https://www.ncbi.nlm.nih.gov/pubmed/25131739 Bulletin of the World Health Organization on measles incidence reporting trends in Germany 2007-2011: http://www.who.int/bulletin/volumes/92/10/13-135145/en/
Malta	http://health.gov.mt/en/phc/pchyhi/Pages/PCYHIU.aspx
Netherlands	National institute for public health website: http://www.rivm.nl/ http://www.rivm.nl/en Article on the IIS in the Netherlands – Praeventis: http://www.eurosurveillance.org/images/dynamic/EE/V17N17/art20153.pdf
Norway	National institute for public health website: http://www.fhi.no/artikler/?id=52966 http://www.fhi.no/artikler/?id=90930 Article on the Norwegian immunisation registry - SYSVAK: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20147
UK (England)	Child health information system service specification: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/chis-provider-service-spec.pdf National Health Service child health digital strategy: https://www.england.nhs.uk/digitaltechnology/info-revolution/digital-primary-care/child-health/

4. Discussion

The findings of the survey provide information on the extent of IIS implementation and systems functionalities in 27 EU/EEA countries (see also the summary table of IIS implementation and characteristics in 16 EU/EEA countries in Appendix 3). Most EU/EEA Member States either have an operational IIS or are piloting one. Of the countries with no systems in operation, Estonia, Luxembourg and Slovenia all have concrete plans to implement an IIS as part of their larger e-Health strategies in the coming years and Cyprus plans to implement a system as part of the new national health system [31]. This wide-scale implementation of IIS is a major achievement and represents a substantial step towards improving the delivery and the monitoring of vaccination programmes in the EU/EEA as part of a broader strengthening of health service capacity.

Monitoring vaccination programmes relies not only on accurate and complete denominators and numerators for calculating vaccination coverage, but also in ensuring that the data captured in the system is reliable. The quality of data contained in each of the IIS in operation was not assessed in this survey. However, with regard to the source used for denominator data, an IIS that is populated automatically from birth and civil population registers, from national health insurance schemes or school registration is more likely to be complete. The countries who responded to the survey were advanced in this area. All countries used either the civil population registry, health care registries, school census or number of newborn children from maternity hospitals as data sources. All countries were also able to estimate coverage at subnational levels. In Finland and Portugal (mainland) for example, coverage can be assessed for populations with the same postal code and for populations using the same healthcare centre. At a population level, it is particularly important to be able to assess coverage in areas that are at high risk of low vaccination uptake. For example, in the Netherlands, the IIS can monitor coverage in areas of known for low vaccination coverage, such as the 'Bible Belt' area, so as to adapt interventions [32].

For the numerator, the recording of vaccinations and vaccine details are also critical pieces of information required for coverage calculation. To minimise errors, manual data entry of vaccine details should be avoided. All the countries can validate the data entered into the IIS through methods such as barcode readers (e.g. in Spain (Andalusia)), drop-down menus to select from a pre-defined list of vaccines (in 15 countries), linking to a product database (e.g. in Finland and Hungary) or uploading from electronic medical records via web services (e.g. in Belgium (Flanders)). This is another major strength of the systems operating in the EU/EEA in that they do not rely on manual data entry to capture information on vaccinations received.

With regard to the characteristics of an IIS, the data captured in the IIS are preferably complete, timely and of high quality. To ensure completeness, the IIS should ideally be populated with data from all vaccine delivery sites (whether public or private providers), they should cover the entire population and hold information on all vaccines recommended by health authorities, regardless of funding. Many countries' systems only capture vaccines provided in public health services and for those vaccines that are recommended and funded under the national immunisation schedule. To ensure timeliness and reduce underreporting it is essential that the time between vaccination and the information being entered into the IIS is minimised so that the information is in real-time, This is particularly relevant during emergency situations [33] or outbreaks when the prompt identification of unvaccinated people is necessary [34]. Systems in Belgium (Flanders), Denmark, Finland, Germany, Iceland, Latvia, Malta, Norway, Portugal (mainland) and Spain (Andalusia) allow for life-course vaccination information to be recorded. In 14 countries it is also possible to add vaccinations that were administered prior to the implementation of the IIS.

The IIS can also be used as a tool for informing public health decisions and research beyond vaccination coverage. The IIS constitutes large datasets that can be used in pharmaco-epidemiological studies to assess vaccine safety and effectiveness. Interoperability of the IIS with other health information systems has been useful in studies such as the investigation of narcolepsy with pandemic influenza vaccination in Finland [35]; and similarly to investigate and provide reassurances following signals or claims of adverse effects, such as the investigation of the occurrence of adverse events affecting adolescent girls after human papillomavirus (HPV) vaccination in Sweden and Denmark [36]; the association of thimerosal-containing vaccines and autism in Denmark [37]; and the investigation of vaccines and auto-immune disorders in France [35].

Other important features of an IIS include automated reminder/recall, access and education. At present, systems in Latvia, Malta, the Netherlands, Portugal (mainland) and the United Kingdom (England) can send reminders to people who are due for a vaccination, and the systems in Latvia, Portugal (mainland), Spain (Andalusia) and the United Kingdom (England) can send automatic reminders to the vaccine provider to call a patient for the next vaccination. Providing public access to the IIS and allowing vaccine recipients to print immunisation records are valuable features. Vaccine recipients can view their records in the IIS in six countries (Denmark, Iceland, Latvia, Malta, Norway and Portugal (mainland)). Six countries allow recipients to directly access an official immunisation record through the IIS. Providing vaccine recipients with some level of ownership over their records and having

online access to information on particular vaccines and the disease they protect against may be beneficial to the uptake of vaccination. Such systems can also be used as educational tools for both vaccine providers and recipients. This can be done by including an easily accessible platform that provides clear information and visualisation of data, for example, using dashboards. The systems in Denmark and Norway are linked to a web-based application that allows users to visualise in real-time the coverage at communal level with a graphical snapshot of current or historical vaccination coverage trends. This can be useful for informing interventions and raising community awareness.

Implementing IIS is a significant commitment at national and subnational levels in terms of financial investment to cover both human resources and technology developments, as well as ensuring supportive legislation to allow for personal data to be recorded and used. Some of the challenges identified through the survey include the need for human resources and funding. Other challenges included the lack of standards. ECDC is well-placed to facilitate such exchange and collaboration in a more systematic way supporting EU countries in developing and agreeing a minimal set of functionalities for an IIS, as a reference to help countries with IIS in the development phase. ECDC could also help in identifying lessons to be learned from other countries outside the EU/EEA. In the US, individuals and organisations with an interest in IIS have formed the American Immunization Register Association (AIRA) which, in collaboration with the US CDC, has published platform-neutral IIS best practices and standards [38]. Moreover, the experience gathered from other countries outside of the EU with long-standing experience in IIS such as Canada and Australia will serve the EU setting. The Australian Immunisation Register was established in 1996, initially to record vaccinations given to Australian children up to seven years of age. In January 2016, the register was expanded to include vaccination history for adolescents up to the age of 20. Later that year the system was also able to capture all vaccines given as part of the national immunisation programme for people of all ages and thereby provide a whole life immunisation history [39].

The survey had some limitations. Firstly, it did not include interviews with immunisation programme managers or other key stakeholders, such as decision-makers, programme and IT staff, which would have been useful to provide a more detailed overall picture of the IIS in countries surveyed. Secondly, the survey did not cover the transition period from paper-based to electronic registries. Lastly, the survey did not cover in detail the measures that countries use to audit the quality of the data in the IIS, such as the use of a paper-based questionnaire to compare with the data captured in the IIS. Despite its limitations this survey has provided critical information about systems across the EU/EEA and can be used as a further step towards in-depth assessment of system performance. The survey also provided key information about the challenges and barriers that countries face at different stages of IIS implementation. Sharing this knowledge and lessons learnt can potentially assist countries in overcoming these issues, especially those countries that are in the early stages or are planning to implement a system in the future.

5. Conclusions

Within the EU/EEA, countries vary considerably with respect to recommended vaccines, organisation of health services, mandate of public health agencies, legislation on confidentiality and other relevant factors. Despite this, the exchange of information and experience between national programmes has been useful in the development of IIS in many EU countries.

The setting up of an IIS is an important commitment for countries and requires careful planning of resources and time. ECDC can play an important role in bringing together key stakeholders, defining common areas of work and challenges, and facilitating exchange of knowledge and experience in order to support countries in implementing or upgrading an IIS. The current focus on e-Health in the EU and at national level provides the perfect opportunity for IIS to become an integral part of electronic health systems.

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Appendices

Appendix 1. IIS Survey - comprehensive version

Immunisation Information Systems Survey(IIS) - EU/EEA - May 2016

Fields marked with * are mandatory.

Dear Colleagues -

Tha Vaccine Preventable Diseases programme at ECDC is hereby launching a survey on the level of implementation of electronic Immunisation Information Systems (IIS) in the EU.

IIS is to be understood as any electronic system that records vaccinations at the individual level. The term IIS hence encompasses terms such as Electronic Immunisation Records, and includes electronic systems that allows aggregation of individual-based records for monitoring of the vaccination programme (e.g. monitoring of vaccination coverage)

Some EU Member States have national systems, others have one or more than one regional or provincial systems that may or may not allow exchange of data with each other. Others still have not yet established IIS.

The purpose of this online survey is to have an overview of IIS implementation, to capture their functionalities and catchment populations as well as lesson learned from development and implementation.

The aim is to make this information available to all Member States and to develop a set of resource materials that will facilitate the implementation of IIS in Europe.

This survey can be revisited several times before being submitted and doesn't require the respondent to have all information at hand in one session.

We would appreciate responding to this survey no later than 20 May 2016.

This survey has been approved by the ECDC survey committee.

For further contact on the survey, even while completing,please do not hesitate to contact Tarik Derrough (Tarik.derrough@ecdc.europa.eu)

We thank you in advance for your participation and for the time you will spend on it. It is expected to take approximately 30 minutes to respond according to the specific situation in your country.

The summary of this questionnaire will be circulated to the addressees by the end of June 2016.

1 Background information

* 1.1 Please indicate your name and email address

* 1.2 Please indicate your country

2 GENERAL

This section will explore the current situation with regards to IIS implementation in your country

* 2.1 Please choose the option that best describes the situation in your country regarding the implementation of IIS

- [ ] A national IIS is operational
- [ ] A national IIS is currently being piloted
- [ ] One sub-national IIS is operational
- [ ] More than one sub-national IISs are operational
- [ ] One sub-national IIS is currently being piloted
- [ ] More than one sub-national IISs are currently being piloted

2.2 If more than one sub-national IISs are operational, please further specify if:

- [ ] They have similar structures, characteristics or data elements and data can be shared among systems
- [ ] They have different structures, characteristics or data elements, but data can be shared among systems
- [ ] They have different structures, characteristics or data elements and data sharing among systems is not possible

2.3 If more than one sub-national IISs are operational in your country, please indicate the number of existing systems:

2.4 If more than one sub-national IISs are operational in your country, please indicate for each of them the approximate size of the population living in the areas covered by the systems

2.5 If possible, please mention which geographical areas are covered by the sub-national system/systems, using the NUTS classification (see this link for NUTS class.)

2.6 Is there an outlined strategy for E-health in place in your country?

- ☐ Yes
- ☐ No

2.7 If yes, is the use of IIS outlined in the strategy?

- ☐ Yes
- ☐ No

2.8 Hyperlink or reference to the E-Health strategy if applicable

2.9 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

3 DESCRIPTION OF THE IIS

This section will explore the national IIS or, if a national system is not in place in your country, the sub-national IIS that covers the LARGEST POPULATION. All the following questions are referring to the system you are describing.
This section is also applicable for systems at national or sub-national level that are currently being piloted and should reflect plans foreseen.

3.1 What is the name of the IIS?

3.2 Is it a national system?

- ☐ Yes
- ☐ No, it is a sub-national system

3.3 If sub-national, please approximatively indicate the approximate size of the of the population living in the areas covered by the systems

3.4 If sub-national, please indicate which area is covered by the IIS, using the NUTS classification: (See http://ec.europa.eu/eurostat/web/nuts/overview for 2013 NUTS classification)

3.5 Does the description of your IIS fits with the following definition of an IIS?

Immunization information systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease (Reference: CDC).

- ○ Yes
- ○ No

3.6 If no, please specify the definition that would best describe your system:

3.7 In what year was the IIS first established in routine use? [or year of planned implementation for

systems being piloted]

3.8 Which organisation or institution holds the governance for the IIS? (can tick more than a one box)

- [ ] National Institute of Public Health (or equivalent)
- [ ] Regional Institute of Public Health (or equivalent)
- [ ] Ministry of Health
- [ ] Regional Health Authorities
- [ ] National health insurance organisation
- [ ] Other (specify)

3.9 If other, please specify:

3.10 Is there a legislation that governs the use of the IIS?

- [ ] Yes
- [ ] No

3.11 Hyperlink or reference to the legal act if applicable

3.12 Who provides the financial resources necessary for maintaining and developing the system?

These changes may be linked to IT improvements, to improving data quality/completeness or trigerred by health regulations changes

- ( ) The national government in full
- ( ) The regional government in full
- ( ) The system if funded through public and private funds
- ( ) It is fully funded through private donor or NGO
- ( ) Other

3.13 If other, please specify:

3.14 Are PUBLIC vaccination providers required by law or regulations to record individual vaccinations in the IIS?

- [ ] Yes
- [ ] No

3.15 Are PRIVATE vaccination providers required by law or regulations to record individual vaccinations in the IIS?

- [ ] Yes
- [ ] No

3.16 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

4 CHARACTERISTICS OF THE SYSTEM

This section of the questionnaire will explore the population that is covered by the IIS and how individuals included in the register are identified.
For systems being piloted, please indicate the population that is planned to be included in the system.

4.1 ALL vaccinations provided (regardless of recommendations, age, risk factors etc..) are recorded in the IIS

- ○ Yes
- ○ No

4.2 Childhood vaccinations included in the national/regional immunisation programmes are recorded in the IIS

- ○ Yes
- ○ No

4.3 Adolescents vaccinations included in the national/regional immunisation programmes are recorded in the IIS

- ○ Yes
- ○ No

4.4 Adults vaccinations included in the national/regional immunisation programmes are recorded in the IIS

- ○ Yes
- ○ No

4.5 Vaccinations included in the recommended school-based vaccination programme are recorded in the IIS

- ○ Yes
- ○ No
- ○ Not applicable

4.6 Only some specific vaccinations (e.g. HPV vaccination register ; influenza) are recorded in the IIS

- Yes
- No
- Not applicable

4.7 If yes, please specify which vaccinations:

4.8 Is each immunised individual, recorded in the IIS, identified with a unique identifier?

- Yes
- No
- I do not know

4.9 if No, please describe how each user is identified in the database

4.10 How is the unique personal identifier generated?

- The IIS uses the unique identifier given to citizens at birth or immigration
- The IIS uses the unique identifier used for healthcare services
- The IIS uses a unique identifier specific for the immunisation registry
- Other

4.11 If other, please specify:

4.12 What is the minimal set of data variables to be recorded for a record to be valid (please list)?

4.13 Can vaccinations administered in the past be recorded in the IIS?

- Yes
- No

4.14 Can vaccinations administered in a foreign country be recorded?

- ○ Yes
- ○ No

4.15 In case of sub-national systems, can vaccinations administered in another region be recorded?

- ○ Yes
- ○ No
- ○ Not applicable

4.16 How is the data that identifies the vaccine administered recorded?

- ☐ Manually
- ☐ Electronically with the help of a bar code reader
- ☐ By selecting from a list of vaccines included in the registry
- ☐ By linking to a product database
- ☐ Other (specify)

4.17 If other, please specify:

4.18 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

5 TECHNICAL ASPECTS OF IIS

This section of the questionnaire will explore some technical issues related to the IT solution used for the IIS you are describing.

5.1 Who is the current owner of the software?

- ☐ Government authority (Nation, Region, District Local Health Unit, Vaccination Center…)
- ☐ Private Company
- ☐ Research Center
- ☐ Other, specify

5.2 If other, please specify:

5.3 The software source code was developed by?

- [ ] Developers/programmers of the government authority
- [ ] Private Company
- [ ] Research Center
- [ ] Other, specify

5.4 If other, please specify:

5.5 What type of software is used for the IIS?

- ( ) Open source (no license is needed)
- ( ) Commercial software
- ( ) Free to use software (license is needed)
- ( ) Other (e.g. partial open and partial commercial source)

5.6 If other, please specify:

5.7 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

6 INPUT, ACCESS AND LINKAGE

This section will explore in detail the links established between the IIS and other registries in your country or region including civil registries and other health-related registries. For systems being piloted, please indicate the plans foreseen.

6.1 Is information included in the IIS fed by any population registry? (can tick more than one box)

- [ ] No, data are entered manually only at time of patient encounter for immunisation
- [ ] Yes, by civil population registries
- [ ] Yes, by healthcare population registries
- [ ] Other (specify)

6.2 If other, please specify:

6.3 Is an individual vaccination record set-up automatically in the IIS at the time of the registration of a

live birth (or a certain time later)?

- Yes
- No

6.4 Is an individual vaccination record set-up automatically in the IIS at the time of immigration (or a certain time later)?

- Yes
- No

6.5 Is formal consent (oral or written) required from the vaccine recipient or vaccine recipient's guardian at the time when an individual record is initiated in the IIS?

- Yes
- No

6.6 If yes, what does consent of the vaccinee/vacinees guardian refer to? (can tick more than one box)

- Consent to enter the data in the IIS
- Consent to make data accessible to other health providers using the IIS
- Consent to the use of aggregate data for statistics and/or research
- Consent to use individual data for research (such as effectiveness studies, safety studies)
- Other (specify)

6.7 If other, please specify:

6.8 Please indicate which actions are possible for each of the following "actors" within the IIS?

	Full access rights i.e. create, read, write, delete individual records	Able to enter and view individual records	Only view data	No action allowed	Not applicable
The vaccine recipient or guardian					
Public healthcare professionals providing vaccinations (GPs, Nurses, vaccination services staff, school health services)					
Private healthcare professionals providing vaccinations					

The vaccine recipient' regular healthcare provider (e.g. GP, Nurses, family paediatrician), also if they do not play role in vaccination delivery					
Other healthcare professionals, also if they do not play role in vaccination delivery					
The National Public Health Institute (appointed staff)					
School immunisation programme (appointed staff)					
The national health insurance organisation (appointed staff)					
Private insurance organisation (appointed staff)					

6.9 If other actors, not mentioned in the table above, are involved, please specify them and indicate what access rights they have

6.10 Who validates the data that is captured in the IIS?

- No one, all entry is considered valid
- Automatically by the system through pre-set rules and similar
- The IIS management team
- Other (specify)

6.11 If other, please specify:

6.12 What is the estimated time between vaccination and the information being entered into the IIS? (only one response possible)

- Data are entered at the time of vaccine administration
- Within 1 day
- Within 1 week (7 days)
- Within 2 weeks
- Within 1 month
- 1-3 months
- Other, specify (e.g. estimated time not mentioned above; depending on vaccination or method used or sub-national area, etc…)

6.13 If other, please specify:

6.14 Are you able to link the IIS records to the following health outcome registers?

	No	Yes, these systems are integrated and appointed staff can navigate from one to the other register/database with the same log-in	Yes, these systems are separate but the linkage of data is routinely done	Yes, systems are separate but the link is possible for specific purposes (e.g. specific research project)
Primary care patient record systems/databases				
Hospital discharge diagnosis register/database				
Notifiable communicable diseases database (national/regional)				
Pharmacovigilance (vaccine safety) registries				

6.15 If the IIS can be linked to other health outcome registers different from the ones mentioned above, please specify

6.16 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

7 OUTPUTS

This section will explore outputs that can be generated from the IIS. For systems being piloted this should reflect the planned outputs.

7.1 Is there public access to the IIS?

- ○ Yes
- ○ No

7.2 Is it possible for vaccine recipients (or their guardians) to obtain an individual immunisation history through the IIS that is accepted as an official immunisation record?

- ○ Yes, at any time by logging on to the IIS
- ○ No, but they can send a request through the IIS
- ○ No
- ○ Other than listed above

7.3 If other, please specify:

7.4 What is the smallest administrative area for which you can compute aggregated vaccination uptake? (only one response possible)

reference: http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_CLS_DLD&StrNom=NUTS_2013L&StrLangua

- ☐ NUTS 1
- ☐ NUTS 2
- ☐ NUTS 3
- ☐ It is not possible to calculate vaccination uptake
- ☐ Other than listed above

7.5 If other, please specify:

7.6 What are the sources of denominator data for the IIS?

- ☐ Civil population registries
- ☐ Healthcare population registries
- ☐ Other than listed above

7.7 If other, please specify:

7.8 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

8 USE OF IIS IN THE PRACTICE - PLANNING OF IMMUNISATION ACTIVITIES

This section will explore how the system is used to plan for immunisation activities. For systems being piloted, please indicate the plans foreseen.

8.1 Can automatic reminders be sent from the IIS to people who are due for a vaccination?

- [ ] Yes
- [ ] No

8.2 Can automatic reminders be sent from the IIS to the vaccine provider to call a patient for the next vaccination?

- [ ] Yes
- [ ] No

8.3 Does the IIS have a built-in decision support system/decision tree that supports the vaccine providers identify which vaccines to give the recipient based for e.g. on age, previous vaccination, allergies, travels and risk factors?

- ( ) Yes
- ( ) No

8.4 In the event of a disease outbreak related to a vaccine-preventable disease, is the IIS able to identify unvaccinated individuals in the outbreak?

- [ ] Yes
- [ ] No

8.5 Is the IIS used to record clinical or lifestyle risk factors of the immunised person?

- [ ] Yes
- [ ] No

8.6 Does the IIS allow to communicate updated information on new vaccines, updated policies, safety

concerns, out-of-stock situations etc... to the vaccine provider?

- [ ] Yes
- [ ] No

8.7 Does the IIS have a function to identify individuals who are incompletely vaccinated according to age?

- [ ] Yes
- [ ] No

8.8 Is the IIS used to record reasons for refusal or hesitancy to vaccination?

- [ ] Yes
- [ ] No

8.9 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

9 VACCINATION PROGRAMME MANAGEMENT

This section will explore how the system is used to support the management of the vaccination programme, and the surveillance of adverse events following immunisation (AEFI) in particular. For systems being piloted, please indicate the plans foreseen.

9.1 Is the IIS used to record Adverse Events Following Immunisation (AEFI)?

- ( ) Yes
- ( ) No

9.2 Is the IIS used for routine passive reporting of AEFIs to national/regional health authorities?

- ( ) Yes
- ( ) No

9.3 Does the IIS have a vaccine inventory function to facilitate vaccine ordering?

- [ ] Yes
- [ ] No

9.4 Which organizations can use IIS immunisation data for research (e.g. vaccine effectiveness study, safety studies)?

- [ ] National Institute of Public Health (or equivalent)
- [ ] Regional Institute of Public Health (or equivalent)
- [ ] Ministry of Health

- [ ] Regional Health Authority
- [ ] National health insurance organisation
- [ ] Medical Products Agency
- [ ] Academic Institutions
- [ ] Other, please specify

9.5 If other, please specify:

9.6 Please list other uses of the IIS not mentioned above

9.7 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

10 CHALLENGES AND BARRIERS

This section will explore challenges that may have been faced at various stages of the implementation of the IIS. We are listed common challenges and would like to explore to what extent they had an impact on developments in your country.

10.1 For each of the following factors, please indicate how much they represented a challenge to be overcome **before** a decision was taken to set up the IIS or **before** a decision was taken to pilot an IIS.

	Yes	No	Somewhat	Not at all
Need to vote a legislation to govern the use of the IIS				
Need to establish governance and ownership (defining who was in charge of responsibility of the system)				
Data protection issues				
Lack of funding				
Lack of human resources				

Definition of users and stakeholders to be involved	○	○	○	○
Decentralisation of immunisation programmes	○	○	○	○
Lack of efficient infrastructure that could support the IIS (e.g. lack of computer or Internet connection at the local level)	○	○	○	○

10.2 If you met other relevant challenges (not mentioned above) in the decision to set up the IIS, please feel free to describe further:

10.3 For each of the following factors, please indicate how much they represented a challenge to be overcome during the **design phase** of the IIS

	Yes	No	Somewhat	Not at all
Expanding the existing infrastructure/lack of efficient infrastructure (e.g. lack of computer or Internet connection at the local level)	○	○	○	○
Lack of standards as point of reference for developing the system	○	○	○	○
Defining the functions required by the systems	○	○	○	○
Defining the core data set of information to be collected	○	○	○	○
Defining rules for access rights to different users (national agency, local health officers, health providers…)	○	○	○	○
Defining rules for data sharing among different users (national agency, local health officers, health providers…)	○	○	○	○
To find out how to register information on the vaccine administered	○	○	○	○
Integration with the population registries feeding the IIS	○	○	○	○

Linkage to other health outcome registers, e.g. notifiable diseases				

10.4 If you met other relevant challenges (not mentioned above) in the decision to set up the IIS, please feel free to describe further:

10.5 For each of the following factors, please indicate how much they represented a challenge to be overcome during the **early use** of the IIS [Please leave blank for systems currently being piloted]

	Yes	No	Somewhat	Not at all
Acceptance of the system by the vaccination providers				
Training needs of vaccine providers for using of the system				
Timely assistance of health providers				
Lack of efficient IT infrastructure				
Lack of resources in term of staff working with vaccine administration				
Quality control of data completeness				
Quality control of data consistency				
Validation of data entered by different users				
Experience of errors like sending invitation to not targeted individuals (e.g. already vaccinated individuals, dead persons)				
Experience of people not wanting to be monitored or identified through unique identification numbers				
Entering of retrospective data				
Difficulties to avoid data duplication				
Importation/merge of existing vaccination data from other health data sources				

Defining a denominator for coverage calculation				

10.6 If you met other relevant challenges (not mentioned above) in the set-up phase of the IIS, please feel free to describe further:

11 COMMENTS

11.1 Do you see any area on the subject of IIS where ECDC should provide technical guidance or other?

11.2 Please add any additional information or links to references or websites to further describe the IIS in your country

Thank you for your participation!

Please do not hesitate to contact Tarik Derrough (tarik.derrough@ecdc.europa.eu) if you have any further questions or you need assistance with filling in this questionnaire.

Appendix 2. IIS Survey - short version

Immunisation Information Systems Survey(IIS) - No system - EU/EEA - May 2016

Fields marked with * are mandatory.

Dear Colleagues -

The Vaccine Preventable Diseases programme at ECDC is hereby launching a survey on the level of implementation of electronic Immunisation Information Systems (IIS) in the EU.

IIS is to be understood as any electronic system that records vaccinations at the individual level. The term IIS hence encompasses terms such as Electronic Immunisation Records, and includes electronic systems that allows aggregation of individual-based records for monitoring of the vaccination programme (e.g. monitoring of vaccination coverage)

Some EU Member States have national systems, others have one or more than one regional or provincial systems that may or may not allow exchange of data with each other. Others still have not yet established IIS.

The purpose of this online survey is to have an overview of IIS implementation, to capture their functionalities and catchment populations as well as lesson learned from development and implementation.

The aim is to make this information available to all Member States and to develop a set of resource materials that will facilitate the implementation of IIS in Europe.

This survey can be revisited several times before being submitted and doesn't require the respondent to have all information at hand in one session.

We would appreciate responding to this survey no later than 20 May 2016.

This survey has been approved by the ECDC survey committee.

For further contact on the survey, even while completing, please do not hesitate to contact Tarik Derrough (Tarik.derrough@ecdc.europa.eu)

We thank you in advance for your participation and for the time you will spend on it. It is expected to take approximately 30 minutes to respond according to the specific situation in your country.

The summary of this questionnaire will be circulated to the addressees by the end of June 2016.

1 Background information

* 1.1 Please indicate your name and email address

* 1.2 Please indicate your country

2 GENERAL

This section will explore the current situation with regards to IIS implementation in your country

* 2.1 Please confirm the option that best describes the situation in your country regarding the implementation of IIS

- [ ] A national IIS is in place
- [ ] A national IIS is currently being piloted
- [ ] One sub-national IIS is in place
- [ ] More than one sub-national IISs are in place
- [ ] One sub-national IIS is currently being piloted
- [ ] More than one sub-national IISs are currently being piloted
- [ ] No IIS is currently is in place or being piloted

2.2 Is there an outlined strategy for E-health in place in your country?

- [ ] Yes
- [ ] No

2.3 If yes, is the use of IIS outlined in the strategy?

- [ ] Yes
- [ ] No

2.4 Hyperlink or reference to the E-Health strategy if applicable

2.5 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here

3 BARRIERS AND PLANS FOR THE FUTURE

3.1 For each of the following factors, please indicate how much they represented **a barrier to the plan/implement** an IIS in your country.

	Yes	No	Somewhat	Not at all
Lack of funding	○	○	○	○
Lack of human resources	○	○	○	○
Need to vote a legislation to govern the use of the IIS	○	○	○	○
Need to establish governance and ownership (defining who was in charge of responsibility of the system)	○	○	○	○
Data protection issues	○	○	○	○
Definition of users and stakeholders to be involved	○	○	○	○
Decentralisation of immunisation programmes	○	○	○	○
Lack of efficient infrastructure that could support the IIS (e.g. lack of computer or Internet connection at the local level)	○	○	○	○
Lack of standards as point of reference for developing the system	○	○	○	○
Defining rules for access rights to different users (national agency, local health officers, health providers…)	○	○	○	○

3.2 If you identified other relevant barriers (not mentioned above) to the planning/implementation of IIS in your country, please describe:

3.3 If there is a plan to develop/pilot one or more IIS in the next 5 years, please shortly describe these plans

3.4 How do you think ECDC could provide technical support the implementation of IIS in your country?

Thank you for your participation!

Please do not hesitate to contact Tarik Derrough (tarik.derrough@ecdc.europa.eu) if you have any further questions or you need assistance with filling in this questionnaire.

Appendix 3. Summary table of IIS implementation and characteristics in 16 EU/EEA countries

Country	Is the IIS National (N) or Subnational (S)?	The description of your IIS fits with the CDC IIS definition?	Is there an outlined strategy for eHealth in place in your country?	Is IIS outlined in this eHealth strategy?	IIS governance level National (N) or Subnational (S)	Is there a legislation that governs the use of IIS?	IIS funding level National (N) or Subnational (S)	Are public vaccination providers required to record data in IIS?	Private vaccination providers required to record data in IIS?	Does the IIS record whole-of-life vaccination data?	Each immunisee recorded with a unique identifier?	IIS use the UI given to citizens at birth or immigration?	Can past vaccinations be recorded?	Can vaccinations administered abroad be recorded?	Is vaccination data entered by selection from a list?	Does the Government authority own the IIS software?	Was the IIS software source code developed by the Government?
BE	S	**Yes**	**Yes**	**Yes**	S	**Yes**	S	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
DK	N	**Yes**	**Yes**	**Yes**	N	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
DE	N	No	**Yes**	**Yes**	N	No	N	**Yes**	No	**Yes**	**Yes**	No	No	No	**Yes**	**Yes**	**Yes**
ES	S	**Yes**	**Yes**	No	S	No	S	No	No	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No
FI	N	**Yes***	**Yes**	NA	N	No	N	**Yes**	No	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
HU	N	**Yes**	**Yes**	**Yes**	N	No	N	No	No	No	**Yes**	No	**Yes**	**Yes**	No	**Yes**	NA
IS	N	**Yes**	No	No	N	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
IE	N	**Yes**	**Yes**	No	N	No	N	**Yes**	No	No	**Yes**	No	**Yes**	No	**Yes**	**Yes**	No
LV	N	**Yes**	**Yes**	**Yes**	N	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No
MT	N	**Yes**	**Yes**	**Yes**	N	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No
NL	N	**Yes**	No	No	N	No	N	No	No	No	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No
NO	N	**Yes**	**Yes**	**Yes**	N	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
PT	S	**Yes**	**Yes**	**Yes**	S	**Yes**	N	**Yes**	**Yes**	**Yes**	**Yes**	**No**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
RO	N	**Yes**	**Yes**	**Yes**	N	**Yes**	N	**Yes**	**Yes**	No	**Yes**	No	**Yes**	**Yes**	**Yes**	**Yes**	No
SE	N	No	**Yes**	No	N	**Yes**	N	**Yes**	No	**Yes**	**Yes**	**Yes**	**Yes**	No	No	**Yes**	**Yes**
UK	S	No~	**Yes**	**Yes**	S	No	N	**Yes**	No	No	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	No	No

** The definition in Finland exceeds the US CDC definition*
~ Some subnational systems in the UK (England) fit the US CDC definition, while others do not
NA – No answer

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