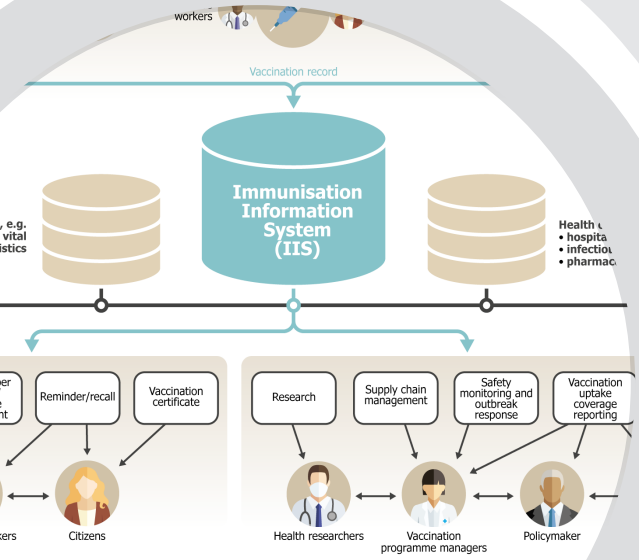

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TECHNICAL REPORT

Designing and implementing an immunisation information system

A handbook for those involved in the design, implementation or management of immunisation information systems

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Abbreviations

AEFI	Adverse events following immunisation
AIRA	American Immunization Registry Association
API	Application program interface
CRVS	Civil registration and vital statistics
DDV	Danish vaccination register
ECDC	European Centre for Disease Prevention and Control
EAP	European Academy of Paediatrics
EHR	Electronic health record
EMA	European Medicines Agency
EPR	Electronic patient record
EU/EEA	European Union/European Economic Area
EVAP	European Vaccine Action Plan
GDPR	General Data Protection Regulation
GP	General practitioner
GVAP	Global vaccine action plan
HIE	Health information exchange
IIS	Immunisation information system
IRD	Institut de recherche pour le développement
MMR	Measles, mumps and rubella vaccine
MoH	Ministry of health
MIC	Mass immunisation campaign
NHS	National Health Service England
NIPH	National institute of public health
NITAGs	National immunisation technical advisory groups
NUTS	Nomenclature of territorial units for statistics
PAHO/WHO	Pan American Health Organization/World Health Organization
RHA	Regulatory health authorities
RIPH	Regional institute of public health
SIP	Session initiation protocol code
RN	Registered nurse
SIA	Supplementary immunisation activities
SIV	The vaccine information system of the Valencia region in Spain
SKOS	Simple knowledge organisation system
SNOMED CT	Systematized nomenclature of medicine – clinical terms
SSI	Statens Serum Institute
SVEVAC	Swedish immunisation information systems
SYSVAK	Norwegian immunisation registry
US CDC	United States Centers for Disease Control and Prevention
VIS	Vaccine information systems
WHO	World Health Organization

Glossary

eHealth	European Commission definition: the use of ICTs in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health [1]
mHealth	European Commission definition: mobile health is a sub-segment of eHealth and covers medical and public health practice supported by mobile devices. It especially includes the use of mobile communication devices for health and well-being services and information purposes as well as mobile health applications [2]

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	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

Purpose

This technical guidance is intended for all those involved in the design, implementation, management or continuous improvement of immunisation information systems (IIS): primarily immunisation programme managers and operational IIS staff; more broadly public health experts and policymakers, health researchers, health information specialists, IT developers, and healthcare professionals and providers.

This technical guidance collates guiding principles and good practices from all aspects of IIS development and implementation. It proposes strategies that build on the experiences of IIS experts; provides case studies from actual programmes to highlight particular aspects of IIS practice, including functionalities, benefits, challenges, and implementation. It aims to share experiences and explore ideas that IIS experts consider valuable for upgrading an existing IIS, or developing a new IIS.

Each IIS will be tailored to a specific set of objectives and thus be unique, both with regard to the type of data it collects and the functionalities it offers.

In particular, this technical guidance aims to:

- define immunisation information systems,
- provide information on immunisation information systems and their added-value to immunisation programmes,
- share best practices to advocate for immunisation information systems towards main stakeholders,
- describe the functionalities and attributes that immunisation information systems can offer, and
- give step-by-step guidance on the major steps to be considered for the design, implementation, or further development of an immunisation information system.

The process of setting up an IIS is broken down into a series of steps that cover the entire project cycle. For each step this document will:

- highlight key considerations,
- give examples of lessons learned in a variety of contexts, and
- provide references to a suite of more detailed resources on IIS.

Overview

Immunisation information systems (IIS) are an important tool for vaccination programmes. They hold data both at the personal and population levels, and are a valuable resource for individuals and the community: individuals are empowered to make informed decisions on vaccination, while improving the ability to detect patterns of vaccination in the community leads to better targeted vaccination programmes and consequently better public health.

Vaccination programmes are complex public health interventions that produce major health benefits. They are vulnerable to changes in public confidence and opinion. Immunisation programmes may be subject to controversy that has prevented achieving high uptake for some vaccines. Mitigating these controversies requires near to real-time demonstration of the efficacy and favourable safety profile of vaccines to reassure all concerned stakeholders, from the patient to the healthcare professionals.

The technology to set up an IIS has been readily available for many years, and IIS are one of the longest-standing interventions in the eHealth[1] arena. In the opinion of European experts working in the area of IIS, the implementation of these systems is running behind the technological capacity that is available in Europe.

There is no single way to develop an IIS, as one solution does not fit all situations, but many of the key challenges encountered in different contexts are similar. By collating the experiences of experts from diverse countries across Europe and globally, this technical guidance aims to outline the key issues to consider when developing and implementing an IIS.

This document is split into five sections:

- **Section 1** (The context) aims to give a contextual background for the handbook and IIS. This section begins by describing the background and objectives of this handbook, provides a definition of an IIS, and outlines the purpose of an IIS. We then summarise the global policy and practice context of immunisation, and the place for IIS within it, before we discuss the eHealth environment and technical context that sets the stage for IIS development at the country level.
  - We recommend that this section be read first by all readers before moving on to the other sections as it provides a holistic perspective of IIS.
- **Section 2** (IIS functions and value) delves deeper into answering the core question of what an IIS is and what it delivers. We describe various potential functionalities and present the added value of IIS for different stakeholders.
  - We recommend this section to readers who are contemplating the development or improvement of an IIS and want to explore how such a system may benefit different stakeholders. We also recommend that stakeholders read this section to better understand what an IIS could provide. Before defining and developing IIS functionalities adequate to your context, we recommend careful consideration of the needs and potential benefits at both the individual and the population levels for a wide variety of immunisation stakeholders.
  - We suggest involving stakeholders at an early stage of design and planning.
- **Section 3** (An enabling environment for IIS) describes the legal environment for IIS. We consider the implementation of the General Data Protection Regulation (GDPR) both across and within countries, particularly focusing on consent.
  - It is important to have regulations governing IIS in place before starting to implement an IIS. We recommend careful consideration of the legal context for IIS before system development so that data protection principles can be built into the system. We recommend this section to IIS programme managers, policymaker, and those working more broadly in eHealth.
- **Section 4** (System design and development) covers several design points that we suggest for consideration when designing an IIS. We consider high-level design of the system and describe the way that different systems have emerged in four countries, noting the difference between centralised top-down and decentralised bottom-up strategies. We then discuss system-level considerations, considering the conceptual design behind each of the key IIS components, and illustrate each with an example of how the component has been implemented into SYSVAK, the Norwegian IIS, and other international systems.
  - We suggest first identifying the problem, and then the IIS needs and key functions that will meet them, before identifying the minimum fields required to support the key functions. We recommend this section to all those involved in the decision-making for IIS design.

[1] See Glossary for definition of eHealth

- **Section 5** (Project planning for sustainability) proposes a roadmap for implementation. We provide a checklist of design and implementation issues that should be considered to help ensure IIS sustainability. These considerations range from the outset of an IIS project to the design, implementation, improvement, oversight and maintenance of the system.
  - We recommend this section to all those involved in project planning, implementation, and budgeting. While these issues should be considered during implementation, the checklist provided in this document should not be seen as fully comprehensive.

Section 1. The context

1.1 Overview

In this section we:

- propose a definition of IIS,
- summarise the global policy and practice context of immunisation, and the place for IIS within it, and
- discuss the eHealth environment and technical context.

We recommend reading this section thoroughly to gain a good overview of IIS before moving onto the other sections of the handbook.

1.2 Defining immunisation information systems

The use of standard definitions and terminology is essential for communicating clearly and developing a common understanding of IIS.

The definition for IIS in this guidance document (Box 1) aims to be sufficiently broad to encompass the wide range of system designs and healthcare settings across Europe. It was based upon existing definitions from the US Centers for Disease Control and Prevention [3] and consultation with international IIS experts. A more comprehensive consideration of the types of needs and range of functions that IIS can fulfil is detailed in Section 2.

Box 1. Definition of immunisation information system (IIS)

Immunisation information systems (IIS) are confidential, population-based, computerised information systems that record, store, and provide access to consolidated individual immunisation information. They aim to be comprehensive and community-wide, covering individuals in a specific geographic area across multiple healthcare providers [4-6].

Timely retrieval of immunisation history at the individual level enables the immunisation provider to determine appropriate individual vaccinations and vaccine recipients to have a complete record of vaccines received. Longitudinal [6] monitoring of vaccine coverage facilitates decision-making at the population level and the monitoring of the epidemiological impact vaccination policies through linkage with other health outcome databases [4-6]. In addition to these functionalities, IIS can offer other capabilities, such as reminder/recall notification, vaccine supply and stock management, and adverse event reporting [4,7,8]. Different systems range in complexity and scope.

Terminology

Throughout this technical document:

- The term 'immunisation' is used with the meaning of vaccine administration. The term 'immunisation' as used in this handbook does not imply immunity.
- The term 'immunisation information systems' refers to using technology to ensure that the collection and sharing of information about vaccination is optimal and standardised.

Scope

In this technical document, we consider IIS from two main perspectives: that of the individual, and that of the population.

- **Individual level.** Information about a person's vaccinations should be consistently recorded and available throughout a lifetime. Traceability, which means retaining the information about the vaccines received by an individual, was the initial requirement for setting up vaccination cards or books (either stand-alone or included within health booklets). Traceability remains the first requirement of IIS at the individual level.
- **Population level.** The success of vaccines and of vaccination programmes is reliant on vaccinating large numbers of individuals, and on having comprehensive, high-quality information on the characteristics (time, place, and person) of the vaccinated and unvaccinated population. At population level, the first requirement of an IIS is to have an overview of vaccination status in a population over a given time period and geographical area.

Technological advances have enabled IIS to evolve both in terms of the functionalities that they offer and in wider stakeholder involvement. In particular, the role of individuals is shifting: individuals increasingly expect to be able

to access and manage their own health data and, simultaneously, individuals are increasingly being given tools that enable them to play a more active role in managing their personal immunisation history.

Distinction between Electronic Immunisation Registries (EIR) and IIS

In the literature, EIR and IIS are often used interchangeably. In order to distinguish them from each other and bring clarity, it is relevant to refer to other commonly used terms:

Immunisation record refers to a written record of vaccination history. An appropriate definition of an immunisation record is provided by the CDC [9]: 'Vaccination records (sometimes called immunisation records) provide a history of all the vaccines you or your child received. This record may be required for certain jobs, travel abroad, or school registration'. At the individual level, this corresponds to a hard-copy vaccination card; at the community level, it refers to paper-based nominal registries or records. Immunisation records have always formed the basis of any immunisation programme as they allow the recording of the vaccination event.

Electronic immunisation record refers to a digitalised written record of immunisation history. Having immunisations recorded in electronic form brings a whole set of new opportunities for improving individual and collective vaccination.

Electronic immunisation records are compiled in a database. This collation of records is referred to as an **electronic immunisation registry**.

The terms 'records' and 'databases' should not be confused with the diverse functions that can be associated with them. In addition to vaccination history, some of these features will also allow for the registration of other information on individuals, for example age, sex, profession, or risk factors, while other features allow for other details to be included such as a vaccine inventory function to facilitate vaccine ordering.

Electronic immunisation registries can then be part of an **immunisation information system** that would refer to the collective dimension of the information system and that offers additional functionalities.

Functionalities

The functionalities of IIS are moving beyond simply recording immunisation and towards the inclusion of advanced features within the systems (Section 4) including:

- personalised information on vaccination,
- a communication platform that allows for targeted communication towards healthcare professionals and the public,
- decision support systems for vaccine providers (e.g. automated protocols for vaccination catch-up),
- recording of reasons for refusal of vaccination, and
- adverse event recording.

1.3 Purpose of immunisation information systems

The purpose of an IIS can best be demonstrated through the direct benefits it provides to stakeholders and the wealth of opportunities offered (Section 2).

Immunisation programmes are complex public health interventions that produce major health benefits. They are vulnerable to changes in public confidence and opinion. Recently, immunisation programmes have been subject to controversy that has hampered uptake for some vaccines. Mitigating this controversy requires real-life demonstration of the efficacy and excellent safety profile of vaccinations within short timeframes.

IIS are an essential tool for the timely documentation of the health benefits of immunisation. Progress in technology has enabled the development of comprehensive nationwide IIS in contexts where legislation to preserve data security and privacy is in place (Section 3).

There is great interest from the public health community and health officials to develop and implement IIS (Section 2). Implementation is nevertheless subject to challenges, as is illustrated in Section 4.

Despite existing hurdles, in 2016, the results of a survey conducted by the European Centre for Disease Prevention and Control (ECDC) showed a positive trend in the implementation of vaccination registries within European countries [10]. Of 27 responding countries of the European Union/European Economic Area (EU/EEA), 21 answered that they have an IIS in operation or being currently piloted, either at the national or subnational levels. Furthermore, of the six remaining countries, four mentioned that they have concrete plans to implement one in the near future [10].

The general purposes of an all-encompassing IIS can be detailed as follows:

Provide information to make better operational decisions

To support the delivery of the immunisation programme at the point of administration

Vaccination schedules are regularly being revised and reviewed in response to newly available vaccines, catch-up campaigns, and the introduction of temporary schedules due to changes in the epidemiological situation, shortages or specific campaigns. There are a number of stakeholders involved in the delivery of the immunisation programmes in some countries, including general practitioners (GPs), paediatricians, nurses, gynaecologists and school nurses. There has been a corresponding increase in need for specialist advice on vaccine indications and contra-indications, and this can be offered by IIS through clinical decision support systems and through the medical information that can be provided. IIS can provide access to consolidated immunisation data at the time and place where a decision on vaccination is to be made. IIS can provide other functionalities that support the delivery of immunisation programmes such as vaccine inventory, vaccine supply or reimbursement management functions.

To enable immediate access to individual immunisation history

IIS enable the consolidation of potentially fragmented immunisation records of all people immunised by multiple healthcare providers. Among other functionalities, IIS enable access to complete records of all vaccinations, which makes it easier for the healthcare provider to offer a tailored immunisation service, ensuring that individuals receive recommended vaccines depending on characteristics including their age, occupation and sex. IIS also give reassurance that the correct vaccine is given at the right time and avoids unnecessary errors such as double-administration.

Provide information to make better informed strategic decisions

To maintain and provide access to consistent and quality data on immunisation and on the population

IIS facilitate the use of standardised terminology that is used throughout health information systems, and ideally increases quality of data captured due to the consistent recording of immunisation and demographic information.

IIS should be designed to allow for the audit of data quality in terms of completeness, reliability, accuracy, and timeliness.

To support the benefit/risk monitoring of vaccines and vaccination programmes

The need for immediate and high-quality data is an essential part of any immunisation programme and further contributes to its delivery.

It is possible with an IIS for:

- citizens to have immediate access to their immunisation history and information on diseases for which they are vaccinated against,
- healthcare providers to have access to their patient's vaccination history to ensure high standard of care and tailored immunisation,
- public health authorities to have access to a large set of data needed to be able to identify and respond quickly to concerns (e.g. vaccine safety signals) in order to maintain the confidence of an increasingly vaccine-hesitant public who are in need of evidence-based data.

IIS provide an estimate for vaccine coverage and also have great potential to be the most robust and systematic approach for providing data to study the safety and effectiveness of specific vaccines when interoperability of the IIS with other health information systems is available, and for gathering information on whether vaccines reach their target communities and birth cohorts. IIS can help to identify groups or areas at risk due to low vaccination coverage. They hold information needed for rapid response (e.g. outbreaks, faulty batch recall), information to support longer-term vaccination efforts, and they can safeguard the immunisation records of individuals over their lifetime. IIS can provide the reassurance that safety can be monitored on demand and without delay.

IIS tend to differ in focus from other patient-centred health information systems such as electronic health records (EHR) and administrative claims data, as these are often driven by the need to support clinical decision at point of care or the need for administrative management of the healthcare system (reimbursement and claims information systems).

IIS place a heavy design emphasis on generating evidence to support decisions that need to be made at the population level.

1.4 Global policy and practice

Globally, immunisation programmes are among the most impactful public health interventions [11]. They are considered integral to well-functioning health systems [11,12]. Immunisation programmes require quality and timely data for their effective and cost-effective management, and for health policy setting and monitoring [11]. Monitoring and evaluation of immunisation programmes is facilitated by IIS through the capture of information that indicates whether programme objectives have been fulfilled, for example through indicators including immunisation coverage. IIS also facilitate immunisation programme reporting, for example the annual reporting from local or regional to national public health offices to WHO regional offices on their progress towards national immunisation targets [13]. More information about the benefits of IIS for different stakeholders can be found in Section 2.

Most countries in the world still rely on paper-based immunisation data systems [14], and on aggregation of data on vaccine doses given [4]. In the decades since the WHO launched the Expanded Programme on Immunisation (EPI) in the late 1970s, some regions have made tremendous progress in the set-up of electronic immunisation records such as Latin America (Box 2).

Box 2. Progress in IIS in Latin America

In all Latin American countries some form of immunisation registration (including paper-based) exists, but as monitoring and follow-up of individual schedules are considered key components of immunisation programmes, they are rapidly progressing toward developing and implementing electronic immunisation records (EIRs). These countries use diverse approaches, from system conception and development to linkage, data collection, entry, and transmission. Some countries are exploring linkages with mHealth[2] for data collection and for automated recall and reminders. Early EIRs focused on childhood vaccination, however, newer ones are expanding to include all vaccinations [4].

Equitable access to immunisation is considered a core component of the right to health. The Global Vaccine Action Plan (GVAP) aims for coverage of target populations to be at least 90% national vaccination coverage with at least 80% vaccination coverage in every administrative unit for all vaccines in the national immunisation programme [11]. Coverage gaps persist between countries and within countries [11,13]. High-quality immunisation information can serve to reduce inequity through the identification of underserved populations. This facilitates improved understanding of the determinants of inequity and access, enabling better targeting of approaches to increase coverage [13]. In addition, the European Regional Vaccine Action Plan, in order to 'strengthen monitoring and surveillance systems', proposes to 'develop and promote the use of new information technologies for collection, transmission and analysis of immunisation data within immunisation information systems that are well integrated with communicable disease and health information systems' [13].

Vaccine hesitancy, which is most commonly referred to as the delay in acceptance or refusal of vaccines despite availability of vaccine services [15], presents a challenge to attaining high levels of coverage in Europe. Transparent post-marketing studies, and studies on the impact of immunisation programmes that are independent from commercial interests, are important for increasing public trust in immunisation [12]. IIS can help mitigate potential rumours and unfounded concerns through the provision of evidence, including on adverse events following immunisation [13]. Another example in the UK (Scotland) has been the added use of 'Onomap' a computer package which facilitates name recognition to attribute ethnicity to investigate vaccine coverage in different communities, for example within the Polish community in Scotland. In an ECDC survey, ten countries out of 16 (63%) had IIS that could be used to record reasons for refusal or hesitancy to vaccination [10].

Key global health policies related to immunisation (Box 3) support the promotion, introduction, development and extension of IIS, and their integration into broader health and social information management systems [13,16].

[2] See Glossary for definition of mHealth

Box 3. Key health policies in the EU related to IIS

2011: The Global Vaccine Action Plan (GVAP) 2011–2020 [11]: Framework approved by the World Health Assembly to achieve the Decade of Vaccines vision by delivering universal access to immunisation. GVAP builds on the success of the first 10-year strategic framework to realise the potential of immunisation – the Global Immunisation Vision and Strategy 2006–2015. It proposes six strategic objectives and the actions that will support their achievement.

2011: Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward [17].

2014: The European Vaccine Action Plan (EVAP) 2015–2020 [13]: Regional interpretation of GVAP which was developed to address the specific needs and challenges of the WHO European Region.

2014: Council of the European Union conclusions on vaccinations as an effective tool in public health: Conclusions developed at the Employment, Social Policy, Health and Consumer Affairs Council [12].

2017: The Consumers, Health, Agriculture and Food Executive Agency of the European Commission launched the Joint Action on Vaccination [16] for EU Member States and included IIS as one work area.

2018: Proposed council recommendation on strengthened cooperation against vaccine-preventable diseases [18].

1.5. Information technology, e-health, and IIS

E-health in the EU

Ehealth is a priority of the European Commission, and is therefore at the forefront of policies and directives related to widespread digitalisation of services in the EU [1] [19]. The definition and goals of eHealth, as per the EU Directorate General on Health, are given in Box 4.

Box 4. Definition and goals of eHealth by the Directorate-General for Health and Food Safety

EHealth:

- Refers to tools and services using information and communication technologies that can improve prevention, diagnosis, treatment, monitoring and management.
- Can benefit the entire community by improving access to care and quality of care and by making the health sector more efficient.
- Includes information and data sharing between patients and health service providers, hospitals, health professionals and health information networks; electronic health records; telemedicine services; portable patient-monitoring devices, operating room scheduling software, robotised surgery and blue-sky research on the virtual physiological human.

Goals of the EU:

- To improve an individual's health by making life-saving information available – between countries when necessary – using eHealth tools
- To increase healthcare quality and access by making eHealth part of health policy and coordinating EU countries' political, financial and technical strategies
- To make eHealth tools more effective, user-friendly and widely accepted by involving professionals and patients in strategy, design and implementation.

The European eHealth action plan developed progressively over a number of years:

In 2004, the first European eHealth action plan was developed. It aimed to increase awareness of the importance of making eHealth an integral part of health systems. It focused on cross-border, interoperable healthcare, led to the funding of EU projects, technical solutions for linking systems, and created an EU-wide telemedicine market [20].

In 2012, the European Commission unveiled the 2012–2020 eHealth Action Plan [1] which addresses the barriers to the full use of digital solutions for health systems in Europe. It provides a roadmap focused on smarter, safer,

patient-centred health services through the empowerment of patients and healthcare workers, interoperability, and investment in research towards the personalised medicine of the future. The action plan has a specific focus on mobile health (mHealth) due to the wide distribution of smartphones and tablets [21].

In 2015, the Digital Single Market strategy (DSMS) was adopted by the Commission [22]. The DSMS was built around three pillars:

- Access: better access for consumers and businesses to digital goods and services across Europe.
- Environment: creating the right conditions and a level playing field for digital networks and innovative services to flourish.
- Economy & Society: maximising the growth potential of the digital economy.

EHealth was recognised as an area of priority, with the need for standards and interoperability between different systems.

In 2017, at the mid-term review of the DSMS, eHealth was recognised as an area of necessary development. The Commission indicated that 'digital transformation of health services holds enormous promise for better quality healthcare at affordable costs, whilst boosting innovation and business growth' [23]. Innovative digital solutions are required to meet critical health challenges such as the prevalence of chronic and infectious diseases and to ease the strain that an aging population puts on national health systems.

The Commission stated that they wanted to

- unlock EU added value for individuals, patients and researchers,
- work with interested Member States to ensure secure cross-border transfer of health records electronically,
- use e-prescriptions to dispense individuals' medication when people are travelling abroad,
- promote high-performance computing capacity to unlock the potential of big data for health through advanced data analytics such as in areas of development of medicines and early detection of emerging infectious diseases.

In its mid-term review of the DSMS, the Commission's Communication on the Transformation of Digital Health and Care of April 2018 identified three pillars around which activities will be based [19,23]:

- Secure access to, and sharing of, electronic health data
- Connecting health data to advance research, prevention and personalised medicine
- Using digital tools to foster citizen empowerment and person-centred care.

IIS may not only benefit from digital health development but their wider deployment may also contribute to the Commission's three pillars for digital health and care in the following ways:

- IIS have a relatively long history of development and standardisation, starting initially with registries, which makes IIS more mature than other population-based health information systems, and one of the leaders in population-based data and healthcare delivery.
- Data collected within IIS have been used in research to inform public health decisions.
- IIS would allow individuals to access their immunisation history and thereby take ownership and manage their vaccination history. Clinical decision support systems allow immunisations to be tailored and adjusted based on individual determinants including age, occupation, medical history and prior immunisation history.

However, IIS should not be seen as independent systems, but instead they would need to be incorporated into the national eHealth strategy in order to gain support and approval for IIS implementation or improvements.

The development of eHealth strategies and IIS has been heterogeneous across countries in Europe, and different countries are in various stages of development. Of 27 countries surveyed by the ECDC in May 2016, 23 reported having a national eHealth strategy in place, with 14 reporting that IIS was outlined in the strategy [10].

IIS can provide a suitable platform for the collection of comprehensive health information, and to establish interoperability with other health information systems [24]. The development of IIS therefore strengthens immunisation programmes while benefiting eHealth infrastructure more broadly.

Integration of IIS in health information exchanges

Immunisation programmes are only viable if vaccination events are closely monitored. This is dependent on accurate and standardised documentation of vaccination events over time and across health settings. Vaccines are often administered in a number of different locations in the public and private sector (e.g. primary care, pharmacies, inpatient and outpatient healthcare settings, child-mother care and schools). Integrated access to immunisation records through the internet (for eHealth and mHealth) can enable standardised recording and simplify work processes, in addition to ensuring the availability of timely, accurate information for both healthcare professionals and vaccine recipients. The timely availability of vaccination information is of paramount importance because verbal immunisation histories taken from the patient or a proxy have been found to be largely incorrect or incomplete [25] and sometimes parents or caregivers have misplaced the vaccination card/book or do not keep it.

Digital archiving of immunisation histories also provides a level of security protection that cannot be achieved in a paper format, where retrieval of lost vaccination records presents a challenge [25].

Health information exchange (HIE) refers to the movement of health information among different health information systems. In Europe, IIS have been established that centralise information, facilitating the development of common software and data consolidation, and enabling the linkage of data at both the patient and population level. Internationally, the need for a standardised patient identifier across multiple information systems is increasingly recognised, and HIE is a component of most eHealth system plans at the regional and country levels. An interoperability framework is being developed internationally [26], although differences persist at the national level. Increasingly, consideration of, and compliance with, the framework is expected of technology providers.

Compared with centrally managed networks, standalone platforms such as mobile applications can be developed rapidly. Many independent developers bring IIS solutions to the market, providing them directly to the consumer. While these independent products address an immediate need, their added value will often be realised through connection to the wider health system: integration of a mobile application into servers or platforms at the regional/national level can slow the diffusion of the app in the short term, but in the longer term, integration yields benefits through the workflow of data. The extensive use of such a tool can increase the chances for its longevity.

Technical tools for the integration of the technology within a multi-source information platform are available to facilitate HIE across health and social care settings, but developing a centralised IIS and integrating multiple data streams can be complex due to fragmentation, which is present in existing systems in many countries. For example, in some countries (e.g. France), vaccination involves many different actors and health structures (e.g. family doctors, pharmacists, nurses or midwives, medical offices, hospitals, occupational health services, health centres or retirement homes, school settings, national and regional health policymakers). In addition, some vaccines will be administered to the patient outside of the regular health system channels (e.g. in supermarkets). It is also important to be able to transfer/upload immunisation data to other databases, for example HPV vaccination records to cervical screening databases. It is very complex to harmonise all of these data and information. In other countries such as Sweden, registries are not consolidated at the national level and no multi-source information system is capable of managing all aspects of immunisation.

Some independent groups who have developed mobile solutions such as MesVaccins.net in France (Box 30) and CANImmunize (formerly known as ImmunizeCA) in Canada are working with national governments to embed their software applications into existing governmental health information platforms. In the case of Canada, which is organised as a highly decentralised federation of 13 provinces and territories, the pan-Canadian mobile application CANImmunize presents an opportunity for the federal government to invest in a product which can augment existing provincial/territorial IIS and provide a digital alternative to paper records in jurisdictions that lack IIS. It also creates an opportunity for portability of records across regional borders.

While a system like MesVaccins.net (Box 30) fulfil a need at the front end (i.e. individuals and health professionals), vaccination is inherently a public health matter, and the back-end data generated are of high value to manage public health interventions at the population level. Integration of independently developed solutions with the back-end systems requires investment from both the solution provider and the government, but also yields benefits to both parties as well as to individuals. For the solution provider, integration facilitates greater reach and usefulness, and consequently sustainability. For the government, integration can improve access to complementary health data and can improve access to data for individuals.

Patient engagement

The conversion of new information and health technologies has led to a 'participatory turn' in the way individuals engage in health-related decisions [27]. Health information technology and eHealth tools and services, particularly those that are web- or mobile-phone based, have expanded. This is engaging individuals by creating new opportunities for active participation in healthcare, e.g. self-tracking and monitoring from nonclinical locations [28].

The incorporation of technology into regular health data acquisition, including self-documented health, means that vast volumes of data are being generated by individuals, and much like any health data, vaccination data are primarily owned by the subject [25]. There is an increasing expectation by individuals to be able to access their personal health data, ensuring that there is high data confidentiality and security. Providing individuals with greater access to their own data empowers them to make informed decisions regarding their personal health, including preventative health measures. This shifts the role of a patient from a minimally informed recipient to an active collaborator. Projects such as 'The Blue Button Project' in the United States (Box 5) have aimed to improve individual engagement in healthcare through improved access to medical data. In Norway there is a one-page-access to all personal eHealth services such as 'insight into your health registry data' for several registries, 'my vaccines' to print out a vaccine card, 'my doctor' to communicate with your doctor, the ability to request medication, book appointments and more [29].

Box 5. The Blue Button Project

A US-based government initiative whereby individuals can, in just one click, get their health information online; downloading their health records in a variety of formats (e.g. text or .pdf) on supported computers and smartphones. Multiple organisations feature 'Blue Buttons' on their websites to enable individuals to access their personal medical information and claims. This gives individuals unprecedented control and management over their own wellbeing [30].

Box 6. eRedbook in England

In the UK (England) there is a National Health Service (NHS) child health digital transformation plan in place which aims to make child health records electronically available both to the patient and to any relevant part of the healthcare system, through the eRedbook.

The eRedbook allows parents/carers to keep track of all the immunisations their child should receive as part of the Healthy Child Programme and the eRedbook will provide reminders for when a child is due immunisations on the 'upcoming' page.

It is also possible to add and record any extra immunisations a child is given by health professionals, and to 'keep health notes and questions record', which allows important information given by a health visitor to a parent/carer to be recorded and can then track a child's wellbeing over time. It also allows a parent/carer to note specific questions for a health professional, so the health professional will have a record of these questions at the next appointment [31].

In addition to individual benefits, patient generated data can complement healthcare systems and improve public health overall [28,32]:

- Two-way communications through the IIS platform can potentially minimise vaccine hesitancy, both through the rapid reporting of health effects and through targeted information dissemination.
- In addition to monitoring information on vaccines delivered and documenting risks or adverse events associated with vaccination, interactive immunisation records can also provide double validation of data (provider and patient), which is also likely to improve data quality and completeness.

Section 2. IIS functions and value

In this section we:

- describe the various potential functionalities of an IIS, and
- present the added value of IIS for different stakeholders

Before defining and developing IIS functionalities adequate to your context, we recommend careful consideration of the needs and potential benefits at both the individual and the population levels for a wide variety of immunisation stakeholders. We suggest involving stakeholders at an early stage of design and planning.

2.1. The need for an IIS and its functionalities

IIS design and development meet needs at both the individual and population levels.

At the individual level, IIS functions facilitate clinical decision support at the point-of-care, personalised vaccination recommendations, and immunisation report generation.

At the population level (for example district, country or EU level), IIS support vaccine coverage monitoring, communication with healthcare professionals, supply chain management, safety monitoring and reporting. This enables the monitoring and evaluation of programme efficacy and/or effectiveness and/or impact.

Figure 1 is to simply illustrate an IIS, linkage with other databases and some of the possible outputs for various stakeholders. It shows the high-level aspects of system integration, however this is just an example of what types of systems might interact with an IIS. Not every system has the same functionalities or is connected to the same data sources.

Figure 1. High level aspects of an IIS – possible system integration and outputs

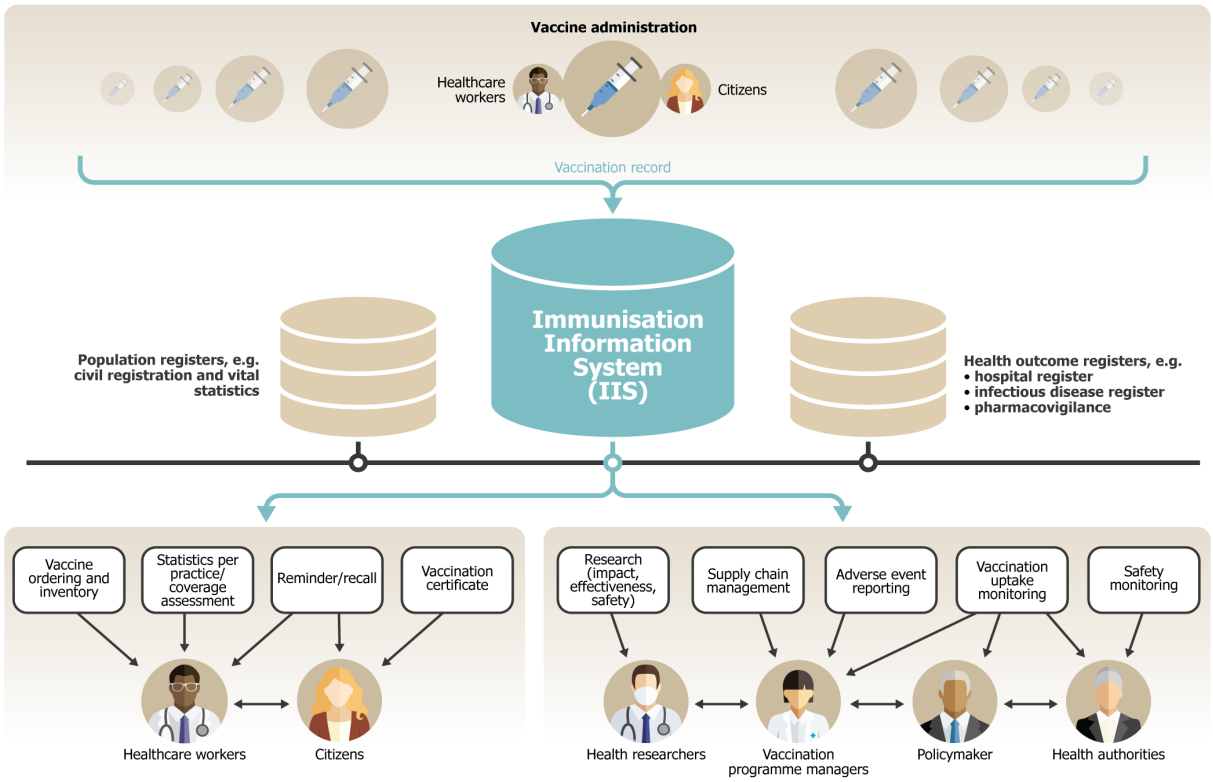
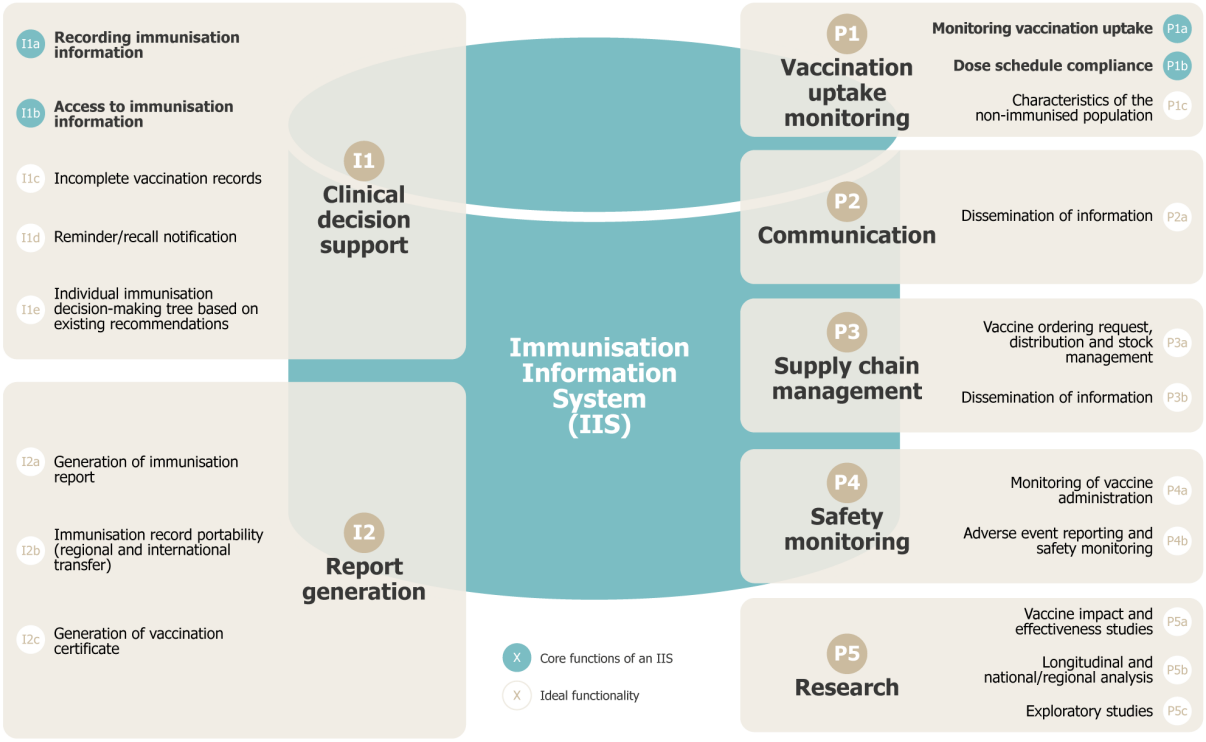


Figure 2 describes the core functionalities of an IIS. The needs at the individual level are indicated on the left side of the figure, while needs at the population level are indicated on the right. Needs are organised into seven 'blocks' or categories: two blocks of need are indicated for the individual level, while five blocks of need are indicated for the population level. Functionalities within each category are listed at the side of each block. Core functionalities (functionalities considered necessary for all systems) are indicated. Additional functionalities selected will be dependent upon the scope of the system in each country.

Figure 2. Identifying IIS needs and corresponding functionalities



It should be noted that while Figure 2 outlines key IIS needs and functions, it is not all-encompassing, and other additional system functions may be included and added in specific contexts. For example, in the Netherlands, IIS is used for the registration and invitation for the heel prick test for newborns and antenatal blood test in pregnancy (for HIV, hepatitis B, rhesus (Rh) factor (RhD and Rhc), and syphilis). In the UK (England), the IIS is integrated into a broader child health record which is used for monitoring both eHealth and social care, such as screening and developmental checks and other social care functions like tracking children that are in care.

The ability to fulfil many of the possible IIS functions is dependent on the design of the system and the interoperability of the IIS with other systems, for example civil registration and vital statistics systems (CRVS) or national identifier number databases.

2.2. Value of IIS for stakeholders

IIS are valuable to a wide range of stakeholders with different perspectives. In this section we discuss the stakeholder perspectives of individuals, healthcare professionals and vaccine providers, vaccine programme managers and policymakers, health researchers, and competent authorities.

To successfully implement an IIS it is necessary to engage with the relevant stakeholders from project initiation. Clear communication on the benefits and opportunities that an IIS can provide is essential from the beginning. The existing structures and stakeholders within different countries can vary considerably.

This section describes key features of IIS that are most relevant for various stakeholders, considers European stakeholder's attitudes to IIS, and discusses some of the approaches that could be used for value demonstration and stakeholder engagement.

We recommend careful consideration of the stakeholder context for IIS before system development.

2.2.1. The individual

IIS improve vaccination services provided to individuals through:

Enabling immediate access to information on the individual's own vaccination status

A consolidated vaccination record available at point-of-care is key. IIS enable immunisation information to be recorded (I-1a), accessed (I-1b), and missed vaccines or doses to be identified (I-1c). As records are electronic, when online, they can be accessed instantaneously at multiple different points of care (Box 7), and immunisation reports generated (I-2a). This is important for situations when there is a need to retrieve immunisation history, such as when a person changes vaccine provider, moves from one country to another, or in other scenarios such as trauma or accident, where timely access is imperative. IIS that provide the public with on-demand access to their immunisation status also address scenarios where this information is needed while not at point-of-care, such as while seeking healthcare when traveling or at school registration (e.g. in Denmark, vaccine recipients can enter and view their records in the IIS; five other EU/EEA countries (IS, LV, MT, NO, PT) allow recipients to view their IIS records) (I-2b). IIS also enable generation of printed home records or vaccination cards.

Box 7. The vaccine information system of the Valencia region in Spain (Sistema de Información Vacunal, SIV) [33]

Authorised healthcare workers can access the IIS (http://www.sp.san.gva.es/rvn) from every health centre, including public and private, within the Valencia region. Healthcare workers have real-time access to the vaccination status of patients.

Individuals can also obtain their individual vaccination records through the SIV.

Personalised, practical decision-support, including information on individual health protection

It is of paramount importance to individuals to enable them to plan and jointly decide on a specific immunisation schedule. This includes well-informed decisions on the acceptance or refusal of specific vaccinations, risk assessment of traveling or other health-impacting activities, and reassurance of protection in case of first responders to health or social crisis (e.g. healthcare workers, humanitarian volunteers). Better recording (I-1a), access (I-1b), visibility (I-1c), and vaccination reminders (I-1d) help to ensure that any gaps in a patients' vaccination record are identified and addressed. In-built clinical decision support trees (I-1e) can further improve the ability of healthcare staff to navigate through what are frequently complex vaccination recommendations, and recommend appropriate vaccinations to patients.

Communication

IIS can be used to improve knowledge and therefore better communicate information to individuals (P-2a) about the personalised benefits and risks of specific vaccines and recommendations.

Improving vaccine equity

Through monitoring vaccine uptake (P-1a), dose schedule compliance (P-1b), and longitudinal and national/regional analysis (P-5b), IIS can be used to evaluate the performance of regions/districts not achieving sufficiently high vaccination coverage. Data about the characteristics of the non-immunised population (P-1c) can be used to implement actions to ensure that all are offered vaccination, ensuring equity in the access, use of vaccination in the population, and improving vaccine effectiveness [11].

Box 8. Improving vaccine equity – use of IIS in UK (England)

The IIS in the UK (England) – the child health information systems (CHISs) – was used to assess childhood vaccination coverage by ethnicity within London between 2006/2007 and 2010/2011. Data on receipt of a full primary course of diphtheria-containing vaccines were extracted from CHISs. It was found that lowest coverage was observed in smaller ethnic groups. Smaller, well-established ethnic groups within a London Primary Care Trust setting may require specific targeting to ensure that children are fully immunised and to improve record keeping [34].

2.2.2. Healthcare professionals and vaccine providers

IIS benefit healthcare and vaccine providers through supporting them in providing up-to-date and personalised preventative care to individuals (Box 9).

IIS streamline processes for the provision of vaccination services by:

Enabling recording of (I-1a), timely access to (I-1b) patients' immunisation status to enable identification of vaccination gaps (I-1c) and the provision of appropriate vaccinations

Box 9. Visualising immunisation status in Belgium, Spain and the UK (England)

In Belgium, the recommended vaccination schedule can be visualised in the online version of the IIS, Vitalink, so the vaccine provider can see what is lacking or not registered.

In the Valencia IIS in Spain, healthcare workers have access to individual vaccination history registered in the IIS. This information is obtained through the individual personal code that identifies each individual.

Healthcare workers who are responsible for a certain health area can obtain lists with the vaccination status for a group of patients by disease. In order to retrieve this list they enter patient identification data (session initiation protocol (SIP) code or surname + birth data), and the IIS generates a file with the immunisation status of the patients by disease. This tool is useful in a disease outbreak. Healthcare workers can also obtain lists of patients vaccinated against a disease in a health centre over a period of time.

In the UK (England), a recently developed immunisation dashboard was set up to quickly visualise geographical inequalities in vaccination coverage [35].

Box 10. The Scottish Immunisation and Recall system (SIRS) [36]

In the UK (Scotland), the SIRS records immunisation data for children up to the age of six years, with a school health module extending this for vaccines given in primary and secondary schools. Healthcare professionals and vaccine providers are able to call, record, recall, check immunisation status, compute population coverage, produce formal vaccine coverage statistics, investigate coverage by specific features (such as geographical area, immuniser, deprivation category) and produce management statistics to see how new immunisation programmes are progressing before formal coverage data are available. The exact format of the invitation for vaccination varies in different areas, but for many parts includes details of a specific appointment. If the parent or caregiver does not attend, a further invitation is automatically sent out.

Providing clinical evidence and support for vaccination of individuals with specific health needs

It is possible to build-in decision support systems that support vaccine providers in identifying which vaccines to give the recipient according to aspects such as vaccination history, age and current health conditions. The link between health data and the IIS can also help in identifying patients who are entering a high-risk group, and who should receive vaccinations (for example, inactivated influenza vaccine for immunocompromised people and pregnant women, etc.). According to an ECDC survey conducted in May 2016, five of the surveyed countries (DK, IS, NL, PT and ES) have decision support systems to help identify which vaccines to give the recipient based on age, previous vaccination, allergies, travel and risk factors, among other things. This is also a key design feature that drives the use of MesVaccins.net (Box 30) (I-1e).

Reducing administrative burden

An IIS can reduce the administrative burden through improved system efficiency. Automation can reduce administrative burden on the health worker and can also enable better planning, for example in scheduling vaccinations for the following month. Having an IIS can also reduce the need for manual efforts (such as sending vaccination reminders or regular reports and as described for Estonia in Box 11) and improve the healthcare provider's ability to predict and schedule their vaccination workload. It can also support healthcare professionals in managing vaccine shortages.

Box 11. Developing an IIS in Estonia

In Estonia, where no IIS is currently in place, all immunisations have to be registered in several documents, including a paper immunisation passport. This system presents difficulties to medical staff because immunisation data have to be documented in several documents and because of lost immunisation passports.

Estonia made a decision to develop an IIS dubbed 'Electronic immunisation passport'. The result of this project will be an immunisation module (electronic immunisation passport) within the framework of an eHealth system through which personal immunisation data will be electronically available to doctors and patients.

Automation of reporting and reminders/recalls (I-1d)

Some countries in Europe have automated systems that can send reminders directly to individuals who are due for a vaccination while other systems send automatic reminders to the vaccine provider to call a patient for the next vaccination (see Box 12). Immunisation recommendations will differ depending on the stage of life a person is in, for example childhood, pregnancy, parenthood, travel, specific jobs and illness. IIS that are linked to personal data at the individual level can facilitate automated alerts, personalised to the individual. The primary benefit of reminders/recalls is to improve the timeliness and completion of recommended immunisations to prevent disease.

Box 12. Vaccination reminders in Denmark and the UK (England)

In Denmark, the NIPH (Statens Serum Institut, SSI) has been sending out written reminders since 2014. These reminders are sent to parents of children who turn 2 years, 6½ years and 14 years of age, provided that the children lack a minimum of one of the vaccinations recommended under the Danish childhood vaccination programme, and are based on information from the Danish Vaccination Register (DDV). Older regulations had to be amended in order to enable reminder letters to be sent. One of the problems encountered was that doctors occasionally entered incorrect or incomplete data in the register, which resulted in reminders for children who had already received the vaccine. The reminders have increased vaccination coverage [49].

In England, the Child Health Information Systems (CHISs) have been using call and recall functions for a number of years (since the 1980s), and this has contributed to improvements in vaccination coverage [37].

Generating quality and timely evidence

By generating quality and timely evidence an IIS can support medical boards and scientific societies in designing, monitoring, optimising, and evaluating immunisation recommendations, policy, programmes and interventions (see Box 13). Ideally, data are available at high spatial resolution – down to the individual-level and from the point-of-care. In the UK (Scotland), for example, the IIS can provide very early coverage data for new vaccines to show how implementation is proceeding.

Box 13. Healthcare professionals' and providers' perspective on IIS value – European Academy of Paediatrics (EAP)

According to Adamos Hadjipanayis, Stefano del Torso and Hans-Jürgen Dornbusch from the EAP, immunisation constitutes a diverse health service that is provided across many healthcare settings and involves a range of different professionals and practices.

In the modern, complex healthcare environment, an IIS becomes a central hub to integrate the information from all involved in the immunisation of an individual. This facilitates the delivery of the most appropriate vaccine and can also improve collaboration between health professionals.

At the point of care, an IIS can support paediatricians and other health professionals to dedicate time to personalised immunisation care, as opposed to routine administrative tasks involved in managing immunisation. Features that enable IIS to do this include reminders, decision support, and communication of information on the value of immunisation.

The main barriers to the full implementation of IIS are perceived to be 1) lack of clarity of the legal framework of immunisation records with regard to 'data ownership'; and 2) data access rights and a clearly defined purpose of data use for individual care or public health decisions.

An ideal IIS would be universal, engaging all professionals involved in immunisation to access, record, and contribute to the system; inclusive, with a broad scope that incorporates all vaccinations nationally, including legacy data; and permanent, managed in accordance with an inclusive and integrated model under a clear legal framework so that the life-long permanence of the immunisation records can be ensured.

2.2.3. Vaccine programme managers and policymakers

IIS improve the efficiency of information processing and the accuracy of health indicators. The timely data that IIS yield facilitate continuous monitoring and assessment. IIS data can facilitate:

- immunisation programme performance monitoring, for example of vaccine coverage, vaccine safety and geographical patterns and temporal trends;
- public health decision-making. Information on vaccination coverage can potentially help to improve vaccine equity and identify subgroups of the population with suboptimal vaccine coverage; and the
- optimisation of the impact of immunisation recommendations that face implementation challenges.

Supporting programme management

IIS can support programme management at all levels of the vaccination programme through the identification of problems and opportunities to improve the use of resources and inputs. IIS also support the fulfilment of national and international public health monitoring requirements (e.g. reporting on vaccination coverage, responding to post-licensure requirements, and investigation of safety signals) [38-40].

IIS can collect data that can be used to monitor immunisation delivery, vaccine safety, information on shortages, and disseminate recommendations necessary for programme implementation (e.g. which vaccine to use). IIS also support programme managers in the tracking of vaccination in people who require vaccination and have migrated across borders.

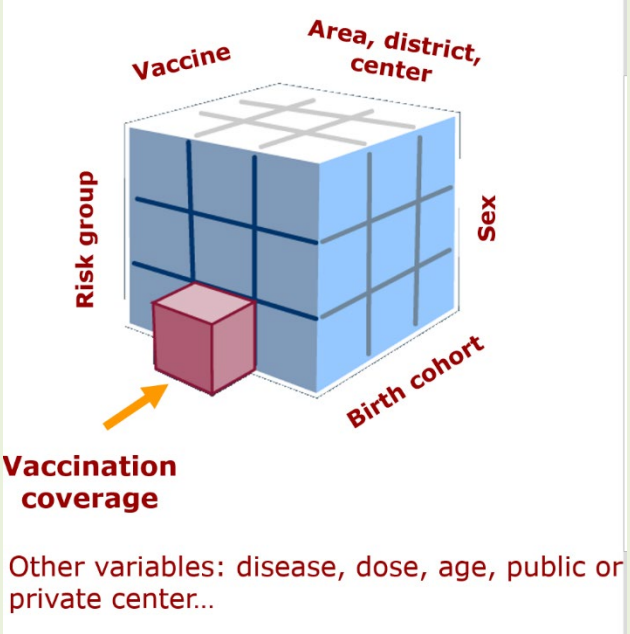
Enabling vaccination coverage monitoring

One of the key performance indicators of a well-functioning immunisation programme is vaccination coverage – the proportion of the population recommended for vaccination that has been appropriately vaccinated. It is an indirect measurement of population immunity level and determines the level of protection against vaccine-preventable diseases. Historically, coverage assessment in some EU countries has been performed through regular cross-sectional surveys (e.g. telephone-based, at school entry) [41], review of claims and social security databases or analysis of data from paper-based registries [10].

Vaccination coverage is computed using data on the doses administered (the numerator) and data on the population (the denominator) in a locality. In Europe, civil population registries and healthcare population registries are commonly used to calculate the denominator.

Box 14. Vaccination coverage data in Valencia, Spain

In the Valencia region of Spain, vaccination coverage data are obtained from a data warehouse that handles population and immunisation data (population information system) [33]. The database includes population data of all people in the Valencia region; individual records are identified by a code. Common indicators are annually analysed and sent to the ministry of health for analysis at the national level.



For example, in Ireland the denominator is manually obtained from school-level census for the National School IIS; in Romania, denominator data from the number of newborn children from maternity hospitals. Germany uses different methods for adults and children: for paediatric and adolescent vaccinations they establish cohorts which resemble the denominator and in which they representatively calculate vaccine coverage, while for adults they refer to the statistics on the numbers of statutory health insurees. There is also some heterogeneity between countries on how to compute aggregated vaccination coverage by the smallest administrative area.

An ECDC survey found that 50% (8/16) of European countries surveyed use the Nomenclature of Territorial Units for Statistics (NUTS) classification 3, and one country computes on NUTS 1. Seven countries had the ability to calculate coverage on a smaller geographical area – Sweden and Denmark can compute data on municipality and Belgium, Iceland and the Netherlands on postal code; Finland and Portugal (mainland) can go as low as healthcare centres [10]. More recently in the UK (England), GP electronic patient record systems are being used to calculate coverage for early assessment of new vaccines, vaccines for older age groups, risk groups, etc. [42].

To address incomplete coverage, IIS can (if they contain information about the population) facilitate the identification of individuals eligible for specific immunisation efforts. In an ECDC survey, thirteen countries out of 16 (81%) had an IIS that was able to support the national immunisation programme to identify individuals who were, according to the vaccination schedule, incompletely vaccinated [10].

For more information on the calculation of coverage, please refer to the sources listed in Annex 1.

Enhances preparedness for emergencies

IIS can enhance response activities and emergency preparedness for disease outbreaks, through estimating the risk of vaccine-preventable diseases and identifying unvaccinated people in the event of an outbreak. In the event of a disease outbreak related to a vaccine-preventable disease, ten countries out of the 16 (63%) surveyed by ECDC had the functionality to use IIS to support the public health emergency rapid response to identify unvaccinated individuals at risk in the case of an outbreak [10]. This is highlighted in Box 15 through the use of Præventis in the Netherlands.

Box 15. IIS in practice: Præventis during a measles outbreak in the Netherlands

During a large measles outbreak in the Netherlands in 2013–2014, infants aged 6–14 months living in municipalities with low (<90%) measles-mumps-rubella (MMR) coverage were individually invited for an early MMR using the national electronic immunisation register, Præventis.

This is the first use of Præventis to perform a novel outbreak control strategy in response to a measles outbreak in the Netherlands and the use of the system to assess early MMR uptake and its determinants. The existence of a national electronic immunisation register such as Præventis allowed a targeted outbreak intervention, whereby infants were individually invited for an early MMR based on their risk (low MMR-1 coverage in their municipality and aged 6–14 months).

The strength of this study was largely due to the availability of individual-level data from Præventis. Præventis provides vaccination status in real-time for every infant born or registered in the Netherlands. This information significantly reduced the risk of bias in terms of the population studied; it also reduces recall bias in relation to the collection of demographic and vaccination history. In addition, the accessibility of immunisation histories in Præventis provided a sufficient number of years of data to assess MMR-0 (in the Netherlands, MMR-0 refers to doses of MMR administered between 6–12 months of age) vaccination coverage prior to the 2013–2014 measles outbreak [43].

Box 16. IIS in practice: Child Health Information Systems (CHIS)

To assess the immediate impact of the adverse publicity surrounding the measles-mumps-rubella (MMR) vaccine in the UK (England), the COVER programme (an acronym for 'cover of vaccination evaluated rapidly') was able to set up a sentinel reporting system for monitoring MMR coverage from an earlier age and at more frequent intervals than routine collections. This has provided a more timely indication of trends in MMR coverage, complementing the routine collections to inform vaccine policy decisions, e.g. the national MMR catch-up programme in 2008 [37].

Vaccine supply management

IIS can be designed to facilitate communication between different actors in the management of the immunisation program. This can help ensure that vaccine supply meets demand and wastage is reduced. IIS can include a vaccine inventory and stock management function to facilitate vaccine ordering, vaccine batch recall, and verification of expiry dates. Some countries, for example Belgium, Portugal (mainland) and Spain (Andalucía), use an IIS to communicate updated information on vaccine supply and availability, for example, on new vaccines, updated policies for recommendation and reimbursement, vaccine batch recalls, out-of-supply situations to the vaccine provider. In the Netherlands, the IIS checks if the vaccine is out of date and has recall procedures in place [10].

Delivers information for continuous communication

IIS deliver information for continuous communication regarding the achievements and impact of immunisation programmes, for example the continuous information on vaccination coverage, the benefits of infection control, reassurance thanks to continuous safety monitoring, and safety information.

Competent authorities responsible for human medicines

IIS can support national competent authorities who are responsible for the authorisation and post-licensing assessment of vaccines available in the EU through activities such as the monitoring of vaccine safety, monitoring of vaccine effectiveness and the impact of vaccines.

Monitoring of vaccine safety

IIS are critical assets for mass vaccination programmes, for example the 2009 influenza A(H1N1) pandemic, when a large population is vaccinated in a short period of time and timely (daily, weekly) safety information is necessary to respond to any potential safety concerns.

Some European countries, for example Belgium, Latvia, Portugal, Romania, Ireland and Spain, use the IIS to report adverse events following immunisation (AEFI).

When health providers are informed of adverse events in Ireland, the IIS is used to record AEFI but the system does not automatically report it to the governing authority. There are manual reporting procedures in place for this, which include either an online reporting system, a postal or a telephone notification. In Belgium, a provider can

add AEFI to the patient record in the IIS. AEFI are marked in colour so they cannot easily be overlooked by the provider at the time of future vaccinations. In Norway maintains a separate system for AEFI (a spin-off from the main IIS) due to privacy regulations; despite these restrictions, the systems can be linked for specific purposes (e.g. research projects).

In the Valencia region of Spain, AEFI are reported to the IIS by the provider; this information appears in the patient immunisation history. It is also connected to the pharmacovigilance centre of the region to provide real-time information of AEFI that are recorded for individual vaccination. AEFI can also be reported directly to the pharmacovigilance centre, but over 98% of reports come through the IIS.

Box 17. IIS in practice: Scottish Immunisation and Recall System – adverse event monitoring

In order to investigate a possible association between fever admission and four-component meningococcal B vaccine (4CMenB), a self-controlled case-series study was carried out, using linked, routinely collected healthcare data (risk period: three days immediately following receipt of a vaccine dose), extracted from the Scottish Immunisation and Recall System (SIRS) [44].

Vaccination records for all children born between January 2013 and August 2016 were extracted from the SIRS. This study concentrated on vaccinations given at 8, 12 and 16 weeks. Combined diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type B (DTaP-IPV-Hib) vaccine records were examined to enable a consistent comparator pre-introduction and post-introduction of 4CMenB. Vaccination records were matched with fever cases using the community health index (CHI) number.

This study has demonstrated the usefulness of proactively monitoring hospital admission data for potential adverse events following immunisation and the ability to further investigate by linking to vaccination records using the CHI number. The results have shown a significantly increased risk of hospital admission with fever within three days of the routine childhood immunisation at 8 and 16 weeks (doses 1 and 3) following introduction of 4CMenB. The results indicate that further understanding of the current use of prophylactic paracetamol is needed [44].

Box 18. IIS in practice: IIS in UK (England) in adverse events monitoring

The IIS in the UK (England) has been used in various vaccine safety studies. The aim of one such study was to evaluate the feasibility of performing collaborative studies across Europe by assessing a known vaccine-associated event. The study also enabled the calculation of a reasonably precise estimate for the risk of thrombocytopenic purpura (TP) following MMR using data on hospital admissions linked to immunisation data from England and Denmark. In England, cases (based on ICD10) occurring between 1 April 1996 and 31 March 2007 were linked using NHS number or gender/date of birth/postcode to immunisation records in regional immunisation registers [45].

Another study used the IISs in England for vaccine status (type of vaccine, date given) of children included in the food allergy and intolerance research birth cohort and found no association between atopic outcomes and type of vaccine used [46].

Monitoring of vaccine effectiveness

Box 19. Value of IIS for the medicines regulator, the European Medicines Agency

From the medicines regulatory perspective of the European Medicines Agency (EMA), IIS systems are of paramount importance in generating timely data to monitor and support the assessment of vaccine benefits and risks across the EU Member States. [47]

When an adverse event is caused by a medicine, it is reasonable to assume that it will be reported more often (above the reporting rate associated with the background incidence), and hence the reporting ratio will tend to be greater than one. High values of the ratio for a given drug–event combination (DEC) suggest that further investigation may be appropriate. In practice, a formal set of rules, or signal detection algorithm (SDA), is adopted. This usually takes the form of specified thresholds that the ratio or other statistics must exceed, but more complex conditions may also be used. When these rules are satisfied for a given DEC, it is called a signal of disproportionate reporting (SDR). Then a decision needs to be made regarding whether further investigation is required [47].

High-quality IIS data linked with electronic health records can be used to monitor benefit–risk balance for vaccinees, particularly for risk assessment, safety and effectiveness studies of new vaccines or for vaccines indicated for new populations. Vaccine batch level data, as provided by IIS, enable the rapid identification, management, and response to vaccine quality issues associated with specific vaccine batches.

The availability of EU-wide IIS data could bring about improvements to vaccine safety monitoring of serious and rare adverse events that require a large population to warrant accurate assessment.

2.2.4. Health researchers

Access to high-quality aggregated or individual-level immunisation data enables health research to be performed in areas such as immunisation impact, vaccine effectiveness, vaccine safety and cost-effectiveness studies. Availability of data for research can enable the generation of high-quality evidence to guide interventions. It can also help identify problems in following recommended schedules, for example immunisation timeliness and vaccine co-administration, such as in the UK (England) where Public Health England looked at the timing of receipt of primary immunisations in London using the IIS records and factors influencing late receipt. Assessment and reassurance of vaccine safety and effectiveness are other areas where high-quality data are essential.

Recording clinical or lifestyle risk factor information can help better understand and optimise the immunisation effects. In a 2016 ECDC survey, four systems (Germany, Latvia, Portugal (mainland) and Spain (Andalucía)) out of 16 (25%) could record clinical or lifestyle risk factors of the immunised person. Germany is currently adding variables for the identification of selected clinical risk groups.

The individual-level health records are regulated by national legal frameworks, which can impact the level of detail allowed to be recorded in the IIS.

Examples where IIS data were used in research in order to inform decisions include the following projects:

- Estimating vaccine effectiveness during the influenza A(H1N1)pdm09 pandemic in Norway [48]
- Written reminders to increase vaccine coverage in Denmark [49]
- Detecting suboptimal MMR2 vaccine coverage in Norway [50]
- Assessing varicella vaccine effectiveness and its influencing factors in Germany [51]
- Assessing the long-term effectiveness of the 4HPV vaccine in Denmark, Iceland, Norway, and Sweden [52]
- Assessing vaccine safety in the Valencia region of Spain [53]
- In regular updates presented to the UK Joint Committee on Vaccination and Immunisation, coverage data are key in modelling, informing the need for catch-up programmes. These data are also used for estimating vaccine effectiveness of numerous programmes, most recently following the introduction of the 4CMenB meningococcal B vaccine in the UK [54].

Access to IIS data occurs within the security parameters established by each country.

Box 20. The value of IIS for epidemiological research

Health research in the context of immunisation encompasses the domains of vaccine usage (coverage), safety and benefits (effectiveness and impact) of vaccines and immunisation programmes. Ultimately, the IIS' function is to accurately record who has been vaccinated with which vaccine, as well as who has not been vaccinated.

When made available for research, IIS data will directly benefit research efforts by delivering high-quality evidence at higher speed and lower cost. This, in turn, will support decisions by public heath agents, healthcare professionals and individuals. Active engagement will enable health professionals to provide optimal immunisation advice and improve individuals' confidence when reasoning about acceptance of specific vaccinations for them or those under their care.

Research using the IIS could deliver high-quality evidence about the use of vaccines, their safety, and the benefits of immunisation programmes. It could also foster the development and improvement of immunisation approaches. This would help to increase confidence in immunisation programmes and facilitate health decisions across all stakeholders in immunisation.

Collaboration could strengthen individual systems: a pan-European network of IIS aligned with public health needs and research priorities would increase the overall quality of data and enable dissemination of good practice. It would enable Member States to develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems, while taking into account all rules on personal data protection as set out in the Commission Communication on enabling the digital transformation of health and care in the digital single market [18].

Independence of IIS from commercial interests

To maintain a high level of trust in the system it is important to ensure its transparency and independence. It is suggested that processes are in place to ensure and monitor this, including collecting, reviewing, updating and disclosing declarations of interests of persons responsible for the IIS and its funding.

Section 3. An enabling environment for IIS

In this section we:

- describe the legal environment for IIS;
- consider the implementation of the General Data Protection Regulation (GDPR) both across and within countries, particularly focusing on consent; and
- outline the principles of the use of IIS data for the benefit of individuals, public health, and scientific research.

It is important to have regulations governing IIS in place before starting to implement an IIS. We recommend careful consideration of the legal context for IIS at an early stage, ensuring that it commences before system development so that data protection principles can be built into system design.

3.1. The regulatory environment: legal and data protection

In 2012, the European Commission initiated a comprehensive reform of the EU's 1995 data protection directive 95/46/EC [55] due to the following facts:

- Rapid technological and business developments have brought new challenges for the protection of personal data.
- The 27 EU Member States had implemented the 1995 rules differently, resulting in divergences in enforcement [56].

Within the common EU rules, the general data protection principles remain unchanged, but are translated into the context of modern technological developments. They aim to:

- strengthen individual fundamental rights in the digital age;
- facilitate business by simplifying rules for companies in the digital single market; and
- reduce fragmentation and administrative burdens [57].

The reformed EU rules provide more clarity on definitions and facilitation of the use of health data for scientific research, public health and social security systems. This has a direct impact for data that will be contained within an IIS.

The EU-wide data protection instrument, the General Data Protection Regulation - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [58] entered into force on 24 May 2016 and became directly applicable on 25 May 2018 [59]. Some key features of the General Data Protection Regulation (GDPR) are given in Box 21.

The official text of the Regulation was published in the Official Journal of the European Union on 4 May 2016.

Box 21. Key features of regulation (EU) 2016/679

- Single and comprehensive set of rules in all Member States
- Reinforced rights of individuals, including the 'right to be forgotten'
- Same rules for entities based within and outside the EU
- The establishment of a one-stop-shop mechanism for businesses and individuals
- Promotion of 'privacy by design'
- New safeguards: privacy impact assessments, mandatory DPOs.

3.2. Implementing the General Data Protection Regulation (GDPR)

Legal principles for the processing of personal health data

Under the GDPR, processing of personal health data is generally prohibited, unless it falls into one of the expressly foreseen scenarios in Articles 6 and 9 of the GDPR (i.e. there is a 'legal basis') [58] .

'Personal data' refers to any information relating to an identified or identifiable natural person; personal data can be either:

- pseudonymised: data that can no longer be attributed to an individual without the use of additional information; or
- anonymised: data that can no longer be linked to an individual.

Accordingly, processing of personal health data is legal if it is for individual level benefit, through informed consent; or in specific situations where consent is not required. For the purpose of IIS, no consent may be required in situations where processing is necessary, referred to in Chapter 11: Processing of special categories of personal data, Article 9, paragraph 2 [58]:

- to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;
- for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems on the basis of a law or pursuant to contract with a health professional;
- for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices; and
- for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

In all these scenarios, a number of general principles should be respected. In particular, the data should be:

- collected for specified, explicit and legitimate purposes;
- adequate, relevant and not excessive in relation to this purposes;
- accurate and, where necessary, kept up to date;
- kept in a form which permits identification of individuals for no longer than is necessary.

Accordingly, the following consent considerations should be taken into account when processing health data:

- **Processing with consent:** An individual needs to provide active, informed consent for data to be collected. Silence, pre-ticked boxes, and inactivity do not constitute consent. Consent can be broader to cover permission for pre-defined scientific research purposes (Recitals 32 and 33, Article 7 of the GDPR). The individual should also be informed why the data are collected, who has access, how long they are kept and where he/she can turn to in case of complaints.
- **Processing without consent**: In many cases, it is required that data processing is conducted by a health professional under professional secrecy or social security systems. In other cases, measures should be taken to limit the amount of personally identifiable information by applying anonymisation or pseudonymisation techniques. For example:
  - Individual-level identifiable data may be processed without consent when vital to the data subject. Only the data strictly necessary for this purpose should be processed and preferably this information should be handled by health professional under professional secrecy.
  - If data are processed because it is necessary for the interests of public health or for scientific research, the data should be (pseudo)anonymised as far as possible.

Implementing the GDPR

The general data protection principles of the GDPR are largely the same as in the Directive, but there is improvement in harmonisation of the data definitions, including clarifications of the notions of 'personal data', 'consent', 'data concerning health', 'genetic data', and 'biometric data'. The GDPR also introduced the new concepts of 'profiling' and 'pseudonymisation'. General principles of the GDPR need to be linked to the specific needs of the IIS.

Member States will need to assess the provisions in pre-existing national laws, and sectoral laws (e.g. for health data) to see if existing legislation can be applied. The GDPR is directly applicable in the national legal system, therefore no implementation measures are needed. However, when references are made to specifications/restrictions by Member State law, the Member State may incorporate elements in their national law, as noted in particular in Article 9(4):

'Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health'.

'Health Data' refers to data collected in the context of provision of healthcare services as defined in Directive 2011/24/EU (Recital 35 of the GDPR).

3.3. Principles of the use of IIS data for the benefit of individuals, public health, and scientific research

IIS functions can be used for the benefit of individuals (Box 22) and for the benefit of public health and scientific research (Box 23).

Box 22. IIS benefits to individuals

1. Clinical decision support

- Recording immunisation information: user-friendly, high-quality recording of data on new vaccinations.
- Access to immunisation information: access to consolidated immunisation records at the point and time of immunisation administration. This enables the immunisation provider to determine appropriate vaccinations.
- Forecasting of immunisation: functions that actively determine vaccinations due, past due, or coming due ('immunisation forecast') for individuals. These are visible to healthcare worker users upon viewing an individual's immunisation record.
- Reminder/recall notifications: production of reminder/recall notifications from within the IIS itself or from interoperable systems.

2. Report generation

- Immunisation report generation: IIS can generate and provide a report of individual immunisation records for authorised health personnel and/or for individuals (or parents/guardians with custodial rights).
- Immunisation record portability (regional and international record transfer).

Box 23. Potential IIS benefits to public health and scientific research at the population level

1. Vaccination coverage monitoring

- Monitoring vaccination coverage
- Dose and schedule compliance
- Characteristics of the non-immunised population

2. Communication

- Dissemination of information, for example on vaccine and programme introduction, changes in immunisation schedules, and vaccine recommendations updates

3. Supply chain management

- Vaccine ordering, request, distribution, and stock management
- Batch recall of vaccines: provide the necessary reports and/or functionality to facilitate vaccine recalls, including the identification of recipients by vaccine lot, manufacturer, provider, and/or time frame

4. Safety monitoring; surveillance of adverse events following immunisation

- Monitoring of vaccine administration
- Adverse event reporting and safety monitoring: facilitate reporting and/or investigation of adverse events following immunisation

5. Research

- Vaccine impact and effectiveness studies
- Exploratory studies, e.g. identifying problems in following recommended schedules, for example immunisation timeliness and vaccine co-administration.

IIS and benefits to individuals and populations

Here are some of the considerations that are relevant in the particular case of IIS and in light of its benefits to individuals and populations:

- **Individual benefit**: processing data for the benefit of individuals in the context of an IIS can be focused on providing immunisation healthcare providers access to individual data as part of routine care.
- **Vital to the individual**: processing individual indefinable data without consent can be a necessity if there is a vital interest of the individual if the individual is temporarily or permanently incapable to give consent, for example, the assessment of tetanus immunity in the event of major trauma on admission to emergency room. In such a case, the data controller could consider sharing the information in existing records with the respective health professionals without consent.
- **Processing data for scientific research in the interest of public health:** The GDPR now expressly foresees the possibility to process personal health data for this purposes, provided that sufficient safeguards are in place:
  - The rationale, scope, and approval process for the processing of IIS data for the purposes of health research should be regulated in detailed governance frameworks to ensure compliance as well as transparency.
  - Only a minimum set of personal data is used and submitted to a shared workspace (data minimisation)
  - Data are pseudonomised (e.g. by removing personal identifiers that are not needed for the purpose of the processing) and data subjects may contact researchers to get their data erased
  - Involvement of the national data protection authority at an early stage is also advisable.
- **Linkage of IIS data with other systems** strengthens both the IIS itself (for example, by reducing the need for entry of data which exist in other systems), and broadens the usability of IIS data for research. Interoperability and standards should be a key issue for consideration when designing any IIS.
- **Determining which stakeholders should obtain access:** it is important to consider competing interests when providing access to stakeholders, particularly regarding the confidentiality of the use of information with regard to market competition.
- **Defining the use of different data elements.** To ensure that patient privacy is maintained, it is important to define the use of each data element and match it with the needs of those who were given data access.

Harmonisation of a minimal dataset and creation of a standardised immunisation record across the EU/EEA could improve continuity of immunisation when citizens, in particular children, move from one Member State to another.

It is important for Member States to work together to develop a common understanding on how the data protection principles shall be applied to the main functions of IIS.

Country-specific examples of practices

Box 24. Addressing privacy concerns in Denmark

In Denmark, there was a concern that too many healthcare personnel can access the complete medical records stored in the electronic medical chart (which incorporates the vaccine register).

In 2015, a law was introduced that specifies who can access the data and what data should be recorded.

Patients can define the use of their data in detail, specifying which information in the medical chart can be viewed by medical personnel. In specific situations, such as emergencies where the patient is unconscious, full record access is granted to medical personnel. This feature is not specific for vaccination data and more relevant for data considered sensitive, such as treatment for HIV.

Informed consent upon record creation

Box 25. Informed consent for CANImmunize

In Canada, CANImmunize [60] is an application (mobile and web) that allows individuals to create accounts within which they can store immunisation records for themselves and their family members. Before a user can create an account, they are presented with a screen which describes in plain language how the application works. This includes sections on what data the app collects, how they are protected, how users can delete their information, and under what conditions the information entered by the user is shared with third parties. The user is also directed to review a comprehensive privacy policy and terms of use, which they must accept before being allowed to access the application.

CANImunize can share data with other IIS, but users must always provide an additional layer of consent indicating that they allow CANImmunize to share their immunisation records with the trusted third-party software before data are exchanged.

Informed consent upon application download

Box 26. Informed consent for MesVaccins.net

In France, when an immunisation record is created on MesVaccins.net, all data are stored in a central, secure server with health data management regulations (approved by the French ministry of health). The data are not portable. When the tool is integrated with the health professional electronic health record system, the data are also replicated locally to the patient file.

In accordance with French regulations, patients who create records themselves must also share personal health information records with health professionals (pharmacists, hospitals, etc.). They can stop the sharing at any time.

When a record is created by a health professional, the following applies:

1. Authorisation from the patient is required for the record to be shared/stored on the MesVaccins.net system. Authorisation is traced through the system.

2. If authorisation is not received from the patient, the health professional can use the information in the record that they have created locally. This provides support to clinical decision-making as part of the integrated patient chart.

Family-based consent applies to children, who are incorporated in an adult's record. Once the child becomes an adult, the record can be transferred from the initial account into their own personal account.

Section 4. System design and development

In this section we propose several design points that we suggest for consideration when designing an IIS.

We consider system design from a 'high level', describing the way that different systems have emerged in four countries, particularly noting the difference between centralised top-down and decentralised bottom-up strategies.

We then discuss system-level considerations, considering the conceptual design behind each of the key IIS components, and illustrating each with an example of how the component has been implemented in practice for SYSVAK, the Norwegian immunisation system and for other contexts internationally.

As outlined below, we suggest first identifying the problem, and then the IIS needs and key functions that will meet them, before identifying the minimum fields required to support the key functions. When considering this, refer to Figure 2.

Identify the problem. The problem or issue to be solved through the setting up of an IIS or alike is dependent on the setting and the set objectives. This is the starting point that will help define system needs, required functionalities and data needs. The problem to be solved may be very complex and could include:

- programmatic needs such as determining immunisation coverage levels in real-time;
- consolidating information from different IIS (e.g. regional IIS); and
- consolidating vaccine information collected by different providers.

Identify the system needs. Consider the problems that you are you trying to solve and determine the corresponding needs of the system.

Identify the key functions to meet the needs. What are the minimum functions an IIS should offer? What will the system do to address the key needs?

In general, the functionalities provided by IIS systems aim to:

- ensure recording of vaccination at the point of immunisation and including all stakeholders involved in vaccination programme delivery;
- increase vaccination data timeliness, quality and completeness, and demographic information;
- ensure the security of storage and guarantee accessibility to data by authorised stakeholders;
- enable linkage of individual vaccination data to other healthcare data information systems to ensure monitoring of vaccine administration and vaccine benefit–risk assessment.

Identify the minimum fields to support the functions. What fields must be captured to support the key functions?

4.1. High-level considerations

A number of different approaches to improving the quality of immunisation data using IIS have emerged in different countries; every approach has both advantages and challenges.

The adapted approach is dependent on the specific setting and context. To develop the most appropriate approach for a context it is important to determine who the target system users are and meet with them to ascertain their needs and incentives for system use.

In this section we describe the way that different systems have emerged in different countries of the EU, particularly noting the difference between centralised top-down and decentralised bottom-up strategies.

In both Denmark (Box 21) and Croatia (Box 22), where a top-down approach was taken, the public health information platform is managed centrally by the National Institute of Public Health. In the UK (Scotland) where the approach to the IIS is top-down and the responsibility of the National Health Service, the IIS is one part of a nationally coordinated immunisation programme, including other elements such as procurement, logistics, public information, healthcare training and impact evaluation. In the UK (England) the process is a mixture of top down and bottom up, with national specifications on what data to collect, but for the local health authorities to decide on how to implement it. In England there is no national IIS but a number of local IIS that are increasingly interoperable and can track people moving from one area to another. The Public Health England central level extracts data from each of the local IIS, using standardised data extraction specifications. Establishing this type of top-down approach to an IIS may be more difficult in countries where multiple stakeholders are involved or where public health responsibilities lie at regional level.

For a bottom-up approach, we look at the initiative started by an independent group: MesVaccins.net in France (Box 30), an approach which is now being considered for national implementation [61], and the IIS in Valencia Spain (SIV) (Box 23). The SIV in Valencia is used only in this region and comes under the responsibility of the

Valencia public health authorities. There are 17 regions in Spain, and each one is responsible for public health in that region, however the national objectives and basic directives are established and coordinated between the health ministry of Spain and the regions (Consejo Interterritorial del Sistema Nacional de Salud). Every region has its own IIS or EIR, but all of them analyse the same indicators that are sent annually to the Spanish ministry of health. The Health Authority of the Valencia region implemented an integrated health system with different, integrated health registries. This included the IIS of Valencia (SIV), which was established in 2002. Since then, the SIV has evolved and new modules, tools and utilities have been developed.

Fundamental differences between different European contexts in terms of legal regulations, IIS management, and user incentives

There exists a large degree of variation between Member States in areas of IIS design and management. This variation can affect the IIS development process and includes factors such as:

- individual data and confidentiality;
- regulation of immunisation programmes, including mandatory vaccinations, record keeping and reporting of administered vaccinations;
- organisation of immunisation programmes, including the division of responsibilities between health providers at local, regional and national health services;
- funding of immunisation programme

In an ECDC survey [10], 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'. Of the seventeen survey respondents with an IIS, thirteen countries have a national system, and four have subnational systems. Governance is the responsibility of:

- the national institute of public health (NIPH) in eight countries
- the ministry of health (MoH) in 2 countries
- the national health service (NHS) in Latvia
- both the NIPH and MoH in Portugal (mainland) and Romania
- the national health information system (NHIS) in Slovakia
- regional health authorities in Belgium (Flanders), Spain (Andalucía) and the United Kingdom (England).

System use can be driven by diverse incentives. A variety of different methods have been used in different contexts to improve data completeness, reliability, accuracy and punctuality :

- In Croatia, financial reimbursement through the health insurance fund directly incentivises the reporting of vaccination data; reporting on vaccinations administered is relatively complete.
- With the French MesVaccins.net system, development has been user centred from the bottom-up, and as the system responds to a need from health professionals, enrolment has been voluntary: health professionals pay EUR 30 per year for a subscription.
- In Canada, CANImmunize is designed to meet the needs of individuals and address the challenge of maintaining paper records. It also provides immunisation reminders and timely and accurate information about vaccination and vaccine-preventable disease outbreaks in the user's proximity. The federal government funds CANImmunize, which is provided free of charge to all Canadians.
- In Denmark where there is a top-down system in place, the use of the IIS is legally mandated.

4.1.1. A top-down centralised approach

In Denmark, the immunisation information system has evolved over time through ongoing modification of existing information systems at the national level, and development of the IIS greatly benefited from existing data and structures (Box 27). In Croatia an IIS is currently being developed and will be embedded within the health information platform. The system is currently being driven by a high-level health information strategy (Box 28).

Box 27. The evolution of systems that capture immunisation information in Denmark

The IIS in Denmark, the Danish Vaccination Register (DDV), is an electronic patient record, populated through linkage to the civil and healthcare population registry, and by real-time data entry at the time of vaccine administration. The system is financed by the national government and governed by the national institute of public health [62] and primarily aims to facilitate calculation of vaccination coverage (previously, calculations were based on distributed doses) and access to individual-level immunisation records. The national board of eHealth is responsible for the IT/technical development and the integration of the systems in the hospitals and GP IT systems.

The DDV in its current form benefitted greatly from existing immunisation information systems:

2000	National childhood vaccination database based on reimbursement data and used for estimation of vaccination coverage and research
2008	National vaccination register (including data on reimbursement of vaccinations outside the national childhood vaccination programme)
2013	Voluntary national system in the form of an electronic patient record with access for citizens and healthcare personnel
2015	National system became compulsory [62].

Development of the DDV benefitted from existing data and structures. In Denmark, all citizens have a unique identifier. This makes it possible to match information from vaccinations from different sources, and ensures easy and secure access to the register [63]. The existing research registry contained immunisation data. This was of great value for piloting the DDV data structure, facilitating system development, and incentivising system use through interest in using the data; although linking and matching existing data was challenging. The vaccine record was made part of the existing electronic medical charts system. These medical charts are accessible to citizens and health personnel, who can access and add information if the citizen is 'in treatment'.

Box 28. A centralised, multi-component platform for health information in Croatia

A top-down driven project was initiated to develop an IIS as there was no dedicated, systematic way of collecting vaccination data in Croatia. Indicators such as coverage had previously been estimated using a variety of sources.

Croatia has an existing public health information platform. Registries are being developed in parallel, and progressively integrated into the health information platform. So far, 15 national registries have been developed in seven domains, including:

- domain of infectious diseases (HIV/AIDS registry, tuberculosis registry, Legionnaires' disease registry, infectious disease registry)
- hospital domain (abortion registry, registry of births, hospitalisation registry and registry of psychosis)
- domain of causes of death (registry of causes of death and registry of suicides)
  domain of resources in healthcare
- domain of chronical non-infectious diseases (cancer registry and diabetes registry (in the making))
- domain of addiction to drugs
- domain of disabilities.

An IIS component has been developed, although not integrated at the time of the writing of this document. The system aims to re-use data that are already collected for the health insurance fund, for the benefit of public health, facilitating data input, data access, reporting, analysis, and surveillance (e.g. assessment of yearly coverage, compliance with the official immunisation calendar, adverse events case identification). It will also benefit individuals through linking to citizens e-portal services which contain administrative data for every Croatian citizen, including health data. Through this, citizens will be able to obtain immunisation certificates.

An external IT vendor is developing the multi-component platform. The design of the IIS component has so far been defined by what is technically possible, so in essence it is driven by top-down needs, e.g. by technical issues such as system interoperability. Once implementation is commenced, the needs of the system (e.g. data

outputs and user experience) will be further considered and the platform will be expanded as is necessary to meet any recognised gaps in the system.

Croatia's experiences with developing a platform of this type are outlined below:

Advantages:

- Simplifies platform-level changes: if changes need to be made (e.g. to ensure compliance with the GDPR), they can be conducted on the platform level.
- Reduces duplication of effort in system development: if a completely new platform were developed for each health information module, there would be repeated effort in set-up processes (e.g. in establishing new legislation, a new framework and protocols, and providing support).
- Improves transparency: in Croatia, IT vendors implement most applications. A centrally managed platform facilitates higher transparency during development processes, and documentation ensures easier maintenance and interoperability.

Challenges:

- IIS prioritisation: as IIS is being developed as part of a multi-component system, resources are not specific to IIS, and project progress is dependent upon whether IIS is considered a priority in the wider health/eHealth system.
- Data completeness: Immunisations are not always recorded in the central healthcare information system as there are different types of healthcare providers: Privately funded services are not likely to be recorded. In Croatia, these currently only represent a very small fraction of immunisation services.
- Standardisation: Due to the integration of the IIS with multiple other system components, modification of shared resources for specific needs is dependent on collaboration (e.g. preferences for different coding system standards, such as ICD-9 vs. ICD-10).
- Compatibility: As new system modules (i.e. IIS) are added, it is necessary to track the impact of their development on the wider system, i.e. other health information modules.

4.1.2. A bottom-up approach

The Valencia region in Spain has independently developed its IIS; it is one of the IIS operating at subnational level in Spain.

Box 29. Valencia – IIS

The IIS in Valencia (SIV) [33] was established in 2002 by the health authority (Dirección General de Salud Pública-Conselleria de Sanidad Universal y Salud Pública-Valencia region). The IIS holds the information on immunisations carried out in Valencia region which has a population of five million inhabitants (slightly over 10% of the Spanish population). The initial objective of the SIV was to record all immunisations. Since its implementation, improvements and new utilities have been incorporated, and it is now a very useful tool for different stakeholders (policymakers, programme managers, healthcare workers, individuals, researchers etc.). It is also used as a tool for the evaluation and monitoring of vaccination programmes.

The IIS provides a population-based nominal record that meets the requirements of confidentiality, security, simplicity, flexibility, compatibility, accessibility, thoroughness, data quality, and information feedback.

Over 64 000 healthcare workers from all the public health centres (around 1 350) and more than 780 private centres of Valencia region have access to the SIV. Individuals also have secure online access to their vaccination records.

Advantages of the system:

- Unique ID allowing linkage: all individuals have a unique health identifier. The SIV allows to link nominal (labelled or named) immunisation data with the information contained in other health record databases (medical history, hospital discharge records, pharmacovigilance, epidemiological and microbiological surveillance system) and population denominators through a unique personal identification number.
- Real-time data: all the information (immunisations, adverse events) is based on real-time reporting. Healthcare workers and health authorities have access to up-to-date data at any given moment.
- Immunisation data by individual characteristics (age, sex, risk group): this benefits data analysis at the individual and global level.
- Data warehouse for immunisation coverage: analysis (by birth cohort, and individual and vaccine characteristics).

- Vaccine refusal registration: identification of vaccine hesitancy.
- Vaccination recall: patient reminders by SMS or possibility to generate letters.
- Programmatic errors registry: programmatic errors in the management of the storage, reconstitution, handling, or administration of the vaccine may contribute to the occurrence of adverse events. The registry and evaluation of them provides quality improvement of the vaccination programmes.
- AEFI registration and monitoring: surveillance and evaluation of the vaccine safety in real-time.

Challenges of the system:

- Different modules: SIV is a multi-component system with five integrated modules. The different modules and utilities have been developed over time. Immunisations, vaccine refusal, programmatic errors and AEFI reports are registered in the nominal immunisation registry (RVN) module; the indicators module provides information on vaccination coverage; the back-office module allows identifying non-vaccinated people and an active recruitment of target populations, extraction and management of the AEFI reports among other actions; the warehouse vaccine register (RVA) allows an effective control of vaccine stocks, thus providing traceability information of all vaccines; the traveller consultation (CONVI) module keeps records of the individual traveller, travel characteristics, vaccinations administered, and malaria chemoprophylaxis.
- Compatibility: with public health, primary, specialised and hospitalised care and management systems
- Standardised codes for risk groups (ICD-9 vs ICD-10).

In France, a system has been developed independently to meet needs expressed by health workers (Box 30). It is to be understood that this is not an established IIS; it responds to specific needs in addition to efforts to develop a national IIS [61].

Box 30. MesVaccins.net in France – an electronic vaccination record incorporating an expert medical decision support system

In France, vaccination recommendations are complex: more than 500 individual characteristics (demographic, health status, etc.) determine specific vaccine recommendations. When vaccination advice given to patients is inconsistent, this can lead to doubts and vaccine hesitancy. MesVaccins.net was established as an initiative to empower patients to make informed choices about vaccination through enabling the right information to be delivered to every person (individuals and health professionals) at the right time.

To support vaccine providers, the system creates personalised vaccination recommendations for patients, using decision rules for different vaccine preventable diseases and individual patient characteristics (e.g. age, gender, profession, medication, chronic disease). An explanation of the reasons for why the vaccination is required, and the conditions under which it can be obtained (e.g. reimbursed under the health system) is provided along with each recommendation, and a double interface enables appropriate messages to be addressed to both health personnel and patients. Rules of the immunisation clinical decision system are written directly by vaccinology professionals without going through the IT team and take into account any relevant information within 48 hours (e.g. new recommendation, change in the summary of product characteristics, vaccine shortage, and ongoing outbreaks).

Beyond the original concept, additional features have been added to the system in response to needs of individuals and the public health system. These have included enabling the system to 'know' if an individual is up-to-date by capturing their vaccination history, and feeding data into a national database to provide information for the calculation of vaccine coverage and for health communication activities.

MesVaccins.net was piloted in the Gironde and Landes regions of France in 2014. As of August 2018, it hosted 500 000 patient records, the website received more than 12 000 visitors per day, more than 13 000 health professionals had paid for the use of the system. The system is free for the general public. The conclusion from the pilot project was that MesVaccins.net could help improve the application of vaccine recommendations and that integration with medical software would facilitate its use on a large scale. The exchange of health data with third-party applications is based on the FHIR (Fast Healthcare Interoperability Resources) standard.

MesVaccins.net started as a private initiative addressing a specific need of health professionals, but the long-term goal is to implement MesVaccins.net as part of the national shared medical records. A government vaccination information service website is already using the MesVaccins algorithm (http://vaccination-info-service.fr/), there is government funding for a pilot in an additional region, and the government has released software for vaccination centres that integrates the electronic immunisation record.

4.2. System-level considerations

There are a number of different considerations to be taken into account when approaching system design (Table 1).

Table 1. System-level design considerations

System-level design	Considerations
Existing system(s) available	It is important to consider how other existing systems can be leveraged to build a comprehensive IIS, as opposed to duplicating efforts and building a new system from scratch.
Spatial scale	Systems can be centralised (national) or decentralised, for example regional systems.
Users	If there is a diversity of users of the system (e.g. nurses, GPs etc.) and vaccine delivery is complicated (e.g. different settings), then the system will need to be more complex to capture this.
Inputs/Outputs	Systems can incorporate one or more input systems. These systems can then communicate to one or more other systems.
Vendors	One or more vendors of one or multiple systems.
Ownership	All private, all public, or a public-private mix.
System interface	Choices include, for example, web or mobile applications.

Country-context-specific factors that will affect design decisions include:

- System purpose and objectives
- Population size
- Government
- Legal limitations
- Infrastructure
- Funding
- Availability of data in other systems, for example a unique identifier number
- eHealth strategy

Most importantly, systems should aim to produce data of high quality i.e. data that is complete, reliable, and accurate. Importantly, all systems should be built with sustainability in mind (see Chapter 5).

When designing an IIS, the following elements, which are outlined in detail on the following pages, should be considered carefully:

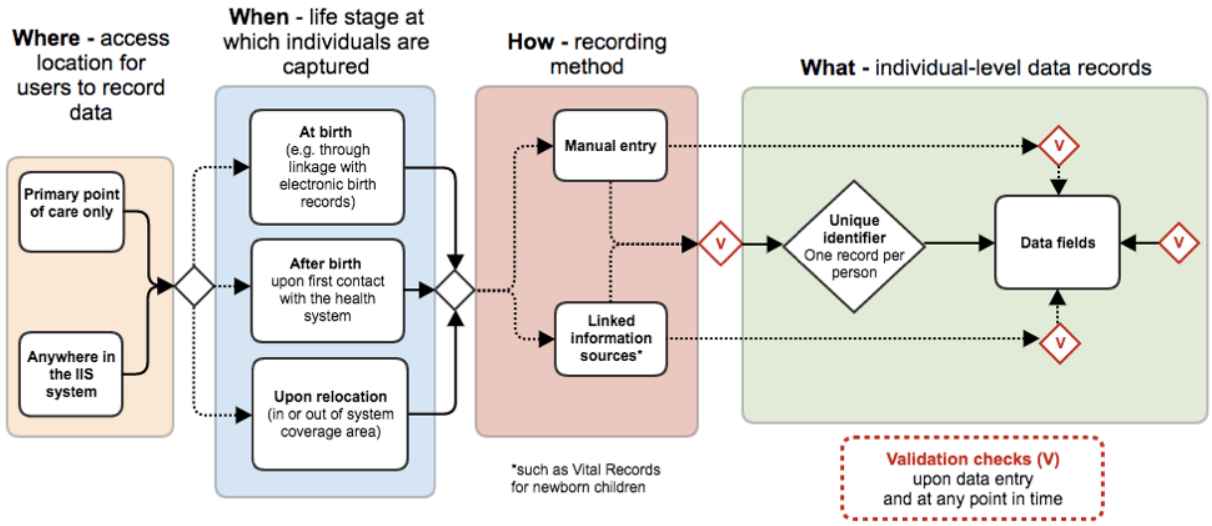
- Recording immunisation event data
- Data elements
- Establishing the denominator
- Ensuring data quality
- Storing data
- User access
- Linkage to other information systems and interoperability

4.2.1. Recording immunisation event data

When designing an IIS, decisions need to be made that are related to system user design for the recording of immunisation information (see Figure 3):

- Who? (Who will be using the IIS?)
- Where?
- When? (Point of capture of the target population)
- How? (Recording method)
- What? (Content)

Figure 3. Recording information on an IIS system: where, when, how and what?



To illustrate this process, the way that information is recorded in the Norwegian IIS SYSVAK is described in Box 31.

Box 31. Recording vaccinations in the Norwegian SYSVAK system

In Norway, IIS software is installed in a variety of different health settings. Most of the electronic patient record systems (EPR) used by the healthcare workers that administer vaccinations include a vaccine module with the option to record vaccination information directly in the national IIS, SYSVAK [64]. In Norway, all citizens have a unique identifier, which makes it possible to match information about various vaccinations from diverse sources.

EPR vendors have to be pre-approved, with acceptance testing towards SYSVAK. At the time of writing of this document, there were four pre-approved vendors in Norway (CompuGroupMedical, Infodoc, Hove Medical, and Visma). The IIS obtains data directly through digital data exchange from the EPR: the system operates in accordance with Norwegian national standards, with data exchanges standards (from the EPR to SYSVAK) based on ebXML technology.

There is also a reporting pathway for file imports and paper reporting for the vaccinators that are unable to connect electronically (e.g. smaller clinics which continue to operate using paper or using a journaling system that cannot connect electronically). In 2017, about 11% of data were reported by file import or paper reporting.

Ensure recording of vaccination: who, when, and where?

Vaccination should be recorded at the point of immunisation, including and accommodating the diverse needs of all stakeholders involved in vaccination programme delivery.

To ensure that all needs are met, it is important to identify the people who will use the immunisation information system and engage them in the design process. User-centred design (UCD) is used to describe design processes in which end-users influence how a design takes shape [65]. Strategies such as watching target users working in their regular environment, early involvement of users (including the design phase), and learning from user interaction with prototypes, enable developers to gain valuable insights [66]. Box 32 provides an example of how an IIS solution has to be tailored to user and communication environments.

Box 32. Choosing a solution that meets user needs in a specific context – the experience of the BID Initiative

The BID Initiative (implemented by PATH) aims to empower countries to enhance immunisation and overall health service delivery through improved data collection, data quality and data use. In Tanzania and Zambia, those involved in the BID Initiative and their government partners knew they had to find an IIS solution to meet the lower-resource settings of both countries. The initial systems developed for both countries required additional development work to address two key differences related to mobility and connectivity:

Mobility: The IIS solution originally selected for Tanzania was based on using desktop computers. However, Tanzania required a mobile-based solution instead because immunisation work in this context involves a lot of movement, both within the clinic and for community outreach. A desktop computer was not an option in this context, and it was decided that phone screens would be too small to complete the data entry work, so a tablet solution was considered a key requirement.

Connectivity: Internet connectivity in Tanzania was intermittent, hence it was considered a necessity to be able to work offline and synchronise later.

Source: [67]

Determining IIS access requirements and rights for different actors and organisations is essential during system development. Required legal and data protection approvals and operating guidelines have to be developed and approved in consultation with the competent data protection authorities.

Timeliness

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 available is updated in real-time. This is particularly relevant during emergency situations [68], including outbreaks when the prompt identification of unvaccinated people is necessary [69] (see also Box 12).

An ECDC survey carried out in May 2016 found that seven European countries out of 15 (47%) enter vaccine data in real-time. Other EU Member States report various lag times, within a range of one day to six months, for reporting. Some countries noted that lag time varies within a country due to geographical heterogeneities in factors such as the vaccine provider or the system of data entry [10]. For example, although the use of paper records is more typical of low-resource settings, the use of paper records still occurs in high-resource settings, for example smaller clinics in Norway.

Setting-up vaccination records

The way that vaccination records are set up will depend on wider systems in place in the country, for example systems for birth registration and national identification. In the EU/EEA countries surveyed by ECDC in May 2016, 63% (10/16) reported that an individual vaccination record was set up automatically at the time of registration of, or shortly after, a live birth (e.g. at the first vaccination visit). Forty-four per cent (7/16) of the countries surveyed set up a vaccination record automatically at the time of immigration [10].

Recording vaccinations administered

Comprehensive records that include all vaccinations (routine and non-routine) are valuable. This includes supplementary immunisation activities (SIAs) and mass immunisation campaigns (MICs) for example, and a whole-of-life approach to recording vaccinations. Comprehensive records are particularly valuable for strengthening childhood immunisation programmes.

In situations where multiple partners can enter data into the system, methodology should be in place to check for duplication of data, for example date of birth, names, initials, vaccine details, and address. In the Valencia region in Spain, the IIS checks and corrects duplication data. This is one of the quality points of the system.

At the time of writing this report, one challenge that Belgium encountered was double registrations: once in the electronic medical file (EMF) of the vaccinating GPs or paediatricians and once in Vaccinnet. To overcome this, there are now more automated uploads from EMF to Vaccinnet.

- **Prospective recording of vaccinations.** Based on an ECDC survey carried out in May 2016, systems in ten countries (63%) can record vaccinations provided at any age. Several systems (e.g. Hungary, the Netherlands, Romania, Sweden and England) do not include vaccination data for those above 18 years of age in their systems. In Ireland, the national IIS only records vaccinations included in the recommended school-based vaccination programme, and eight regional IIS only record the primary childhood immunisations [10].

- **Retrospective recording of vaccinations.** The May 2016 ECDC survey found that fourteen (88%) European country systems could record vaccinations that were given in the past. These can include vaccines administered across administrative boundaries both within and between countries. The May 2016 ECDC survey found that 13 countries (81%) enable vaccinations administered in another country to be recorded in the IIS. In four countries with subnational systems (Belgium (Flanders), Portugal (mainland), Spain (Andalucía) and the United Kingdom (England)), vaccinations administered in other regions can be recorded in the IIS. In the UK (England), there is no automated way to transfer vaccination history, however Public Health England are developing a tool to facilitate the coding of vaccines given abroad, using the Systematised Nomenclature of Medicine (SNOMED CT[70]) or Read Codes so they are included in the IIS and accounted for in coverage figures. In Belgium, the population living in some parts of the country is not included in the IIS, however they can request to be added through the federal government. The population database (additions, deletions and changes) is updated twice weekly [10].

How: methods for recording data in the system

IIS should enable two-way communication as a way to 1) enable vaccinations to be registered, and 2) facilitate search for vaccination data held in the IIS. The different stakeholders and their need for information, as well as the different mechanisms for information flow and interaction, should be considered at this stage. This functionality is available in a number of IIS and allows healthcare facilities to remind incompletely vaccinated individuals that they should book a time for the missing vaccinations; this feature is already available in Norway [50].

What: individual-level data records

A minimum set of information must be documented for immunisation event tracking. Data fields should capture this information, while keeping in mind the purpose of the system and legal limitations. The data elements structure should be sufficiently flexible to:

- accommodate the consolidation of demographic information and immunisation history for individuals;
- enable querying and analyses of data for population-level reports; and
- adapt to new vaccines, new schedules, and special situations as they arise.

4.2.2. Data elements

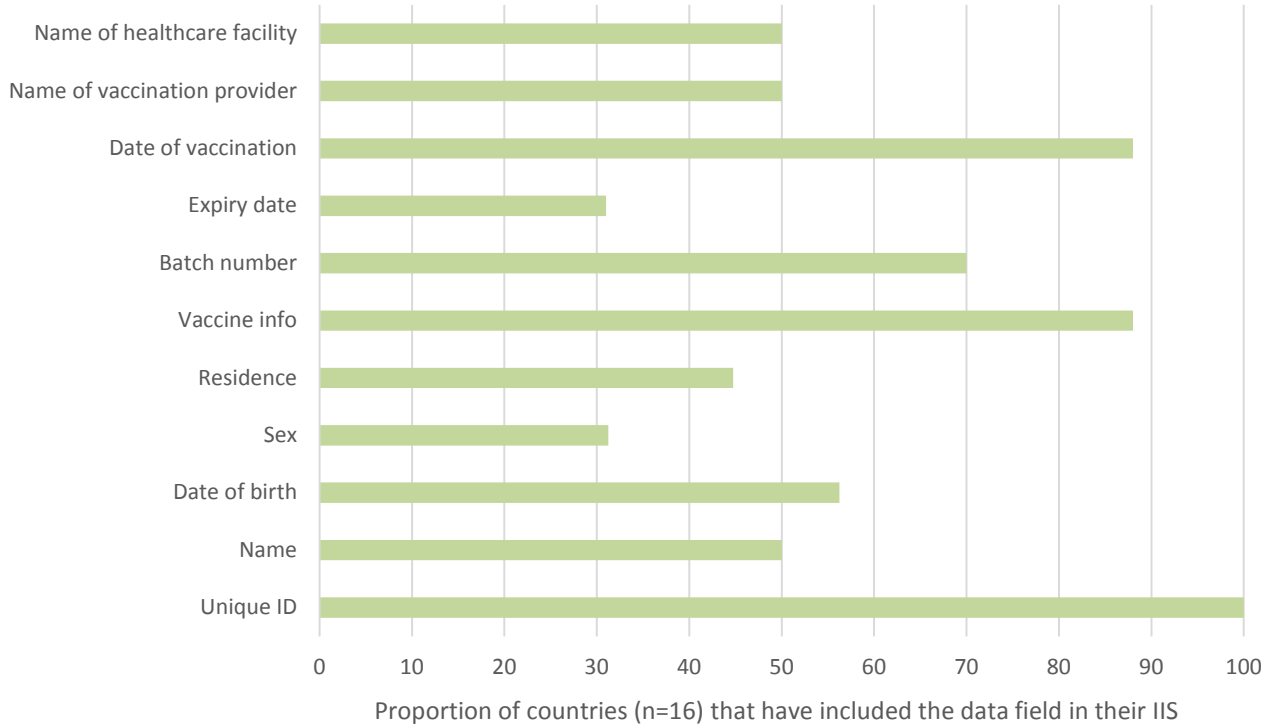
Each variable added to the system increases the collection costs, for example in terms of the time needed for a healthcare worker to enter the data into the system compared with a barcode reader that directly inputs the data into the system. When considering which data elements should be collected, the balance of the cost of entry versus the need for the data should be weighed up. The need for the data is dependent upon the objective of the system and its required functionalities. It is also extremely important to make a distinction between data that are immediately needed and data that are not routinely collected but can be obtained on an ad-hoc basis when necessary.

Standardisation

To facilitate interoperability between systems, standardisation at the level of data elements is essential [25]. Keeping data standardisation requirements simple and practical should remain a priority [25]. There is variation in the data elements captured within IIS in Europe (Figure 4). ECDC proposes an approach based on clearly defined standards (Box 33).

Standardised terminology is important for building a system that can communicate with other systems. It is imperative that standardised terminology is established at the project outset. Without that, the IIS will not function well, and it will be very difficult to alter terminology after project initiation. We recommend upfront investments in terminology standardisation. More information on how this topic was approached in some EU countries is given in Boxes 34–37.

Figure 4. A subset of data elements captured in IIS in EU/EEA countries (n=16)



Source: ECDC survey, May 2016 [10]

Box 33. ECDC proposal: standardisation

The IIS community is particularly interested in interoperability and data exchange. If the majority of partners exchange data only bilaterally (i.e. based on bilateral or limited multilateral agreements), the results will be inconsistent and lack transparency.

Data standards are the easiest way to generate high-quality, comparable data. Data standards are 'documented agreements on representations, formats, and definitions of common data' (structural standards, semantics), but also agreements on 'rules to describe how the data is recorded to ensure consistency across multiple sources' (process standards, e.g. syntax). 'Without data standards and data quality, the future of interoperability is bleak. Data fields and the content of those fields need to be standardised'. (This definition is indebted to the work of the Public Health Data Standards Consortium [71]).

The IIS community has the choice to develop its own standards (these have to be developed/kept available, regularly updated, etc., i.e. 'curated') or use external reference standards developed and maintained by standards development organisations (SDOs). We suggest that developers use reference standards established by SDOs as much as possible. The IIS community is not an SDO as such; managing standards needs human, organisational and financial resources and special expertise.

Introduction to data exchange standards – a multilayer approach

Data exchange is essentially messaging between systems. In this context, human users can also be considered a system. To communicate a message, multiple layers are involved, including:

- an 'envelope' that makes sure the content goes where it should and is not altered;
- a message holder (e.g. the paper we write on);
- an agreed language we use to formulate the message; and
- an agreed vocabulary of the content of the message presented in the agreed language.

Standards are needed across these multiple layers. ECDC followed this multilayer model to establish a set of reference standards for public health data exchange. The selection of standards was based on a literature study, best practice. consultations with experts from EU Member States and the evaluation aspects formulated into a series of evaluation criteria. We suggest the following standards for the various layers:

Layer 1. Message data dictionary

- Reusable content. MeSH (medical subject headings) is the National Library of Medicine's controlled vocabulary thesaurus used for indexing articles for PubMed; SNOMED CT is a multilingual comprehensive clinical terminology created by a range of healthcare specialists to support clinical decision-making and analytics in software programmes [70]; ICD11 (International Statistical Classification of Diseases and Related Health Problems) is now in its 11th revision [72]; MeDRA is a standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans; LOINC is a universal standard for identifying health measurements, observations, and documents.
  For EU administrative terms there is the EUROVOC, the multilingual, multidisciplinary thesaurus covering the activities of the EU. It contains terms in 23 EU languages, plus Macedonian македонски (mk), Albanian *shqip* (sq) and Serbian српски (sr).
- Standard structure of the dictionaries. A Simple Knowledge Organisation System (SKOS) [73] is an area of work developing specifications and standards to support the use of knowledge organisation systems (KOS) such as thesauri, classification schemes, subject heading systems and taxonomies within the framework of the Semantic Web. SKOS provides a standard way to represent knowledge organisation systems using the Resource Description Framework (RDF). Encoding this information in RDF allows it to be passed between computer applications in an interoperable way. Using RDF also allows knowledge organisation systems to be used in distributed, decentralised metadata applications. The World Wide Web Consortium (W3C) [74], which is an international community that works together to develop Web standards, has published the SKOS specifications as recommendations, which means that they are in a stable state.

Layer 2. Message logical data model

This layer is essentially context specific and has to be established primarily by the IIS community. Here are some considerations to guide this work:

- The data model must allow mapping with legally binding logical data structures used by Member States.
- The data modelling can/should use reference standards; ECDC uses UML (Unified Modeling Language), which is a general-purpose, developmental modelling language in the field of software engineering, intended to provide a standard to visualise the design of a system.

Layer 3. Message syntax (serialisation): XML, mappable to CSV or JSON

This layer standardises the grammar of the message.

The most common machine readable standard grammar is XML. XML stands for Extensible Markup Language. It was designed to store and transport data and is a W3C recommendation.

JavaScript Object Notation (JSON) is a syntax for storing and exchanging data. Any JavaScript object can be converted into a JSON string and sent to the server. As a result, systems can directly work with data objects without parsing and translating them first.

Any chosen protocol must allow for the mapping of legally binding logical data structures as used by the Members States. Integrating the Healthcare Enterprise (IHE), for example, is an initiative designed to stimulate the standards-based multi-vendor integration of the information systems [75]. IHE promotes the coordinated use of established standards such as the Health Level Seven International (HL7) [76] standards that have been developed for the exchange, integration, sharing and retrieval of electronic health information.

Layer 4. Message semantics (protocols)

Customised XSD (an example: BioXSD); XSD is an XML-based grammar that describes the structure of an XML document.

Layer 2 should be seen a context-specific task for the health community; the main stakeholders are the national public health authorities, which all have their own legacy data structure and reporting systems. Despite the many national systems in use, there is a good chance that Europe can build a common data model based on professional consensus.

For Layers 1, 3 and 4, reference standards are already provided by various standardisation bodies.

Box 34. Standardised terminology in Denmark and the UK (England)

Denmark's eHealth agency maintains two separate lists of standardised codes for the Danish DDV system:

- Products used in Denmark
- Historical vaccines.

The brand name of vaccines obtained in another country can only be added in free text.

In the UK (England), the various IIS and GP IT systems use international Read codes and SNOMED CT or map local codes to these standards [77].

Box 35. Standardised terminology for Canada

In Canada, standardised terminology for immunisations has been created in an effort to promote the standardisation of immunisation records and IIS. Canada Health Infoway maintains the Canadian SNOMED CT extension through which SNOMED CT [70] codes can be created for concepts specific to the Canadian context. Two subsets of immunisation concepts were created: one to identify administered vaccines where the vaccine product is known, and another to identify historical vaccination records where the vaccine product is unknown. This terminology is used in a number of IIS and other applications in Canada, including CANImmunize, and is now included in the Canadian Immunisation Standard [78]. The relationships component of SNOMED CT is also used to facilitate mapping between the historical and trade name concepts, which is useful for immunisation forecasters.

Box 36. Standard vaccine codes for the IIS in Norway: SYSVAK

When SYSVAK [64] was established in 1976, substantial work was done to harmonise the old national vaccine code terminology (SYSVAK code) with the ATC (Anatomical Therapeutic Chemical Classification System) code. With the advent of new vaccines, the original coding system was no longer considered safe because of the possibility of vaccine recording errors and low data quality.

The HPV quadrivalent vaccine, for example, was coded as HPV01, but as additional HPV vaccines with different valences became available, the coding became confusing: HPV nonavalent vaccine is now coded as 'HPV09' in the new terminology, whereas it would have been recorded as 'HPV03' in the old system (ATC code J07BM03).

SYSVAK constantly reviews and assesses its approach to terminology and standards. For example, the system considers introducing barcodes to record vaccinations.

Based on their experience, the developers of SYSVAK promote connecting vaccine distribution system with the IIS vaccination records. One benefit of doing so would be the possibility to validate vaccine registrations in the IIS by looking at the vaccines that were actually distributed.

A combination of several approaches would be necessary to ensure that all currently available vaccines could be recorded in the IIS, in addition to recording all vaccinations that were received before the vaccine recipients took up residence in Norway; a similar mix of methods would be necessary for those who were not registered electronically in Norway at the time of their vaccination.

Box 37. Standardised terminology in MesVaccins.net

The French system MesVaccins.net [79] has maintained its own structured terminology since 2010. It gathers data on vaccines both marketed in France and outside of France, so as not to compromise data precision when vaccine records from outside of France are added to the system. The data model of this terminology is rich and highly structured. It is gathered from a variety of official sources, including the French medicines agency Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) and the European Medicines Agency (EMA). ANSM publishes marketing authorisations (for vaccines as well as other medicines) that are identified by CIS codes (code identifiant de spécialité) and CIP codes (code identifiant de présentation). These codes are transcribed in the terminology of MesVaccins.net. They are readable as DataMatrix barcodes on all vaccines available on the French market.

One plan for the future is to add a mapping feature that would provide a link between MesVaccins.net codes and international terminologies such as SNOMED CT in order to facilitate interoperability and harmonisation across systems.

For more information on standardisation, please refer to the sources listed in Annex 1.

Unique identification of individuals

Unique individual identifiers enable the identification of unique persons in the database, and can enable linkage between systems (dependent on legal framework approving such linkage). Some potential fields for the unique identifier in an IIS are:

- Identification number;
- Assigning authority ID (i.e. owning source);
- Type (e.g. medical record number, IIS ID).

All of the 16 countries in the ECDC survey used a unique personal identifier for each immunised individual recorded in the IIS.

In the EU/EEA countries surveyed by ECDC in 2016, eleven countries (69%) used the unique identifier that is given to individuals at birth or immigration in the IIS. For four countries (25%) the unique identifier is specific to the IIS. One country (6.3%) uses the unique identifier used for healthcare services [10]. The Norwegian approach is described in Box 38.

Box 38. Advantages of using the unique personal identity number as an identifier in SYSVAK, Norway

In Norway, the IIS incorporates electronic messaging directly from the electronic patient record (EPR) so that vaccinators only need to use one tool to enter data. This is considered a key element for the success of the IIS because vaccinators have a minimally increased burden to register the data.

The Norwegian personal identity number (which is assigned at birth) is also used to identify vaccinations registered in SYSVAK [64]. The most important advantage of using the personal identity number is ensuring that data records are not duplicated: by only taking into account actual, individual vaccinations, it is ensured that vaccination coverage calculations are as accurate as possible.

Another advantage of using the personal identity number is the ability to electronically connect personal data across systems and registries, both for research purposes and for patient care. For example, electronic data exchange through the EPR can be used to retrieve complete vaccination records in SYSVAK, regardless of how they were entered into the system. This gives vaccinators a fuller picture of the vaccination status and helps them offer better recommendations for further vaccinations.

Box 39. Use of the National Health Service number in IIS, UK (England)

In England, a unique NHS (National Health Service) number (introduced in 1990) is assigned at birth. Safe care or treatment of a person relies on the information held being particular and pertinent to that person. Using the NHS number helps identify the person and reduces the risk of confusing two people's records.

The NHS number helps to share patient or service user information efficiently and accurately and improves financial flows. As the delivery of care is now often shared across a number of health and social care organisations, the effective linking up and flow of information related to a patient or service user becomes ever more important.

Capturing information about vaccination events

Data fields should capture information on who administered the vaccine and to whom, the time when the vaccination took place, and which vaccine was administered.

The set of data fields that may be used will vary according to country and legislation and the information needs for the management of the programme. These needs will have to be balanced against the effort needed to obtain complete, high-quality information. For each variable, a justification needs to be indicated. It is also very important to consider whether the data need to be collected immediately or if they can be obtained at a later stage.

Vaccines can be registered in different ways in an IIS. The list below highlights some of the approaches that are currently used (either alone or combined) in different Member States [10]. When determining the vaccine registration method, the data quality and the cost of accuracy should be the primary consideration.

Linkage to other systems (e.g. for vaccine distribution) or existing code lists are likely to help secure better data quality than manual entry, which is more prone to human error. Combinations of solutions may be necessary to ensure data completeness.

A number of different options are available for the entry of vaccine information into the IIS.

Vaccines can be:

- selected from a list of vaccines that are:
  - on a list of standard vaccine codes created for the IIS;
  - uploaded (e.g. from electronic medical files) by a web service or similar;
  - available through linkage to a product database of vaccines;
- identified electronically using bar code reader (see Box 40 for information about implementing a barcoding system in Canada and France);
- entered manually in the IIS.

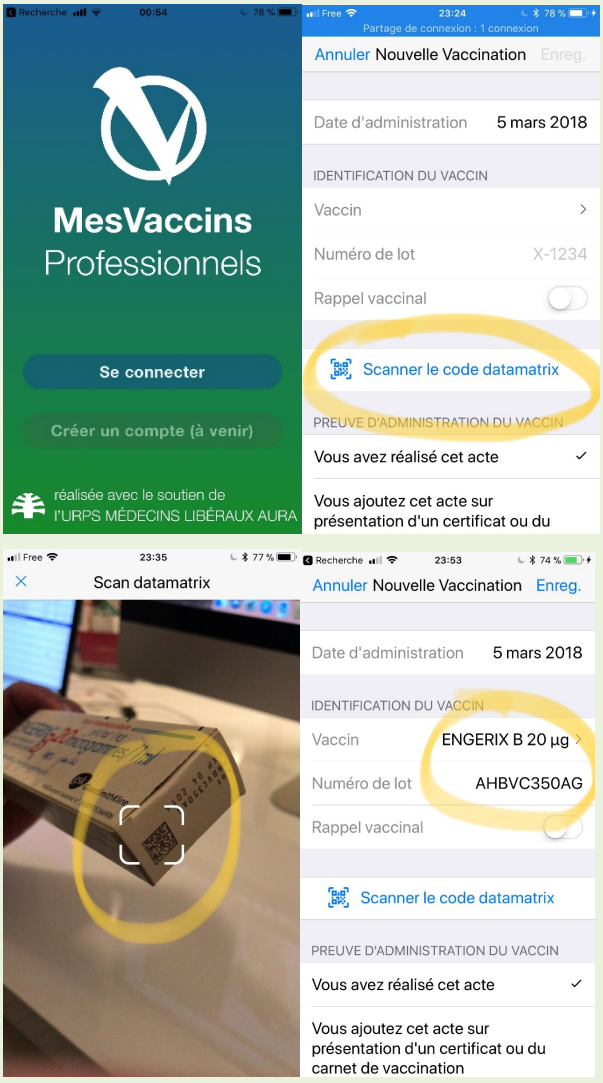
Box 40. Barcode scanning within CANImmunize in Canada and MesVaccins.net in France

Canada: Early in the development of the CANImmunize app, it was identified that vaccine barcode scanning may serve as a more efficient mode of data entry to free text entry of vaccine names and product information. Barcode scanning has also been shown to improve the data quality of vaccination records. Canada has since mandated that vaccine manufacturers print a 2D DataMatrix barcode containing global trade item number (GTIN), lot number, and expiry date on the vaccine vial and secondary packaging.

Allowing CANImmunize users to scan these barcodes using an app can enhance vaccine safety. For example, users who received a dose of a recalled lot could be contacted or identified through the CANImmunize app. A study was conducted to evaluate the efficacy of using mobile devices to scan vaccine vial barcodes. It was found that barcode scanning was feasible as a means for data entry during a vaccination visit [80].

While barcode scanning itself was feasible, clinical workflow presented a challenge to implementation. It was also identified in the course of this work that Canada lacked a source-of-truth database containing vaccine product identifiers (GTIN, lot number) mapped to the vaccine concept identifiers (SNOMED CT), which are required to store the immunisation record in an IIS conforming to the Canadian Immunisation Standard [78]. The lack of such a data source would make it difficult to maintain barcoding functionality that could identify all vaccines. More work is needed to realise the potential of barcodes in the context of immunisation apps for the public.

France: The IIS MesVaccins.net uses 2D DataMatrix barcode scanning that returns the trade name, the lot number, and the expiry date of the vaccine as illustrated below:



Data fields

Table 2 details potential data fields to be included in accordance with current practices in existing IIS and expert opinion. The data fields selected will be different in every context to meet local needs. Two particularly important design aspects that require further consideration are the unique identification of individuals and capturing information about vaccine events.

Table 2. Potential data fields for an IIS

Proposed variable	Justification and purpose
Vaccine provider	
Name, surname and ID of the vaccine provider	Identification of vaccine provider
Location of the health facility or vaccination centre	
Type of vaccine provider (private/public)	
Contact telephone	
Email address	
Vaccine recipient	
Unique ID	Identification of vaccine recipient
Name, surname, second name	
Date of birth	Identification of vaccine recipient; analysis
Sex	
Place of residence	Identification of vaccine recipient, contacting the vaccine recipient, monitoring, analysis of vaccination coverage by place of residence
Telephone number and e-mail address	Contacting vaccine recipient
Occupation	Determination of specific at-risk occupational group
Name, surname, unique ID of parents or legal tutor, and relationship to the patient	Identification of vaccine recipient's parents or legal guardian
Vaccine recipient status indicator on the IIS: provider facility level	
Other potential information fields: ethnicity, patient multiple birth indicator, patient birth order, birth region, birthing facility name	Analysis
Vaccination details	
Date of administration	Determining vaccination status of vaccine recipient; determine appropriate upcoming vaccination
Dose #	
Brand name	Identification of administered vaccine
Antigen(s)	Identification of administered antigen
Batch number	Identification of administered vaccine; analysis
Reason for refusal	Specific analyses; inform actions
Reason for contra-indication	
Type of vaccination (on/off-routine programme, catch-up campaigns)	Specific analyses

4.2.3. Establishing the denominator

In order to make an assessment of coverage, establishing the denominator is essential to compare the total population in the vaccination programme area with the number of people who have received the vaccine from the vaccine programme. Potential sources for establishing the denominator can include, for example, census data, population registers such as civil registers, and healthcare registers.

Thirteen of the 16 countries (81%) surveyed in May 2016 also include data from a population registry in the IIS. In the Netherlands, for example, the IIS has a link to the population register; it receives continuous updates on all newborn and deceased children, and on changes in the addresses of children (due to change of address within the country or immigration/emigration). At this stage, the Dutch IIS does not capture complete vaccination data for refugees, asylum seekers, and diplomats. According to the 2016 ECDC survey, the IIS in seven countries receive data from the civil population registry, three from the healthcare registries, and in Denmark and Iceland, data are received from both the civil and the healthcare registries. In Finland, data are entered by extraction from patient data system records. Three countries (Germany, Ireland and Romania) enter data manually at the time when patients receive a vaccination [10]. The denominator for the IIS in the UK (Scotland) is for babies born in Scotland, which is defined at birth, most often by a visit by the health visitor when the baby is ten days old, in their own home, where permission is asked for the infant to be included in the system.

Individuals who should be part of the denominator data, but are not included, are a challenge. It is of particular importance to include migrants especially if they come from areas with low vaccination coverage and an increased risk of transmission of VPDs.

Box 41. Denominator challenge – Denmark

In Denmark, all Danish citizens get a personal identification number at birth, called 'central person register' (CPR). Asylum seekers are offered healthcare services in asylum centres managed by the Red Cross. Vaccinations are usually registered in patient records but since asylum seekers do not have a CPR number, vaccinations are not registered in the IIS. If asylum is granted to an asylum seeker and a CPR number is issued, previously given vaccines should be added to the IIS. GP offices and hospitals can generate 'substitute CPR numbers' so they can give vaccinations free of charge, but these vaccinations cannot be registered in the IIS. At the time of writing, the Danish eHealth Authority was working on substitute CPRs that could be shared between sectors and reused with repeated contacts.

4.2.4. Ensuring data quality

The utility of captured IIS data is dependent upon their quality, e.g. accuracy and completeness. Data quality checks and consistency rules at the time of data recording are important features to minimise data errors and guarantee quality of data by design. It is also important to be able to assess the validity of a vaccination recording according to the delivery scheme. Existing systems ensure quality through a variety of different methods:

Validation checks (upon data entry and at any point in time) facilitate error prevention, identification, and resolution. This includes checking for duplicate and fragmented records, and documenting the active/inactive status of individuals. Seven countries out of 16 (44%) reported that data in the IIS were validated automatically by the system through preset rules and similar methods. Sweden has selected validity checks for some variables, e.g. validity of batch number, personal identifier, data of immunisation, and selected vaccine. In the UK (England), when data from the local IIS are submitted to the central level for vaccine coverage estimation, the data quality processes are published [81].

Examples of data entry validation are given in Boxes 42–44.

Box 42. Data quality in Mesvaccins.net in France

Mesvaccins.net is [79] centred on patient-recorded data – it acts as an interface for the general public to create their own electronic immunisation record and enter their personal vaccination history through website-based recording. After a patient enters vaccine history data, the software indicates that the data should be forwarded to the patient's regular caregiver who then validates the data. This enables the health professional to verify that the vaccinations submitted by the patient are confirmed by another type of record, e.g. a vaccination certificate on paper. Although Mesvaccins.net is a paid service, data verification can also be done by health professionals with a free account; insisting on the paid version would present a barrier to system use and, ultimately, data quality.

Health professionals (e.g. GPs, pharmacists, and other health professionals) can also create electronic immunisation records and enter data through a website or professional health software; these records can then be shared through a link to the patient's personal account.

A mobile application (iOS or Android) is available for healthcare professionals. It can read the DataMatrix barcode of the vaccine and thus contributing to error-free recording. Using this type of validation, Mesvaccins.net ensures a high data quality through validation at the front end of the system.

Box 43. Validating data in an IIS: SYSVAK in Norway

The Norwegian SYSVAK [64] system automatically conducts data validation on the back end. Electronic data get validated automatically as soon as they are received by the system. Automated checks are conducted to ensure completeness of the message (do all obligatory fields contain information?) and that there are no errors (valid personal identity number, valid date, valid code, etc.). The data are automatically validated when they are uploaded to the IIS, and errors have to be corrected manually. Manual data entry (paper registrations) is done by back-end access to SYSVAK, by a team at NIPH.

Box 44. Validating data in an IIS: Germany

In Germany, population-level coverage estimates from the IIS are validated with other spatially and age-matched coverage estimates from primary data collections (e.g. kindergarten and school entrance examinations) [82].

Mandatory fields. To secure reliability and accuracy of the recording, it has to be decided which fields should be mandatory. At the same time, the need for data completeness needs to be balanced with a realistic number of mandatory data fields. It may be possible to capture the information through non-mandatory fields also. In general, open text fields in registries are not recommended as they are difficult to control, and there is always a potential lack in data quality. The baseline for assessing the need for mandatory fields should be part of the business case and purpose for the IIS. The regulatory acts that govern a national IIS also inform which fields will be mandatory or optional.

The fields classified as mandatory vary by context. In the 2016 ECDC survey, 14 countries (88%) required the date of vaccination. Other mandatory fields differ between Member States; for example, an insurance number was required in Hungary, Malta requires the dose number, the school and academic year needs to be recorded in Ireland, and in Latvia it is mandatory to record the type of syringe used (e.g. pre-filled syringe) [10].

Triangulation and concordance of multiple data streams. Triangulating data and establishing their concordance can enable the identification of data quality issues.

Box 45. Data quality in Denmark

In Denmark, different sources feed into the system, improving data completeness: imported reimbursement data are integrated with the data entered at the point of vaccine administration. Data are validated automatically [62]. Some challenges encountered with data completeness include:

- Lack of data on certain indicators (e.g. product name). To overcome this, it became mandatory for the GP to register all vaccines at the time of administration, including, for example, the product name indicator and batch number.
- Delay between vaccine administration and time of entry into the system. If vaccinations are not entered into the system by the GP, delays of up to three months are possible; vaccinations will be eventually registered during the reimbursement process.
- Limited system use in some settings. Not all settings (e.g. some hospitals and travel clinics) are able to register administered vaccinations at the time of writing.

In Canada, CANImmunize plans to use data generated by the vaccine recipients to assess the consistency of other sources of vaccination data (Box 46).

Box 46. Improving data completeness in Canada

In Canada, vaccination information comes from diverse sources and settings (e.g. pharmacists, schools, and doctors). For a complete vaccination overview, an IIS needs to capture and combine all this information.

Empowering vaccine recipients to capture vaccination information makes it possible to create a complete record that cuts across multiple vaccine delivery settings. Concordance with this source could present the ultimate source of data validation.

Box 47. Triangulation of data in the UK (England)

In the UK (England), IIS data are routinely triangulated with the primary care system. Ad-hoc triangulation is also conducted at times. When a study estimated measles susceptibility in individuals born between 1985 and 2014, the coverage data were taken from both the Child Health Information Systems and the ImmForm (which was extracted from GP data).

4.2.5. Storing data

It is important that an IIS can guarantee the security and privacy of personal health information. IIS should be hosted on secure hardware and software and in accordance with appropriate standards for protected personal health information, i.e. security/encryption, disaster recovery, confidentiality and privacy practices, and policies based on pertinent laws or regulations that protect subjects whose data are recorded in the system. An overview of EU data protection regulations is given in Section 3.

Anonymisation. To protect privacy, where it is non-essential, personal health data should not be linked with an individual identity. One technique to protect individual-level data, which is frequently used in IIS, is **pseudoanonymisation**. Having a pseudoanonymised unique code lets system managers link identifiable stored demographic information from a population registry to immunisation information. This information is only combined if a request for data is issued by a user with access credentials that authorise re-linking demographic and immunisation data (Box 48).

Box 48. Storing data in the Norwegian IIS SYSVAK

In SYSVAK [64], data are identifiable through the 11-digit national personal identity number. The identity number is stored in a separate population database, but can be connected to SYSVAK with a unique message ID. This enables access to identifiable individual data through the electronic patient record.

Storage location

Consideration should be given to the physical location of data storage and archiving. Procedures should be in accordance with the GDPR.

Administrative area

Box 49. Storage of data within national borders

The BID Initiative [67] reported that a key concern at the regional level in African countries (including Zambia and Tanzania), is the location of stored data. Countries want to ensure that all health data are located on servers inside the country, and not abroad or in the cloud.

Device or cloud storage

Box 50. Cloud and device-based storage in CANImmunize

CANImmunize [60] was originally designed to be an application available to the general public, a public-facing application. To meet the needs of Canadians, data resided on the device (to enable vaccine scheduling). Now, CANImmunize is creating a cloud-based server to store the data and facilitate an account-based system. This will make it possible to:

- backup data on behalf of CANImmunize users; and
- permit users to access their records on other devices, including web browsers, and share their records with family members.

The storage of user data on a centralised server also makes it easier to exchange and share data with other IIS.

CANImmunize has launched a pilot project whereby CANImmunize users in the Ottawa region can report their children's immunisation records to the local public health authority, which is required for school entry.

Work is also underway to connect CANImmunize to an IIS at the provincial level, which would enable the bidirectional flow of immunisation data between CANImmunize and the provincial immunisation repository, and any other connected client (e.g. provider EMRs, public health terminal, etc.).

4.2.6. User access

To fulfil the functions of an IIS at both the individual and population levels, data need to be accessible. This includes access to the IIS for healthcare providers at the point of care, access for healthcare providers more widely in the system, and access for individuals so they can view their immunisation records. User access controls (log-in) should be based on distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.

Establishing access requirements

Within an IIS operating guidelines or legal framework, different access permissions need to be established for different types of users working in different capacities in the health system. The Belgian approach is explained in Box 51.

Box 51. Access to IIS in Belgium

Data from the IIS Vaccinnet are available on a platform for visualising medical data (Vitalink [83]). These data can be viewed by vaccinees and healthcare providers if the vaccinee permits it. All healthcare providers with access to Vaccinnet can add adverse events following vaccinations to a vaccination record, even if vaccination was given by a different provider. Only medical system managers can edit the content of the records.

Ensuring that data are used ethically is imperative. This can result in restrictions across a number of domains including legal regulations, infrastructure options, and operations after implementation. An example of how Norway ensures ethical access to data is given in Box 52.

Box 52. Ensuring ethical data access in Norway

In Norway, the regulatory act states a number of requirements that must be met to secure ethical use of data. One of the criteria for data access required by the ethics committee is a research component. Regulations explicitly state that data cannot be shared between the national IIS and reimbursement institutions or be used for insurance purposes, irrespective of consent. If there are any doubts regarding ethics, the application must be escalated for assessment by an ethics committee.

Access for different actors can include the right to create/read/write/edit/delete vaccine records.

Some potential access options for different actors are highlighted below:

Vaccine recipient. In some European countries, the general public has access to view their immunisation records, and in some countries unofficial/official vaccine records can be obtained. These are obtained through a range of methods, some via a request sent through a health provider, others through direct log-in to the system/exchange platform of the IIS. Some examples of different systems are given in Table 3.

Table 3. A range of access permissions for the general public in European countries (not an exhaustive list)

Country	Access permissions
Malta	Vaccine recipients can send a request for an official record. Records are either sent by email or mailed as a print-out.
Netherlands	Vaccine recipient requests immunisation history through the IIS.
Spain (Andalucía)	Vaccine recipient can obtain an immunisation history; this document is not an official immunisation record.
Romania and Sweden	Recipients can request an immunisation record through their health provider.
Belgium	Data from Vaccinnet are transferred (updated daily) to Vitalink, a platform which provides access to vaccination records. Log-in is possible with an eID-card.
Portugal (mainland)	Recipients can access their records by logging in into the Health Data platform.

Source: [10]

Some systems let vaccine recipients add vaccinations to their personal record; for example, the Danish vaccination register offers access to all end-users. General access rights to the IIS for different groups are outlined below (see also Box 53).

- Vaccine recipient's **regular healthcare provider**, regardless of involvement in vaccination delivery. Some countries allow full access to regular healthcare providers in the public and/or private sector. Access is permitted either for viewing purposes only, or for viewing and data entry.
- **Other healthcare professionals** not involved in vaccine delivery. Some European countries give full access to other healthcare professionals, others only give viewing access. In Denmark, non-authorised healthcare professionals at regional or private nursing homes in charge of medication have view-only rights. In England, only child health records department staff have full access to the records. Specific public health staff at the local level have access to individual level data, whereas national level only has access to aggregated data.

In some countries, access is also given to appointed individuals who work in the following areas or institutions:

- **National public health institutes.** Some countries provide full access, while others provide only viewing access.
- **School immunisation programmes.** Some countries grant full access, while others provide only viewing access.
- **National health insurance organisation.** In Latvia, the national health insurance has the right to view vaccination records.
- **Insurance companies.** At the time of writing, no European countries are known that grant IIS access to private insurance companies.
- **Research.** In the Netherlands, anonymous data can be accessed for research upon request by researchers and approval by data access body.

Box 53. Access to data in SYSVAK in Norway

Front-end refers to the visual and interactive side of an application. In SYSVAK, front-end access to immunisation records is provided through the EPR for healthcare personnel, with user-end security managed through the EPR system. Public access to immunisation information is provided through the 'My vaccine' page at www.helsenorge.no, where it is also possible to print out vaccination certificates.

Back-end refers to the server side of an application, e.g. how the database communicates with the browser. In SYSVAK, back-end access is enabled through multiple applications, but restricted to a small management team. SYSVAK enables access to both aggregated and individual data, e.g. 1) identification of a person and/or registration of their vaccinations; 2) vaccine registration data aggregated by clinic for different time periods.

Transfer of communication messages is secured through a national secure network for the communication of health data called 'Norwegian Health Network'.

Source: [64]

4.2.7. Linkage to other information systems and interoperability

Linkage to other health and/or population information systems can facilitate data recording, the receipt of queries, the generation of automatic responses, and the receipt of submissions. Data exchange format options and transfer protocols need to be established to enable messaging between different systems. Linking data from different systems requires interoperability as defined in Box 54 and highlighted in Section 4.1.3. The European interoperability framework and IIS use cases are outlines in Table 4.

IIS might be linked to systems holding different types of data as well as to other IIS, for example if there are multiple subnational registers. Linkage between different IIS systems (e.g. multiple subnational systems) is standard practice in several countries (see Table 5).

Box 54. Definition of interoperability

Interoperability in eHealth refers to the ability of two or more eHealth systems to use/exchange both computer interpretable data and human-understandable data and knowledge. Three aspects characterise interoperability:

- 'Legal interoperability covers the broader environment of laws, policies, procedures and cooperation agreements needed to allow the seamless exchange of information between different organisations, regions and countries.'
- 'Semantic interoperability refers to the ability to ensure that the precise meaning of exchanged information is unambiguously interpretable by any other system, service or user.'
- 'Technical interoperability means the ability of two or more information and communication technology applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.' [84]

To achieve interoperability in eHealth for a given use case, all of the above aspects of interoperability have to be considered. The way to attain interoperability – generally across systems – should be based on common technical and semantic standards [84].

Box 55. Example of interoperability – MesVaccins in France

MesVaccins.net [79] provides a web API designed along current industry trends (JSON data format, open documentation). This API provides access to both its IIS (with an authorisation system centred on the person, who owns her or his data) and its immunisation-oriented decision support system. This API is integrated in medical software for GP and vaccination centres.

Drawing from this experience with the API, the French ASIP ('Agence nationale des systèmes d'information partagés de santé'), a national agency that regulates shared data exchanges between health information systems in France, will develop a standardised, immunisation-oriented decision support service. Standardisation will take the form of a custom profile based on the upcoming international FHIR standard, a new standard for health information exchange.

Box 56. Interoperability: Child Health System in Northern Ireland

The electronic Child Health System (CHS) has been in place in Northern Ireland for many years. It contains a variety of information on children's health, including their immunisations. It is also used to perform the call and recall of children for their immunisation appointments in primary care and the calculation of coverage rates. Although managed separately by the different health trusts that cover Northern Ireland, data are easily transferred between systems when children move to different areas.

A recent system upgrade made it possible to synchronise data with the electronic school roll. The CHS now contains an accurate record of all children in primary and secondary schools across Northern Ireland, including their school and class. This has been extremely helpful for the creation of class lists and consent forms for school-based immunisation programmes, mainly for influenza in primary schools and HPV, Td/IPV, Men ACWY and MMR catch-up in secondary schools. The automatic generation of class lists has substantially reduced the work load for the school health teams when organising immunisation visits to schools.

Table 4. European interoperability framework – interoperability levels with an IIS use case

Interoperability level	IIS use case
Legal	• Identify the stakeholders and the impact of the current legislative framework, both nationally and internationally (e.g. GDPR). • Formulate the governance and procedural documentation of the IIS to be in compliance with applicable laws and ordnances (operational procedures, data access, etc.).
Organisational	• Ensure that the proper stakeholders have been identified and that there is a clear delineation of internal and external users of the IIS (who has direct access to the system, and who merely has access to its outputs) • Governance documentation must clearly define who owns and operates the system and provide the background for these arrangements. • Clearly define all user roles and responsibilities in the IIS.
Semantic	• Define specific semantic standards (e.g. international classifications are always preferred to national ones). • Define rules for data collection and use (e.g. which source of information is preferred when the same data point is collected or used from more than one place).
Technical	• Produce clear technical documentation: technical specifications, maintenance, hosting, and administration manuals • Produce documentation for integration with external sources (e.g. connection to external systems via web services) or procedures for future IIS upgrades.

Table 5. IIS linkage in a selection of EU/EEA countries with subnational systems

Country	Current IIS structure	Plans for future development
Belgium	Two regional systems are in place. The structures of the two systems are identical and although there is no exchange of data at the time of writing, both systems are completely compatible.	Exchange of data between databases; use of hubs (common data source).
Ireland	National school IIS and eight separate primary childhood IIS at local level. There is currently no interoperability between the primary childhood systems.	A combined national immunisation/child health information system which will replace the existing separate child health systems and will essentially be a module of the planned national electronic health register (EHR). Future linkage to other relevant health information systems to facilitate information sharing is intended.
Portugal	Two systems: one on the mainland covering 9.5 million people, another one in Madeira , covering 267 000 people. Data sharing between systems is not possible.	A new IIS is being piloted in mainland Portugal; and it will have more features than the current one.
Spain	Eight IIS are in operation, the largest of which covers 8 400 000 citizens. Data sharing between systems is not possible.	Working on establishing a national IIS.
England	Five main Child Health Information Systems (CHIS) in operation, with just under 75 local databases recording vaccination status at the local level. Interoperability varies between systems, with some having electronic interoperability and others only allowing for manual data sharing.	A new system has been developed, the Children and Young People Health Dataset. It aims to create a national, individual-level register and is being populated, but not yet in use. Heterogeneity and decentralisation make it difficult to reconstitute a national register.

Source: [10]

Across Europe, IIS are linked to a range of health outcome registers [10]:

- **Patient record systems/databases.** In Denmark, Latvia, Portugal (mainland), Spain (Andalucía) and Sweden these systems are integrated, and appointed staff can switch from one register/database to the next with the same log-in. In Finland, the systems are separate, but data are linked routinely. In Belgium (Flanders), Iceland, and the Netherlands the systems are separate, but linking is possible for specific purposes (e.g. research projects). In Norway, electronic patient record systems communicate electronically to/from SYSVAK, securing two-way messaging functionality of vaccination data. Data from SYSVAK can be linked to all types of registry data that are connected to the personal identity number (a regulatory act for SYSVAK regulates this).
- **Hospital discharge diagnosis registries.** In Finland and Spain (Andalucía), data are linked routinely. In Belgium (Flanders), Denmark, Iceland, Latvia, Portugal (mainland) and Sweden, data can be linked for specific purposes.
- **Infectious disease databases.** Notifiable communicable disease databases are routinely linked with IIS systems in Finland, the Netherlands and Spain (Andalucía). In other countries (e.g. Belgium (Flanders), Denmark, Iceland, Latvia, Norway), the communicable disease databases are only linked for specific purposes. Romania started a pilot project that will link the IIS with the notifiable communicable diseases database. In Sweden, the IIS can be linked to various disease-specific registers.
- **Pharmacovigilance registries.** In Latvia, pharmacovigilance registries are integrated with the IIS. In Spain (Andalucía), registries are routinely linked with the IIS. Belgium (Flanders), Denmark, Finland, Iceland, Norway and Sweden link their vaccine safety registries only for certain purposes.
- **Health claims data.** In Germany, GP claims data on administered vaccines can be matched with GP claims data from the diagnoses of selected vaccine-preventable diseases at the individual level. ICD-10 codes for selected vaccine-preventable diseases are transferred and analysed by using the same personal identifier.
- **Population screening registries.** In Ireland, linking the IIS with the national cervical screening programme to provide HPV vaccination data is in progress.

Linkage to health outcome registers different from the ones mentioned above occurs in a number of countries. In England, the future Children and Young Persons Health Services dataset (CYPHS) aims to allow linkage of vaccination status to clinical episodes and other data sources such as the child protection register (see Figure 4).

Linkage to other systems speeds up IIS data entry, reduces the need to enter data into more than one system, and simplifies finding immunisation information (one central search instead of many in several systems).

Section 5. Project planning for sustainability

In this section, a roadmap for implementation is proposed. We provide a list of design and implementation issues that should be considered to help ensure the sustainability of an IIS. These considerations range from the outset of an IIS project through to the design, implementation, improvement, oversight and maintenance of the system.

The setting up of an IIS is an important commitment and requires careful planning and a long-term, sustainable strategy. The development of an IIS can be approached in many different ways, and challenges can be specific to different contexts.

In order to mobilise adequate resources, there needs to be a high level of commitment from country/health authorities and sectors. To ensure that a project meets its targeted needs and is sustainable it is vital that:

- the vision and aims are adequately defined;
- dedicated project teams are set up;
- strong project leadership is enabled;
- a good business case is developed: objectives of the project, detailed plan of how the objectives will be met, scalability of the system.

In this section, we highlight key considerations of development and implementation approaches for IIS and provide references to further resources. We recommend reference to more detailed techniques on project planning to drive the process; for example the PRINCE2 (Projects in Controlled Environments) framework, and methods such as SWOT (strengths, weaknesses, opportunities, and threats) analysis.

5.1 Project management and leadership

Interdisciplinary team

Developing and implementing an IIS may/should involve establishing and leading an interdisciplinary team. It is essential to identify the right person/organisation to lead (this person/organisation may differ at different stages of development/implementation). Interdisciplinary collaboration is also needed to ensure successful interoperability between systems. Some lessons learned from Croatia and the US North Dakota IIS are provided in Box 57.

Box 57. Inter-disciplinary collaboration in Croatia and North Dakota (US)

In Croatia, IIS programming is provided by an IT vendor. They have to ensure that the specific business needs of the health professionals and other stakeholders are translated into technical specifications for coding development by programmers. To do this, it is essential that the people who develop the specifications understand the exact process. This involves ensuring two-way communication: the documentation and communication of critical business specifications (both front- and back-end design) for the vendors, and communication from the vendor about what is possible from a technical perspective. In the Croatian Institute of Public Health, the Division of Health Bioinformatics and Biostatistics acts as a liaison between medical professionals, who specify the needs, and programmers, who are in charge of the technical implementation.

In 2014, the North Dakota IIS received a grant to establish interoperability between provider-run electronic health record systems and the IIS. Both involved parties had a shared interest in the other's success – the IIS team wanted to be able to rely on the health information network (HIN) team and their resources for project sustainability, and the HIN team wanted to use the IIS connection to recruit providers. There was representation from each project on the other's team to ensure that the interests of each were communicated and addressed at every stage. As of 2015, the IIS is connected to 203 individual provider locations, and 201 of these connections are through the HIN; 100% of planned, future connections have been referred to the IIS from the HIN.

Mapping the context

Before project initiation, it is important to establish a clear understanding of the stakeholders and the technical, legal and regulatory environment. Taking stock of what already exists and identifying any gaps will help establish the needs that the IIS aims to address and help identify the main issues to be addressed in the short to medium term. This stage of the process also provides an opportunity to involve internal and external IIS stakeholders and gain their early input. Gaining an idea of stakeholders' perception of IIS (e.g. through stakeholder consultation) could inform system design, improve understanding of some of the internal and external challenges, and increase project acceptance.

The following stakeholders may be worthy of particular consideration at both the national and subnational-levels:

- Public health institutes, ministry of health, regional health authorities
  - IT units
  - Child healthcare
  - School healthcare
  - Primary care
  - Infectious disease specialists
  - Paediatricians
- Medical products agency
- Directorate-General for Health and Food Safety
- Vaccine producers
- Researchers
- Software vendors
- Professional groups (e.g. general practitioners, paediatricians, infectious disease specialists, nurses, midwives)

There is a need for stakeholders to negotiate and reach an agreement on various aspects of the IIS, such as objectives, responsibilities, organisation, regulation and funding.

A description of how the BID Initiative carried out context assessments in their countries of operation and how they consequently developed a road map for Tanzania is described in Box 58.

Box 58. Developing a road map for Tanzania – assessing the data systems and use context

Before programme implementation, the BID Initiative [67] aimed to get a comprehensive picture of the actual processes associated with immunisations within the local context and the issues and barriers experienced. They worked with other African countries and partners to:

- prioritise which data collection problems should be focused on first;
- collect functional and non-functional requirements for any desired information system solutions;
- understand existing strategies and policies;
- assess existing information systems deployed in the field and how they match the requirements; and
- assess the financial ramifications of possible solutions.

Once the BID Initiative work was underway in Tanzania, the government conducted an even more in-depth process to look at digitising their entire health system, with a piece of work called the Data Use Partnership. The methodology used by the Data Use Partnership in Tanzania is described below.

Investment recommendations for health information systems, including IIS, were developed through a collaborative process led by the Ministry of Health: Community Development, Gender, Elderly, and Children and the President's Office of Regional and Local Government. This process lasted ten months and included:

- a literature review of more than 60 government and donor strategies, press reports, and external assessments;
- interviews with more than 180 stakeholders from the government, implementing partners, and health teams and facilities at all levels of the health system;
- extensive analysis, including systems mapping and prioritisation of investment recommendations; and
- six meetings with a core group of more than 15 government and other stakeholders.

Potential assessment tools used for similar programmes development include the WHO CRVS rapid assessment tool [85,86].

Making a high level but comprehensive conceptual model of the system

Developing a model that considers both the perspective of the user (front end) and the system/data structure (back end) will help conceptualise the system. This enables testing the prototype system with actors, allows for better feedback and modification, and facilitates better presentation of a business case (Boxes 59 and 60).

Box 59. Improving the success and timeliness of IIS projects – process for developing, planning and completing enhancement projects to the North Dakota IIS

The user accepting test phase was the first time that the staff working with the IIS could provide feedback on the design of a new function. This led to delays in production deployment and additional development time that was not anticipated in the cost estimate. There were functions in the system that did not fully meet the needs or expectations of the IIS staff; thus, a considerable amount of time was spent making changes during the advanced phase of the development lifecycle.

To address this challenge, the staff working with the IIS reviewed the processes and saw the need for detailed business requirements from the very beginning. It was clear that more time was needed to be spent on the front end (i.e. planning and design) of the project to avoid wasting time making changes on the back end. A template was developed for formal business requirements, which was to be completed after funding was secured and before any development work started. It was decided that key stakeholder input would be gathered during the drafting of requirements.

Source: [87]

Box 60. Business requirements for enhancement/changes to IIS – example from North Dakota IIS

The requirements document utilised for the North Dakota IIS tracks revisions and includes six detailed chapters:

1. General information

- Scope
- Project references
- Acronyms and abbreviations
- Points of contact (key stakeholders and others who provided input)

2. Current system summary

- Background (reasons for enhancements/changes)
- Current system functionality (details on how current process works)
- Current methods and procedures (flow diagram of current workflow)

3. Proposed methods and procedures

- Summary of improvements/enhancements (short overview of project)
- Functional improvements (details about project requirements, flow diagram of new workflow after enhancements)
- Summary of impacts

4. Detailed characteristics (i.e. specific performance requirements)

- Accuracy and validity checks needed in new functionality; timing of functions; capacity limitations or requirements)
- System functions (including flow diagrams)
- Input and output requirements

5. Design considerations

- System design including screen mock-ups and descriptions of changes to current screens

6. Security

- Security control points (input controls, output controls, process controls)
- System monitoring and auditing (considerations for logging, triggering criteria and identification information; audit trail considerations)

Source: [87]

An iterative approach

An iterative approach refers to a process where system development is conducted incrementally in cycles. In this way, rapid feedback and modification of the system occurs to enable it to best meet the identified needs. An example of an IIS being developed through an iterative approach is given in Box 61.

Box 61. Canada: rapid, agile development through user-feedback

One of the factors contributing to the success of CANImmunize [60] has been its development as an independent initiative outside of the public health system. The first version of the app that was released publicly was a prototype. The team quickly received feedback from users and adapted the product accordingly. This process has continued throughout the development of the platform. The full requirements of the application were not set in stone at the outset of the project, and as such, the product has evolved to meet the needs of its users and has capitalised on opportunities that were not possible at the start of the project.

CANImmunize captures feedback directly from users, through reviews on the app stores, and can evaluate usage through tools like Google Analytics. Examples of changes to the application made due to user feedback are the creation of a cloud-based server to help users backup their data, and the introduction of a trade name field to allow users to track their vaccinations in greater detail. Users have also asked for CANImmunize to facilitate reporting to public health, which has prompted work in this area.

Data quality: A preliminary assessment of data quality was conducted which found some errors in inputting, largely around the date. Consequently, iterations were made to improve the system.

Approaches for system roll-out

Different deployment and roll-out approaches include:

- piloting of new systems at a small geographic scale;
- expansion of existing systems;
- staggered roll-out (see Box 62) with modifications to the system made iteratively after each phase of the roll-out;
- vaccine specific roll-out; for example, in Hungary the system was first operated for the HPV vaccine.

Box 62. Canada: staggered roll-out

A provincial prototype was released initially in Ontario, followed by a national version. As the platform developed, CANImmunize began rolling out updates to beta-testing groups that validated new features before they were released to all users.

The project does not have a projected end date because it is anticipated that there will be a continued need for such a platform which will evolve to address the needs of stakeholders.

When the transition is being made from paper to electronic-based immunisation records, a number of issues need to be considered. For example:

- What are the available options to migrate electronic data from existing legacy systems?
- Should the transition of data from paper to electronic-based records be conducted before the launch of the IIS or in parallel?
- Which population should be included in the electronic IIS in the transition phase? All living people? Or specific age groups, for example a cohort of individuals up to 20 years or 30 years of age?

User training

Ensuring that system users are adequately trained involves identifying users (at the input and output sides of the system), and then developing, implementing, and monitoring trainings. Training requires a sustained effort throughout past initial implementation, including training of new users, and training of new features and functionalities.

A number of different approaches can be used to train users. If the IIS will be accessed by the public, interactive support is particularly important. Some key considerations of things to prepare for are given below (note that this is not an exhaustive list):

- Continuous information sharing with healthcare providers
- Face-to-face and/or online courses for healthcare providers
- Healthcare IIS champions
- User support, e.g. by email and phone. A well-kept, informative website (including online FAQs for example) can help to decrease the need for two-way user support.

Box 63. BID Initiative trainings

The BID Initiative [67] reported that having some on-the-job training for the entire health facility staff helped raise the knowledge about using the system beyond the level of training only the staff working in immunisation at the time of training. In addition, identifying key champions within the facility as well as at district level helped facilitate the training of new health workers past initial implementation.

Performance and sustainability

To ensure that the high performance of an IIS is maintained it is important that standardised coding is used and that essential knowledge of the system and database is retained through adequate documentation (Box 64).

Box 64. Improvement of performance and sustainability – lessons learned from the North Dakota IIS

Standardised coding: As the system has been around for over 20 years, there have been multiple different developers working on the system. The coding of the IIS had been completed using more than one coding standard, with a lot of redundancy in the code. The redundancies have now been removed and data have been standardised.

Documentation: Another major issue was the lack of documentation outlining the system or the database. Only one lead developer knew and understood the system completely, and there was a large risk that this person could leave and take this knowledge with him. In order to avoid this risk, a single document with over 3 000 pages long was put together which describes the entire system and its database. The vendor has also been training two other developers so that there are more people with the same level of knowledge and expertise regarding the IIS.

The take-away from this experience is to make sure that an IIS has detailed documentation. Documentation has to be produced from the very beginning and it should be reviewed and updated periodically. The second important issue is human resources: there should always be several employees that have the same level of knowledge and expertise of the IIS to ensure that work can continue should one person leave the team.

Detailed documentation on coding conventions and system structure will help avoid standardisation issues by offering a common frame of reference for new and existing team members.

Source: [87]

5.2 Challenges to anticipate

Learnings from the ECDC survey

It is important to anticipate the types of challenges that may be encountered and add them to the project plan.

A 2016 ECDC survey asked IIS experts in European Member States which challenges they had faced during the design phase and during the early implementation stage. The most common challenges included:

- a lack of human resources (12/15; 80%);
- a lack of funding (11/15; 73%); and
- issues relating to data protection (9/14; 64%).

The majority of countries did not find that decentralisation of immunisation programmes, or the lack of a specific legislation on IIS were challenges during the IIS system set-up and implementation period.

During the design phase, challenges faced by most countries included:

- defining the functions required by the system (12/15, 80%);
- a lack of standards to provide a point of reference for developing the system (10/15; 67%); and
- defining the core data set of information to be collected (10/15, 67%).

During the early use phase (not pilot systems), the main challenges encountered included:

- training vaccine providers to use the system (10/14; 71%);
- validation of data entered by different users (9/13; 69%); and
- quality control of data completeness (9/13; 69%).

Figure 5. Challenges to overcome at different stages of IIS system set-up and implementation taken; survey of EU/EEA countries (N=16)

Figure 5a. Challenges to overcome before a decision was taken to set up the IIS (N=16)

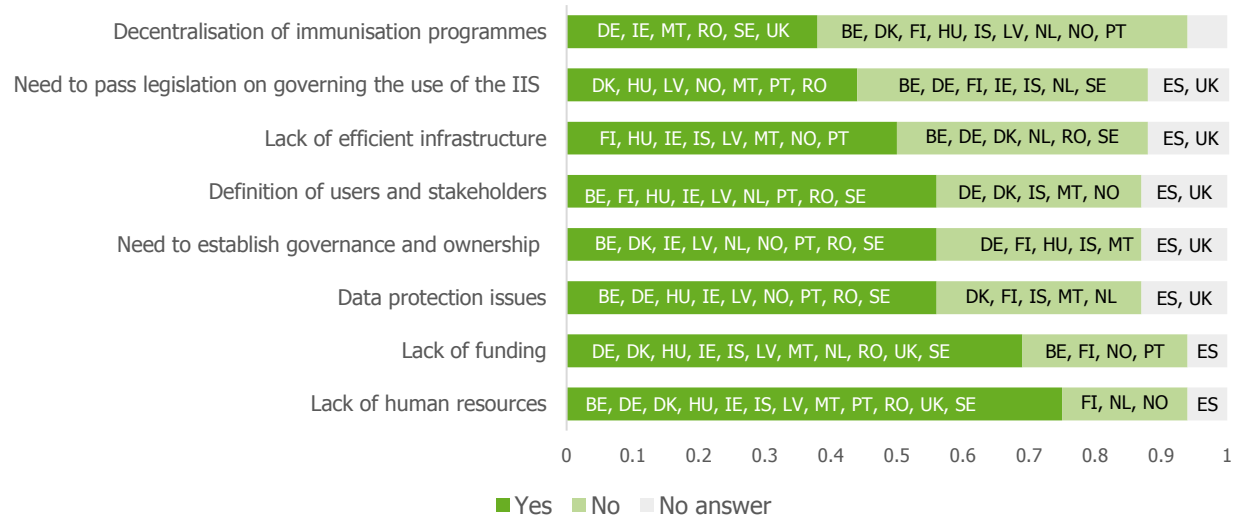


Figure 5b. Challenges to overcome during the design phase of the IIS (N=16)

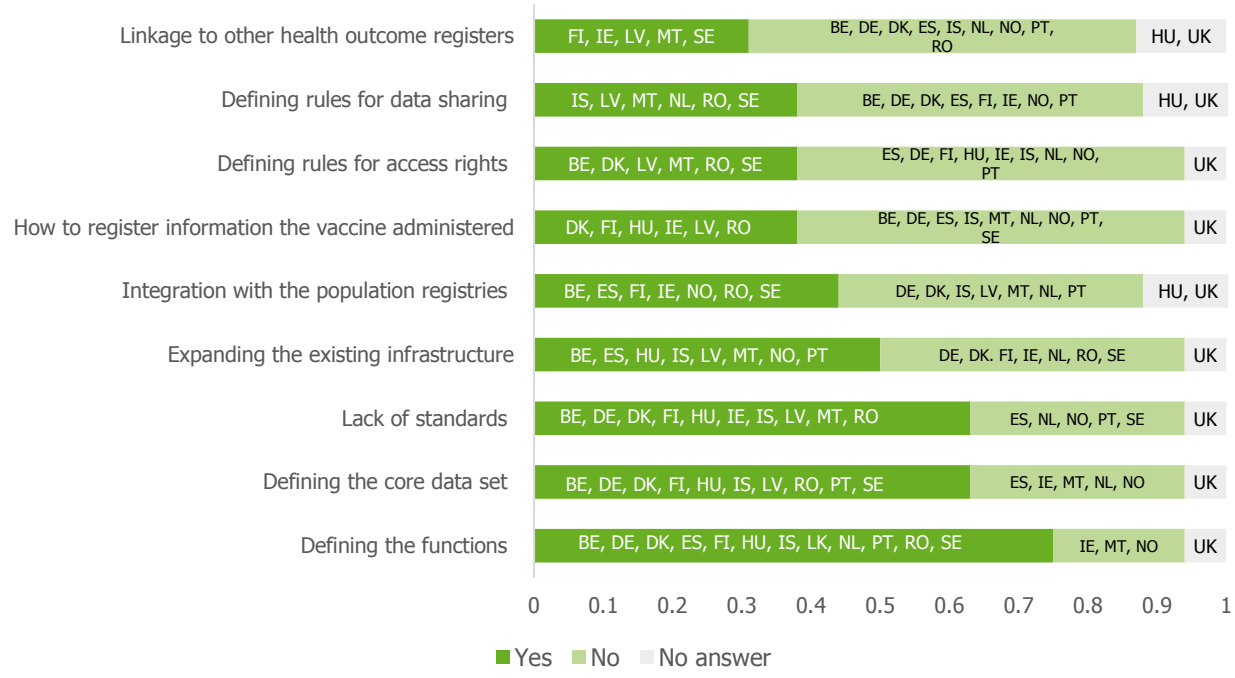
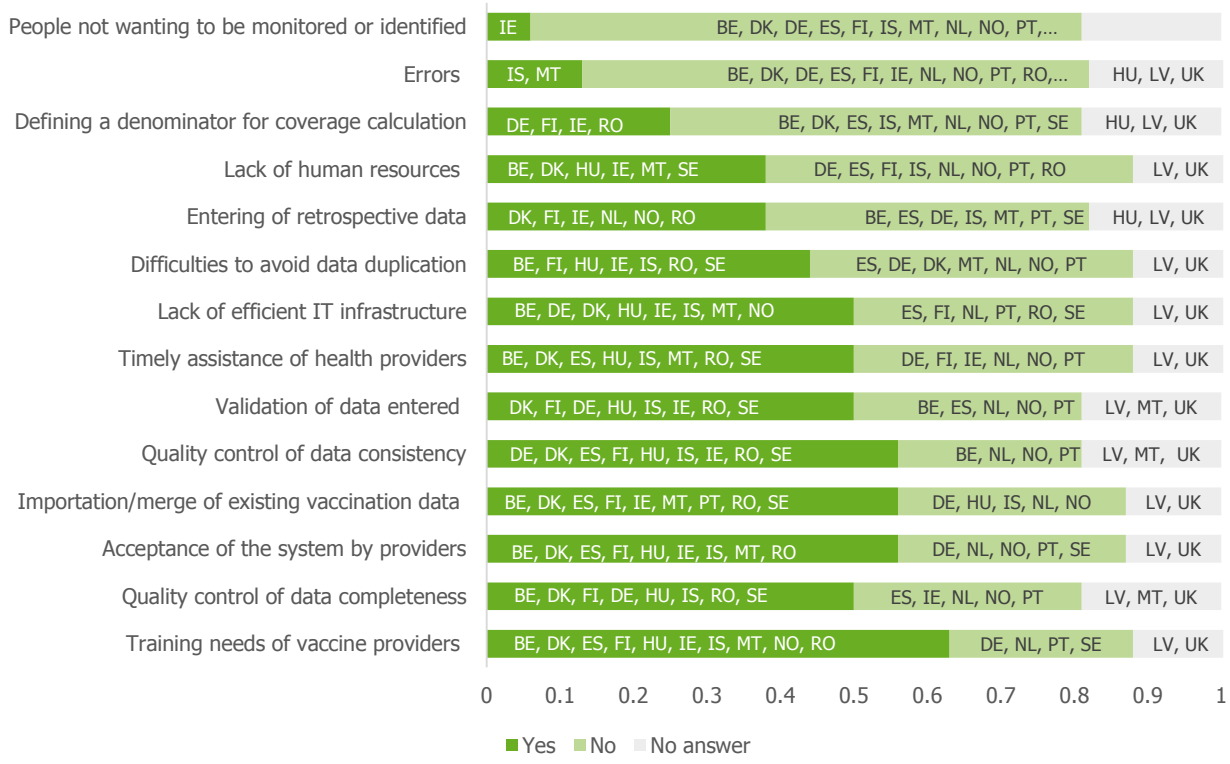


Figure 5c. Challenges to overcome during the early use of the IIS (N=16)



Source: [10]

It should be noted that it is likely that IIS project implementation may face issues that cannot be anticipated. For example, the BID Initiative's project in Tanzania encountered a problem regarding the barcodes that were placed on the child health cards that neither local nor international staff had anticipated: most people were not comfortable with the use of barcodes as identifiers for their children and perceived their use as marking their children for something potentially harmful. To overcome this, posters about the purpose of barcodes were developed and healthcare workers were educated in how to answer questions in relation to the use of the barcodes.

Different system development options are used in Europe

A 2016 ECDC survey [10] found that in the vast majority of European countries the government authority (including national, regional, district local health unit or vaccination centre) owned the IIS software. By comparison, in the United Kingdom (England) there are five major private sector software suppliers. In the countries surveyed, 15/16 provided information on software source code development. Seven countries (47%) used a private company, and six countries (40%) used programmers from the government authority. Two countries (13%) operated systems that were developed by a mix of private and government programmers. The type of software used included:

- open source software (no licence is needed);
- commercial software that may be free but usually requires the purchase of software licenses;
- a mix of open source and commercial software; and
- MoH software.

See Table 6 for example.

Table 6. IIS development in four European countries [10]

Country	Description
Belgium	Software was developed by the IT team at Child and Family, a Flemish agency organising well baby clinics. It was built on their existing vaccination database for infants (generally used since 1999 but only for well baby clinics).
Germany	The software for clinical records at practitioner level is owned by the physician (practitioner's general documentation system). These data are then forwarded to the Associations of Statutory Health Insurance Physicians (ASHIP). The software used for extracting, anonymizing and formatting the data from the ASHIPs' databases is written/owned by Robert Koch Institute and has been designed for the IIS. .
Latvia	The software developed for the IIS is the property of the national health service of Latvia. Healthcare institutions can use it for free as long as they do not modify it. The national health service provides training and support for healthcare institutions on electronic data exchange.
Sweden	Sweden's IIS was developed by the public health authority's in-house developers, with commercially available software

Source: [10]

Care should be taken, particularly when contracting out, that ethical standards are adhered to, e.g. following national and international rules on confidentiality.

Balancing costs against benefits and acquiring sustainable funding

Considering the costs and benefits of an IIS

When making a decision to implement an IIS, a cost-efficiency and cost-effectiveness assessment is important; it should include an appraisal of the following factors:

- Establishing the level of human resources (e.g. staff functions and competencies) needed throughout the various stages of the project, with approximate timelines.
- Planning and estimating the costs of implementation, operation and maintenance. This includes: database development, database maintenance, software and security feature updates, staff training costs, type of IT vendor–government relationship and cost models, need for retroactive recording and legacy data migration, and retroactive population of the IIS database. The distribution of costs across stakeholders should be considered.
- Considering the types of benefits an IIS can deliver, including cost savings (see Box 65) and their distribution across different stakeholders. See Box 28.

Box 65. Potential cost savings

- During an outbreak, an IIS can rapidly provide an overview of vaccination coverage, which has the potential to save costs on ongoing vaccination efforts. There could also potentially be fewer and less widespread disease outbreaks due to the ongoing monitoring of vaccination coverage.
- Lower number of duplicated vaccinations will reduce costs for individuals and providers.
- Less need to convert paper copies to electronic formats.
- Automated supply chain management reduces manual administrative tasks.
- Less time needed for individual vaccine schedule decision-making.
- Less time spent trying to track down vaccination histories.

Funding

The funding model should ensure the sustainability of the project. The budget needs to include formative research, and the development, implementation, and maintenance of the system. For example, to reach the implementation stage, a project may initially seek funding for at least five years. Beyond this period, a project can either seek to secure further funding from the same source or establish a different funding model for the implementation stage.

Box 66. Opportunity costs

There may be opportunities to reduce the burden of reporting on healthcare workers. For example, healthcare workers may collect a range of data elements in immunisation register books. There may be ways to reduce the opportunity cost of reporting by health workers by moving paper reporting of health indicators to an electronic form. By facilitating automated reporting, healthcare workers will have more time for other work task (e.g. clinical tasks).

Models of financing vary between European countries and are dependent in part on ownership: at the time of writing, 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 financial means for the IIS in Belgium (Flanders) and Spain (Andalucía). For more examples, see Box 67.

Box 67. Seeking funding for IIS in Denmark, France, Canada, Bulgaria and the Netherlands

In Denmark, initial funding for the development of the IIS was originally one million euros over three to four years. Securing funding for maintenance in the implementation phase turned out to be rather difficult, and the people involved in the establishment of the IIS found it challenging to make a business case for this. This is partly because IIS maintenance is conducted by the national board of eHealth and not by the IIS team.

In France, the MesVaccins.net system is funded by paid user subscriptions. Health professionals pay 30 euros/year to use the system, with system access being paid by the physician and pharmacists union in some regions.

In Canada, the CANImmunize app was developed by the Ottawa Hospital Research Institute. A private company was created to develop and implement the first national version of the app. To improve access to sustainable funding for the app, the company was merged into the Ottawa Hospital mHealth Lab, with funding from the Public Health Agency of Canada. Having a private company in charge of the project made integration projects and government endorsement of CANImmunize a challenge, but after the merger this was no longer an issue.

In 2014, Bulgaria received a project grant contract under Programme BG 07 'Public Health Initiatives', based on the Norwegian financial mechanism 2009–2014 and the financial mechanism of the European Economic Area 2009–2014. The project title was 'Improving the surveillance of vaccine-preventable diseases: Development of a model of a web-based immunisation registry.' The project contributes to the improvement of governance in healthcare and the quality of the national immunisation programme through a web-based immunisation register. The project ran from November 2014 – April 2017; pilot tests in one region of Bulgaria are ongoing.

In the Netherlands, the IIS is part of a broader renewal programme of information systems for prevention programmes. The renewal programme is commissioned to the National Institute for Public Health and the Environment, which is under the auspices of the Dutch Ministry of Health, Welfare and Sport. The budget for programming and hosting of the IIS is provided by the Ministry of Health.

Budgeting for continuous improvement, oversight and system maintenance

To ensure that the IIS does not become yet another legacy system, it is important that the IIS project plan sufficiently budgets for continuous improvements, oversight, and system maintenance.

The scalability of an IIS should be taken into account. It is important to ensure that the IIS can support and sustain a large amount of data that continuously increases. Systems should be scalable if a large increase of data is expected over a short period of time, e.g. during a pandemic. Scalability may also refer to the number of users and the support of interoperability connections. The number of users and/or connections may be low at first but will continue to increase; the IIS has to be able to accommodate a growing number of users.

Once an IIS is built and implementation is underway, further adjustments – and costs – should be expected. For example, an IT developer will be required to conduct system adjustments and general system maintenance, while a public health professional should be in charge of overseeing the system including monitoring, evaluation, and identifying and implementing further adjustments.

In addition, there may be other technical costs (for example, data hosting costs, costs for short codes for phone numbers) that need to be considered in order to ensure the proper maintenance of the system.

Concluding remarks

There are many ways to design, develop and implement an IIS, and there are various factors that need to be taken into account at different steps. This technical document collates guiding principles and good practices from different aspects of IIS development and implementation and aims at expanding the stakeholders' knowledge of IIS. Having a clear idea of the scope of the work and the potential risks and challenges, can greatly influence the success of a project.

Here is a brief summary of important points to take into account:

- **Stakeholders.** Stakeholders have to be informed about the needs and potential benefits of an IIS, both with regard to the individual vaccine recipient and the population as a whole. Involving stakeholders at an early phase of the design and planning stage increases the chances of acceptance and successful implementation. This document outlines the added value of IIS for different stakeholders, including the general population, healthcare professionals, vaccine providers, vaccine programme managers, policymakers, competent authorities responsible for human medicine, and heath researchers.
- **Legal and data protection.** Understanding the regulatory environment and how to implement the General Data Protection Regulation (GDPR) is essential for the implementation of an IIS. The basic principles on how IIS data should be used for the benefit of individuals, public health and scientific research are outlined in this document. It is vital that the legal context of an IIS is taken into account at an early stage so that data protection principles can be built into the system.
- **IIS functionalities.** Designing and developing IIS functionalities that fit the particular context is essential, as is ensuring that all recorded data variables are appropriate and support these functionalities. Core features include consolidating records of vaccination administered by different providers; determining which vaccinations are due or overdue; and determining immunisation coverage levels. A description of ideal system functionalities is helpful when designing an IIS. A description of the minimal outputs that an IIS ought to offer in order to support the delivery and monitoring of immunisation programmes can be found in this document.
- **System design and development.** Developing a centralised top-down system is fundamentally different from designing a decentralised bottom-up system. But both approaches have to first identify system needs, key functions, and data fields to ensure a fully functional IIS. System-level considerations and the conceptual design behind each key IIS component have a direct impact on decisions around data elements, standardisation, establishing the denominator, data quality, storing data, user access, and interoperability.
- **Project planning for sustainability.** Establishing an interdisciplinary team is important to ensure the support of the various stakeholders. Other important steps include mapping the context to build up the knowledge around what already exists for IIS and eHealth; developing a high-level model of the system to help conceptualise the system; ensuring an iterative approach with system design and development; and choosing an approach for system roll-out and user training. Defining and acquiring sustainable modes of funding is essential for the longevity of the project.

At any project stage, problems can arise, for example a shortage of staff. These and other problems should be anticipated well in advance, and mitigation strategies should be part of the project plan.

IIS are considered valuable tools for vaccination programmes. At the community level, IIS allows for rapid information on vaccination coverage and let public health authorities react quickly to events such as safety alerts or disinformation campaigns. At individual level, IIS provide people with access to their vaccination records, which helps make informed decisions about vaccinations.

IIS technology has been available for several years and supportive legislation in the EU for these systems has been in place since 2011. IIS are also considered a priority in the WHO European Vaccine Action Plan 2015–2020. There are a number of functioning IIS in EU/EEA countries, but there is still some way to go before all countries operate such a system.

IIS are dynamic systems that are continually evolving and developing. They require long-term planning and sustainable resources to ensure their longevity. There is much to learn from different countries and regions that implemented or upgraded their systems, and the exchange of this knowledge is extremely valuable for the successful implementation of an IIS.

Annex. National IIS, immunisation registers and systems in pilot testing

Country	IIS name and link (if available)
Belgium (Flanders)	Vaccinnet http://www.vitalink.be/wat-is-vitalink/vaccinatiegegevens-delen
Bulgaria	No direct link
Croatia	National Public Health Information System No direct link
Denmark	The Danish Vaccination Register (DDV) http://sundhedsdatastyrelsen.dk/vaccinationsregister
France	Mesvaccins https://www.mesvaccins.net/
Finland	The National Vaccination Registry https://thl.fi/en/web/rokottaminen/kansallinen-rokotusohjelma/rokotusrekisteri
Germany	KV-Impfsurveillance (Associations of Statutory Health Insurance Physicians (ASHIP) vaccination monitoring) http://www.rki.de/kv-impfsurveillance
Ireland	National School Immunisation System (SIS) https://www.hiqa.ie/areas-we-work/health-information/data-collections/national-school-immunisation-system-sis
Italy	Information on the various regional systems: http://www.seu-roma.it/riviste/annali_igiene/open_access/articoli/30-02-01-DAncona.pdf
Malta	National Immunisation Electronic Database No direct link
Netherlands	Praeventis No direct link
Norway	SYSVAK https://www.fhi.no/hn/helseregistre-og-registre/sysvak/
Portugal	Vacinas http://spms.min-saude.pt/
Romania	National Electronic Registry of Immunisation https://www.renv.ro/renv/login.php
Spain (Andalucia)	Módulo de vacunas DIRAYA http://ws140.juntadeandalucia.es/formacion-tic/mod/page/view.php?id=5418
Sweden	National Vaccination Registry https://www.inera.se/svevac
UK (England)	Child Health Information System https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/chis-provider-service-spec.pdf
UK (Scotland)	Scottish Immunisation Recall System (SIRS) http://www.ndc.scot.nhs.uk/National-Datasets/data.asp?SubID=12
UK (Wales)	National Community Child Health Database (NCCHD) http://www.publichealthwalesobservatory.wales.nhs.uk/ncchd
UK (Northern Ireland)	Child Health System (CHS) No direct link

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