



Survey on Functional Standards for Computerised Immunisation Registries in Europe 2008

VENICE

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Abbreviations

ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
MSs	Member States
MCV	Measles containing vaccine
VENICE	Vaccine European New Integrated Collaboration Effort
NAC	National Advisory Committee
CIR	Computerised Immunisation Register

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ISO 3166-1 Country Codes

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

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Summary

Immunisation registries are confidential, population-based, computerised systems for maintaining information regarding children's vaccinations. A population-based registry includes the majority of children in a geographic area, regardless of health-care source. Children's names can be entered into the registry at birth (e.g., through a link with electronic birth records) or at first contact with the health-care system. If a registry includes all children in a geographic area and all providers report vaccination and immunisation data, the registry can provide a single data source for all community vaccination partners. Registries enable audit of implementation of vaccination strategies, and they decrease resources needed to measure, achieve, and maintain increased levels of vaccination coverage. Immunisation registries offer potential benefits to parents, communities, health-care systems, and the public health system.

The objective of the survey is to describe the minimum set of core data for functional standards among those EU and EEA Member States which indicated having immunisation registries at the local and/ or national level in previous studies conducted by VENICE project.

A cross-sectional survey was undertaken. Survey was conducted by VENICE Project in European Union (EU) and European Economic Area (EEA) Member States (MS). Each MS previously identified and enrolled gatekeepers, who are responsible for conducting all VENICE surveys inside their countries. Currently in the VENICE project there are 27 EU and two EEA (NO and IS) participating countries. Sixteen EU/EEA countries were contacted and asked to complete questionnaire that reported that they have local or national immunisation registries in a previous survey on vaccination coverage assessment carried out by VENICE project in 2007. A standardised questionnaire was developed and administered by email. The data were analysed using the computer-based STATA software. A preliminary report with a summary of survey analysis was sent to the relevant gatekeepers and were asked to validate the results.

The response rate was 100% to the survey. Thirteen countries have CIR. UK completed questionnaire for NI, SC, WL separately as the CIR systems are different in these countries. It was considered as three countries in this report. Overall 15 countries were included into analysis.

Thirteen (13/15; 87%) countries have a document in relation to the official policy for a minimum set of functional standards and a document regarding security in place. Fourteen countries (14/15; 93%) reported that they have a written confidentiality policy and eleven (11/15; 73%) have a document for electronic data storage approved by the NAC or corresponding body.

All countries (15/15; 100%) reported that they have fields in CIR for patient date of birth, gender, vaccine type, date of vaccination and unique identifier. Fourteen countries (14/15; 93%) have data for patient name (first and last) and address, 12 countries (12/15; 80%) have fields for patient social security number, vaccine dose and lot number. Eight countries (8/15; 53%) indicated that they have information or flag for not immunised and seven (7/15; 47%) information on adverse event (flag).

Three countries (3/15; 20%) reported that they have a field for collecting information on subgroups (one country has data on ethnicity, two on country of birth). Eleven countries indicated that they have field for vaccine provider. Seven (7/15; 47%) and eight (8/15; 53%) countries have fields in their CIR systems on vaccine dose number and expiration date respectively. Between four and five countries (27% or 33% respectively) have data on patient birth registration number, medical insurance number, mothers social security number, fathers name or vaccine injection site.

Five countries (5/15; 33%) reported that they establish a CIR record after birth of each newborn child in the catchment area within seven days, four countries (4/15; 27%) within one month and three (3/15; 20%) at the time of first vaccination.

The immunisation provider have access to information from the registry of immunisation records at the time of the patient's visit in ten (10/15; 67%) countries. The immunisation provider can submit core data on immunisation at the time of patient encounter for vaccine administration in nine countries (9/15; 60%). Data are submitted electronically or by paper report form in ten countries (10/15; 67%).

The immunisation registries have a function:

- In 13 countries (13/15; 87%) for recover of lost data (disaster recovery), seven (7/13; 54%) of them have a system of daily back up.
- In 13 countries (13/15; 87%) system are able to produce a reminder or recall notices and automatically produce immunisation coverage reports for provider's practice.
- In 14 countries (14/15; 93%) the automated function that generates a list of individuals due to or late for immunisations.
- In ten countries (10/15; 67%)
 - the automated function at providers level that determines immunisations in compliance with NAC (or corresponding body);
 - that allows authorised users to produce an individual's immunisation history that is accepted as an official immunisation record;
 - that can consolidate all immunisation records from multiple providers (using de-duplication procedures).

Although this survey demonstrates a lot of agreement on the core data elements, functions and capabilities for CIR between countries, it is clear that immunisation registries also vary across the countries greatly that has implemented them in place. Approximately half countries have CIR in EU/EEA. Some countries have different CIR systems inside the country or CIR covers only part of country. However this study provides baseline information and was able to provide an accurate picture of the European situation in relation to CIR.

Introduction

Vaccinations are a critical public health tool: they save lives, reduce health-care costs, and improve the quality of life for persons of all ages. After safe and effective vaccines were introduced countries have experienced $\geq 95\%$ reductions in cases of childhood vaccine-preventable diseases, compared with prevaccine-era levels. Reported cases are at record low levels; however, vaccine-preventable diseases will return if vaccination coverage levels decrease. (1)

Efforts to improve access to vaccines and improve delivery of vaccination programmes are a major priority for health services worldwide. However, many European countries have failed to achieve immunisation coverage rates needed to prevent on-going disease transmission and outbreaks. Increasingly, the ability to measure immunisation coverage at national and sub-national levels is used as a key indicator for monitoring performance of immunisation programmes in order to identify the best and sub-optimal practices.

In recent years improvements in information technology has facilitated monitoring of immunisation uptake. In those countries or regions where disaggregate data on each individual vaccinated is collected this has enabled a more detailed analysis of the performance of vaccination programmes, including indicators on timeliness and quality (eg. number of valid doses), and coverage by geographical area and sub-populations. A number of European countries which have developed immunisation registries for the express purpose of monitoring vaccination uptake provided information on the type of system used in their respective countries- detailed in this report.

The Vaccine European New Integrated Collaboration Effort (VENICE, <http://venice.cineca.org/>) project was launched in January 2006. It is funded by the European Commission Directorate General for Health and Consumer Protection (DG SANCO) within the framework of the EU Public Health Programme and supported by the European Centre for Disease Prevention and Control (ECDC). Twenty-seven EU Member States and two EEA countries (Norway and Iceland) participated in the project whose aim is to establish a European network of experts who work with national immunisation programmes.

Previously published reports from the VENICE project have demonstrated the wide variation in immunisation programmes and vaccination policies across Europe, schedules often differ from country to country and sometimes even within countries. Much of this variation can be attributed to historic and current differences in healthcare delivery systems and resources available for immunisation programmes. In relation to monitoring immunisation coverage there is a need to improve knowledge of computerised vaccine registries working in European countries.

Computerised immunisation registries (CIR)

Immunisation registries are confidential, population-based, computerised systems for maintaining information regarding children's vaccinations. A population-based registry includes the majority of children in a geographic area, regardless of health-care source. Children's names can be entered into the registry at birth (e.g., through a link with electronic birth records) or at first contact with the health-care system. If a

registry includes all children in a geographic area and all providers report vaccination and immunisation data, the registry can provide a single data source for all community vaccination partners. Registries enable audit of implementation of vaccination strategies, and they decrease resources needed to measure, achieve, and maintain increased levels of vaccination coverage. Immunisation registries offer potential benefits to parents, communities, health-care systems, and the public health system.(1)

Registries must be able to detect whether incoming information is already in the registry or is new. The majority of registries have developed processes for detecting when a registry contains multiple records for one child. Registries normally collect timely and complete immunisation information for a substantial proportion of their target population or a subgroup of their population. (1)

Immunisation registry enable immunisation providers to check on the immunisation status of an individual child, regardless of where the child was immunised; form the basis of an optional recall/reminder scheme; provide a measure of immunisation coverage at national, provincial/territorial and local level; provide effective management tool for monitoring immunisation coverage and service delivery. In some settings (e.g. Australia), parents have web-based access to their child's immunisation records and can check on their child's immunisation status. (3)

Some countries have developed national immunisation registries whereas others have developed regional ones. For instance, each province and network in Canada developed its own electronic immunisation registry. Provinces and territories are responsible for maintenance of immunisation registries. Each registry is required to contain records of all children <7 years of age (all Canadian citizens and landed immigrants who have lived in Canada for ≥ 3 months.) Only authorised practitioners will have access to registries. (2)

Aim Objectives of the Study

The objective of the survey is to describe the minimum set of core data for functional standards among those EU and EEA Member States which indicated having immunisation registries at the local and/ or national level in a previous study conducted by VENICE project.

Methods and Materials

Study Design

A cross-sectional survey was undertaken. The survey was conducted by the VENICE Project in the European Union (EU) and European Economic Area (EEA) Member States (MS). Each MS previously identified and enrolled gatekeepers, who are responsible for conducting all VENICE surveys inside their countries. Currently in the VENICE project there are 27 EU and two EEA (NO and IS) participating countries.

Sixteen EU/EEA countries were contacted and asked to complete a questionnaire (BE,DE,ES,HU,IE,IS,IT,NL,NO,PT,RO,SE,UK,SI,DK, MT). Fifteen of them reported that they have local or national immunisation registries in a previous survey on vaccination coverage assessment carried out by the VENICE project in 2007 (final report for this survey is available on line at

http://venice.cineca.org/Report_I_WP3.pdf). MT joined the VENICE project later in January 2008 and was also contacted and asked to fill in questionnaire in relation to an immunisation registry in the country. Countries which do not have immunisation registries in place according VENICE study: AT, BG,CY,CZ,EE,FI,FR,GR,LV, LT,PL,SK; LU did not respond to that survey.

The expected output of this survey is development of a technical report, which describes current situation in EU/EEA countries which have immunisation registries. The preliminary data have been presented in a workshop organised by VENICE project, which was held in Rome on 1st -3rd December 2008.

Data collection

A standardised questionnaire was developed using close-ended questions predominantly. Information was sought on:

- Policy for functional standards: whether countries had official policy for functional standards, confidentiality and security;
- Capabilities and functions of immunisation registries: whether immunisation registries have function for recovery of lost data, function to generate list of unimmunised person's, ability to produce reminder notices, immunisation coverage reports locally and for entire area, ability to produce individual official record and ability to consolidate records.
- Core data set elements: demographic details (name, surname, date of birth, patient address, date of birth, gender); type of vaccine, vaccine dose and lot number, date of vaccination, site of vaccination; unique identifier, social security number; not immunised (flag), adverse event (flag).
- Optional data set elements: patient alias, telephone number, birth facility, information on subgroups, patients medical insurance number, mothers/father's name and social security numbers, vaccine expiration date, dose number, provider (questionnaire available on Appendix 1).

Data handling

The questionnaire was developed in early November 2008 and administered by email. The accompanying letter to MSs explained the objectives and rationale of the study. The questionnaire was filled in by gatekeepers in each country which has immunisation registries and sent back to WP3 for analysis.

Data processing

The VENICE project WP3 staff developed database with EpiData 3.1 software. Single data entry was introduced.

Pilot study

The questionnaire was not piloted.

Study time

MSs were asked to complete the questionnaire between 17th and 24th November 2008. Data were analysed to the end of November and preliminary results were available in early December 2008. Additional data from countries that completed the questionnaire after the deadline were added later (early January 2009).

Data analysis

The data were analysed using the computer-based STATA software. Frequencies of all variables and the appropriate descriptive statistics were produced.

Data validation

As part of the data validation process a preliminary report with a summary of survey analysis was sent to the relevant gatekeepers on April 1st 2009. Gatekeepers in each country were asked to check the report and presented data and validate the results by April 15th.

Background for some countries

Background information for Belgium:

Belgium has a partially decentralised health care system and the responsibility for health care is shared between the federal Government and several regional authorities: the community Ministries of Health (Dutch, French, German and the Common Community Commission of Brussels Capital Region). One of the responsibilities of the community governments is immunisation. Currently there is no national computerised immunisation registry for Belgium. Only in Flanders a web-based ordering system for vaccines exists, “Vaccinnet” and is linked to a population database in which vaccinations are registered. This builds a vaccination registry. The answers to the questions in this survey reflect what exists in Flanders.

Background information for Spain

Spain does not have a national registry but has local and regional registries in almost 50% of Autonomous Regions.

The Spanish gatekeeper completed the survey based on one of the Autonomous registries in Spain, but other registries are similar.

Spain has a registry of adverse events at national level, not as a part of immunisation system.

Background information for Italy

Italy does not have a national immunisation registry, but local registries.

At the time of the survey, about 70% of the Italian health local units have a Computerised Immunisation Registry; they don't use the same software.

Background information for Ireland

IE does not have a national immunisation registry. Each health region has its own system. However there are standards that are similar across these registries.

Background information for UK

The UK does not have a single computerised immunisation register, but has several different child health computers systems operational across the four countries. The success of the UK immunisation programme has been built on these computerised child health systems, initially pioneered in West Sussex in the 1960s and, by the mid-1980s, deployed in most health districts. These resulted in a real improvement in both immunisation programme monitoring and vaccine coverage in districts using computer-managed systems. The systems were at the cutting edge of clinical information systems and a model for how an IT system can integrate several functions with benefits to all, supporting clinical decision making at local level as well as ensuring local implementation and national monitoring of a major public health

programme. Information from such systems is used operationally at local level to send out invitations for childhood immunisations, produce lists of children who do not attend for health visitors to follow up, and to produce general practice level coverage data for local action.

Scotland, Wales and Northern Ireland each have their own national child health computer systems. In England there several different child health systems in use. Some of these have recently or are currently being replaced by systems that link to other community-bases systems and offer appropriate interoperability with other systems. The Department of Health recently established a National Child Health Immunisation Standards Board, the aim of the board is to re-establish the ‘norms’ comparable across the country with respect to information and IT systems to enable all children to have the same immunisation protection, ensuring the new child health computer systems developed nationally are the best possible set of systems, which can manage data in the most efficient way, minimising excess resources and duplication.

Results

Response rate (100%)

The questionnaire was completed by 13 (BE, DK, IS, IE, MT, NL, NO, PT, SI, ES, SE, IT, UK) out of 16 EU/EEA countries. DE, HU and RO returned partly completed questionnaires and explained that there are no CIR in these countries. UK completed questionnaire for NI, SC,WL separately as the CIR systems are different in these countries. Overall 15 countries were included into analysis.

Official policy and procedures for CIR

Table 1 presents detailed information for the official policies that are available in countries with CIR. Thirteen (13/15; 87%) countries have a document in relation to official policy for minimum set of functional standards and a document regarding security in place. Fourteen countries (14/15; 93%) reported that they have written confidentiality policy and eleven (11/15; 73%) have a document for electronic data storage approved by NAC or corresponding body.

Table 1. Available official policy and procedures for CIR. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

	Policy available	Total	Policy not available	Total	Unknown /Not responded	Total
Official policy for minimum set of functional standards	BE,IS,IE,IT,MT,NL,NO,PT,SI,ES,SC,WL*,NI	13	DK,SE	2		0
Electronic data storage approved by NAC	BE,DK†,IE,MT,NO,PT,SI,ES,SC,WL,NI	11	IT,SE	2	IS,NL	2
Confidentiality policy and procedures	BE,DK,IS,IE,IT,MT,NL,NO,PT‡,ES,SE,SC,WL§,NI	14		0	SI	1
Security policies and procedures	BE,DK,IS,IE,IT,MT,NL,NO,PT‡,SE,SC,WL§,NI	13		0	ES,SI	2

*In WL (released and cascaded through DSCN system)

†DK Store electronically data but not approved by an official body

‡ In PT policy for confidentiality and security are not specific for immunisation but general for all health registers.

§ WL Policies are in place at regional NHS Trust level governing data collection, storage and submission, national policies are in place in Health Solutions Wales and NPHS Wales governing collection, use of and secure storage/ transfer of patient identifiable information.

Core data elements for CIR

All countries (15/15; 100%) reported that they have fields in CIR for patient date of birth, gender, vaccine type, date of vaccination and unique identifier. Fourteen countries (14/15; 93%) have data for patient name (first and last) and address, 12 countries (12/15; 80%) have fields for patient social security number, vaccine dose and lot number. Eight countries (8/15; 53%) indicated that they have information or flag for not immunised and seven (7/15; 47%) information on adverse event (flag). Detailed information on electronic data storage for core data elements is presented in table 2.

Optional data set for CIR

In table 3 presented data on optional data set for CIR. Three countries (3/15; 20%) reported that they have a field for collecting information on subgroups (one country has data on ethnicity, two on country of birth). Between four and five countries (27% or 33% respectively) have data on patient birth registration number, medical insurance number, mothers social security number, fathers name or vaccine injection site.

Table 2. Core data elements for computerised immunisation registries. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

Core data elements to CIR	Data available	Total	Data not available	Total	Unknown /Not responded /Not applicable	Total
First Name	BE,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	14	DK	1		0
Middle Name	BE,IS,NL,NO,PT,ES,SC,WL	8	SE,DK,IE,IT,MT,SI,NI	7		0
Last Name	BE,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	14	DK	1		0
Date of birth	BE,DK,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	15		0		0
Patient address	BE,DK,IS,IE,IT,MT,NL,NO,PT,SI,ES,SC,WL,NI	14	SE	1		0
Patient Gender	BE,DK,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	15		0		0
Patient birth state/ country	NL,PT,ES,IT,WL	5	BE,DK,IE,MT,NO,SI,SE,SC,NI	9	IS	1
Patient social security number	DK,IS,IE>,IT,NL,NO,SI,ES,SE,SC,WL,NI	12	BE,MT	2	PT	1
Type of vaccine	BE,DK,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	15		0		0
Vaccine trade name	BE,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE	11	DK,SC,WL,NI	4		0
Vaccine dose number	BE,DK,IS,IE,IT,MT,NL,PT,SI,ES,WL,NI	12	NO,SE,SC	3		0
Vaccine lot number	BE,IE,IT,MT,NL,PT,SI,ES,SE,SC,WL,NI	12	DK,IS,NO	3		0
Date of vaccination	BE,DK,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	15		0		0
Anatomical site of vaccination	IE,IT,NL,SI,SE	5	BE,DK,IS,MT,NO,PT,ES,WL,NI	9	SC	1
Vaccine expiration date	IE,IT,MT,NL,PT,SI,SE	7	BE,DK,IS,NO,NI	5	ES,SC,WL	3
Vaccine provider	BE,IS,IE,IT,MT,NL,NO,PT,SI,SE,NI	11	DK	1	ES,SC,WL	3
Not immunised (flag)	IS,IE,MT*,NO,PT†,SE,SC,WL‡	8	BE,DK,IT,NL,NI	5	SI,ES	2
Adverse event (flag)	BE,IE,MT*,PT†,SI,SE	7	DK,IS,IT,NL,NO,SC,NI,WL§	7	ES	1
Unique identifier	BE,DK,IS,IE±,IT**,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	15		0		0
If no, unique personal identifier available						
Patient alias	IS,IE,NO>	3	BE,MT,SI,IT,SC,NI	6	DK,NL,ES,SE,PT	5

Patient phone number	IS,IE,IT	3	BE,MT,NL,SI,SC,NI	6	NO,DK,PT,ES,SE	5
Mother's Maiden name (first, middle last)	IS,NO>,IT	3	BE,IE,MT,NL,SI,SC,NI	7	DK,PT,ES,SE	4
Mother's Social Security Number (or equivalent unique identifying number)	IS,IE,NO>,NI	4	BE,MT,NL,SI,IT,SC	6	DK,PT,ES,SE	4

* In MT defaulter list available (not immunised flag). Adverse event flag is being developed.

† In PT not a “flag” but non vaccinated people are identified by immunisation registry; adverse events are registered in individual vaccination record.

‡ WL The Child Health system in Wales has the facility to set flags for unimmunised children.

§ WL This information is recorded by the MHRA yellow card system.

± In IE not routinely used or always available.

** In IT, the unique personal identifier is the tax code number (“codice fiscale”).

> In NO if the “patient” is vaccinated before being given a unique identifying number from the Norwegian population registry, i.e. vaccinated shortly after birth or newly immigrated to Norway then alias, mothers maiden name and social security number is available.

Table 3. Optional data elements for computerised immunisation registries. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

Optional core data set	Data available	Total	Data not available	Total	Unknown /Not responded /Not applicable	Total
Patient alias	IE,PT,NO	3	BE,DK,IT,MT,NL,SI,SE,NI	8	IS,ES,SC,WL	4
Patient address	BE,IE,IT,MT,PT,SI,SE,NO,NI	9	DK,NL	2	IS,ES,SC,WL	4
Patient phone number	IE,IT,MT,PT,SE,NI	6	BE,DK,NL,SI,NO	5	IS,ES,SC,WL	4
Patient birthing facility	NI	1	BE,DK,IE,IT,NL,PT,SI,SE,NO	9	IS,MT,ES,SC,WL	5
Patient Social Security Number (or equivalent unique identifying number)	IE,MT,PT,SE,NO*,NI	6	BE,DK,IT,NL	4	SI,IS,ES,SC,WL	5
Information on subgroups						
Ethnicity	NI	1	BE,IS,IE,IT,MT,DK,PT†,NL‡,NO,SI,SE	11	SC,WL,ES	3
Country of birth	IT,NL	2	BE,DK,IS,IE,MT,PT,SI,SE,NO,NI	10	ES,SC,WL	3
Marginal groups		0	BE,IS,IE,IT,MT,DK,NL,NO,PT,SI,SE,NI	12	ES,SC,WL	3
Patient primary language		0	BE,IS,IE,IT,MT,DK,NL,NO,PT,SI,SE,NI	12	ES,SC,WL	3

Patient birth order		0	BE,IS,IE,IT,MT,DK,NL,NO,SI,SE,NI	11	ES,PT,SC,WL	4
Patient birth registration number	IS,NO*,NL,SI,SE	5	BE,DK,IE,IT,MT,NI	6	ES,PT,SC,WL	4
Patient medical insurance number	IE,PT,SI,SE	4	BE,DK,IS,IT,MT,NL,NO,NI	8	ES,SC,WL	3
Mother's social security number (or equivalent unique identifying number)	IS,IE,MT,PT,NI	5	BE,DK,IT,NL,SI,SE,NO*	7	ES,SC,WL	3
Father's name	IS,IT,MT,PT	4	BE,DK,IE,NL,SI,SE,NO*,NI	8	ES,SC,WL	3
Father's social security number (or equivalent unique identifying number)	IS,MT,PT	3	BE,DK,IE,IT,NL,SI,SE,NO*,NI	9	ES,SC,WL	3

*In NO all persons have a unique identifying number, which is the same as a "birth registration number". This number, for the child being vaccinated, is available in the immunisation registry. The personal data (name and unique identifying number) for the mother and father, can be obtained from the National Population Register

† In PT information on subgroups like country of birth is individual and administrative. It cannot be used for statistical purposes or to identify sub groups.

‡ In NL information for ethnicity only based on country of birth from child/mother/father is available.

Time for immunisation record establishment

Five countries (5/15; 33%) reported that they establish a CIR record after birth of each newborn child in the catchment area within seven days, four countries (4/15; 27%) within one month and three (3/15; 20%) at the time of first vaccination. More detailed information in relation to this question is presented in table 4.

Table 4. Time period for record establishment. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

Record establishment	Countries	Total
Within 1 week (7 days)	IE,MT,PT,ES,WL	5
Within 2 weeks	NL	1
Within 3 weeks	SE,NO*	2
Within 4 weeks (1 month)	BE,SI,IT†,NI	4
Within 2 months	BE	1
Within 3 months	NO*	1
At the time of first vaccination	DK,IS,SE	3
Unknown	SC	1

* In NO usually at age of 3 months at first vaccination, but some children are given vaccination at birth in hospital, then record is established within 1-3 weeks.

†In IT not all the immunisation computerised registries are linked to population registries.

Access to data and data submission to CIR

The immunisation provider have an access to information from the registry of immunisation records at the time of the patient's visit in ten (10/15; 67%) countries.

The immunisation provider can submit core data on immunisation at the time of patient encounter for vaccine administration in nine countries (9/15; 60%). Data are submitted electronically or by paper report form in ten countries (10/15; 67%).

Detailed information provided in table 5.

Table 5. Data access and submission to computerised immunisation registries. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

Data submission	Function available	Total	Function not available	Total	Unknown /Not responded	Total
Provider access to CIR records	BE,IS,IT,MT*,NL,NO,PT,ES,SE,SC	10	DK,IE,WL†,NI	4	SI	1
Provider submit core data at time of encounter	BE,IS,IT,MT,NO,PT,ES,SE,NI	9	DK‡,IE,NL,SI,SC,WL§	6		0
If no, when provider can submit data						
Within 1 week (7 days)	IE,NL,ES,SC,WL	5		0		0
Within 4 weeks (1 month)	SC	1		0		0
Within 3 months	SI	1		0		0
Information submitted						
Electronically	BE,DK,IS,MT±,NO**,PT,SI,ES,SE,IT	10	IE,NL,WL,NI	4	SC	1
Paper report form	IE,MT§,NL,NO**,SI,ES,IT,SC,WL,NI	10	IS,SE	2	BE,DK,PT	3

Verbal report	NL,ES	2	IS,IE,IT,MT,NO, SI,SE,SC,NI	9	BE,DK,PT, WL>	4
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* In MT provider have access to CIR only at the national immunisation centre but not at the immunisation centres at health centres in different towns.

† WL The Child Health system generates a list of due immunisations for the routine schedule, if the vaccination is delivered in general practice the immuniser will also have access to the patient's records.

‡ The vaccination registry in DK is created by extracting data from the data base containing immunisation providers' bills for all services provided to the national health insurance system. The provider is not submitting data to the registry and is not supposed to send the bills by a given day.

§ WL The immuniser gives details of immunisations given using a paper form which is returned to the administrative office as soon as possible. The immuniser is not able to enter data directly onto the child health system (the 'register') but does enter details of the vaccination given onto the practice computer system.

± In MT information electronically is submitted to national immunisation centre. Online reporting for private doctors is being developed. For private sector paper form is in use.

** In NO 99% information submitted electronically and about 1% using paper report form.

>WL Information usually submitted through a standard paper form, however regional administration offices can be contacted by telephone or email to request data or submit data in extenuating circumstances.

Functions and capabilities of immunisation registries

The immunisation registries have a function for recover of lost data (disaster recovery) in 13 countries (13/15; 87%), seven (7/13; 54%) of them have a system of daily back up. The automated function at providers level that determines immunisations in compliance with NAC (or corresponding body), function that allows authorised users to produce an individual's immunisation history that is accepted as an official immunisation record and the function that can consolidate all immunisation records from multiple providers (using de-duplication procedures) is available in ten countries (10/15; 67%). Thirteen countries (13/15; 87%) reported that there are functions that are able to produce a reminder or recall notices and automatically produce immunisation coverage reports for provider's practice. The automated function that generates a list of individuals due to or late for immunisations is available in 14 countries (14/15; 93%). Details on capabilities and functions of immunisation registries are presented in table 6.

Table 6. Functions and capabilities of computerised immunisation registries. Survey on functional standards for computerised immunisation registries in Europe, 2008. (n=15)

Functions of immunisation registries	Functions available	Total	Functions not available	Total	Unknown /Not responded /Not applicable	Total
Recover lost data (disaster recovery)	BE,DK,IE,IS,MT,NL,NO,PT,ES,SE,SC,WL*,NI	13		0	SI,IT†	2
Back - up systems	BE,DK,NL,PT,SE,NI,WL	7		0	SC	1
Other server	DK	1		0		0
Patient journal in health institution - medical records	NO	1		0		0
Automated function at provider level that determines immunisations, in compliance with NAC	BE,IT,MT,NL,PT,SI,ES,SE,SC,NI	10	NO,DK,IS,IE,WL‡	5		0
Automated function that generates a list of individuals due or late for immunisations	BE,IS,IE,IT,MT,NL,NO,PT,SI,ES,SE,SC,WL,NI	14	DK	1		0
Ability to produce reminder or recall notices	BE,IS,IE,IT,MT,NL,NO,PT,SI,SE,SC,WL,NI	13	DK	1	ES	1
Automatically produce immunisation coverage reports for provider's practice	BE,IS,IE,IT§,MT±,NL,NO,PT,SI,ES,SC,WL**,NI	13	DK,SE	2		0
Automatically produce immunisation coverage reports for catchment area	BE,DK,IS,IE,MT±,NO,PT,SI,ES,SC,WL**,NI	12	NL,SE	2	IT†	1
Automatically produce immunisation coverage reports for subgroups	BE,IS,MT,NL,NO,PT,WL>,SC	8	DK,IE,SI,SE,NI	5	ES,IT†	2
Individual official immunisation record	BE,IS,NO,PT,SI,ES,SE,SC,WL,NI	10	DK,IE,NL	3	IT†,MT	2
Combine all available information relating into a single immunisation record	BE,IS,IE,MT,NL,NO,PT,ES,SE,SC,WL<	11	DK	1	SI,IT†,NI	3
Consolidate all immunisation records from multiple providers, using de-duplication procedures	BE,DK,IS,IE,NL,NO,SE,SC,WL,NI	10	MT,PT***,ES	3	SI,IT†	2

Opt out of the recall/ reminder scheme or to prevent any details from being released from registry	BE,DK,IE,NL††,PT,SE,SC,NI	8	IS,MT,NO	3	IT†,SI,ES,WL‡‡	4
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* WL The national dataset is updated from regional records quarterly and backed up by Health Solutions Wales, should this fail regional records can be re-accessed. Regional records are electronically backed up according to the individual NHS Trust policy.

† In IT not all the local health units use the same software. The functions are not known of each software.

‡ WL This is achieved through routine clinic lists sent to practitioners and invitation mailers, for opportunistic immunisation practitioners can access their own computerised patient records.

§ In IT at the time of survey about 80% of local health units automatically produced coverage data.

± In MT function to produce vaccine coverage at providers or all catchment area is possible at the National immunisation centre.

** WL Totals for immunised and unimmunised children can be generated at a treatment centre (practice) level. Practice level uptake reports are generated from the national dataset and distributed on a bi-annual basis by NPHS Wales. These tasks are largely automated, but do require user input and expertise.

> WL The software which the child health system in Wales runs on can produce totals and lists of children within user defined age groups, and can generate lists by school groups. Coverage data is available from the national dataset is available by Middle Super Output Area though linking with the NHS administrative record.

< WL Scheduling is carried out by regional NHS Trusts, who have policies in place to ensure data quality. All NHS Trusts in Wales use the same database system and work cooperatively in transferring records when the need arises. Bi-annual meetings are held with participation from all Trusts.

***In PT function for consolidation of all immunisation records was in the process at the time of study.

††In NL people can make objection to vaccination and in that case do not receive calls for vaccination for a certain period. Explicit permission is needed for passing on personal data.

‡‡WL Parents may refuse to consent to the call/ recall system. Anonymised records for these children are present in the national dataset, the same as for children of parents who have consented.

Conclusions

Official policy and procedures for CIR

- Most countries reported that they have an official policy for minimum set of functional standards and an official document regarding security policies and procedures (87%); official document regarding confidentiality (73%); document for electronically storage data on all core data elements which are approved by NAC or corresponding body in the country (73%).

Core data elements and optional data set for CIR

- Most countries contains the fields on core data elements (first and last name, date of birth, patient address, gender, social security number, vaccine type, trade and lot number, date of vaccination) in their immunisation registries (from 73% to 100%); half countries contains information on adverse events or not immunised flag and only one third countries collects information on anatomical site of vaccination.
- Approximately half countries have information on patient phone number, social security number, vaccine dose number and expiration date; most countries (73%) have data on vaccine provider. Approximately one third countries contain the data on patient birth registration number, medical insurance number, mother's social security number and father's name. Only three countries indicated that they collect information on subgroups (20%; ethnicity and country of birth).

Time for immunisation record establishment

- Approximately one third countries indicated they establish the immunisation registry record within 7 days or within one month after birth of each newborn child. Three countries reported establishment of immunisation record at the time of first vaccination.

Access to data and data submission to CIR

- In most countries (67%) immunisation provider have an access to CIR records and can submit core data on immunisation to CIR at the time of encounter for vaccine administration. Most countries (67%) submit immunisation information electronically and/or using the paper report form.

Functions and capabilities of immunisation registries

- In most countries CIR have disaster recovery function (87%); CIR is capable to produce official immunisation record or can consolidate all immunisation records from multiple providers using de-duplication procedures (67%); CIR can produce recall notices or automatically can produce vaccination coverage reports (87%). CIR in almost all countries has function that generates list due to or late immunisations (93%).

References

1. Initiative on Immunisation Registries. CDC recommendations and reports. October, 2001 / 50(RR17);1-17.
Available on: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a1.htm>
2. Functional Standards and Minimum (Core) Data Sets for a National Immunisation Registry Network and Vaccine Associated adverse Events Surveillance System. Canada. December 2002. 28S6. Available on: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/02vol28/28s6/index.html>
3. Australian Childhood Register. Information kit.

Appendices
Appendix 1. Questionnaire

**Survey on Functional Standards for Computerised
Registries in Europe, 2008
VENICE project**

Please Return Questionnaire by 24 th of November, 2008

COUNTRY: _____

GATEKEEPER: _____

Name of Person who fills in questionnaire (if different from above):

Title: _____

Contact email: _____

Contact Phone Number: _____

Q1. Does your country have document (policy) for minimum set of functional standards for immunisation registries?

Yes No Don't know

Q2. Does your country store electronically data on all core data elements approved by the National Advisory Committee (or corresponding body in your country)?

Yes No Don't know

Q3. Do core data elements include these data?

Q3a. First Name

Yes No Don't know

Q3b. Middle Name

Yes No Don't know

Q3c. Last Name

Yes No Don't know

Q3d. Unique identifier*

Yes No Don't know

Q3e. Date of birth

Yes No Don't know

Q3f. Patient address

Yes No Don't know

Q3g. Patient Gender

Yes No Don't know

Q3h. Patient birth state/ country

Yes No Don't know

Q3i. Patient social security number (or equivalent unique identifying number)

Yes No Don't know

* **Q3d.** If no, unique personal identifier available then may require multiple means of identification.

Q3d1. Patient alias

Yes No Don't know

Q3d2. Patient phone number

Yes No Don't know

Q3d3. Mother's Maiden name (first, middle last)

Yes No Don't know

Q3d4. Mother's Social Security Number (or equivalent unique identifying number)

Yes No Don't know

Q4. Do core data elements contain following information?

Q4a. Name of vaccine

Yes No Don't know

Q4b. Trade name

Yes No Don't know

Q4c. Vaccine dose number

Yes No Don't know

Q4d. Vaccine lot number

Yes No Don't know

Q4e. Date of vaccination

Yes No Don't know

Q4f. Anatomical site of vaccination

Yes No Don't know

Q4g. Not immunised (flag)

Yes No Don't know

Q4h. Adverse event (flag)

Yes No Don't know

Q5. When an immunisation registry record is established after birth for each newborn child born in the catchment area?

Q5a. Within 1 week (7 days)

Yes No Don't know

Q5b. Within 2 weeks

Yes No Don't know

Q5c. Within 3 weeks

Yes No Don't know

Q5d. Within 4 weeks (1 month)

Yes No Don't know

Q5e. Within 2 months

Yes No Don't know

Q5f. Other, please specify:

Q6. Does the immunisation provider have access to information from the registry of immunisation records at the time of the patient's visit?

Yes No Don't know

Q7. Can the immunisation provider submit core data on immunisation at the time of patient encounter for vaccine administration?

Yes No Don't know

Q7a. If no, within how many days can the immunisation provider submit data on vaccine administration?

Q7a1. Within 1 week (7 days)

Yes No Don't know

Q7a2. Within 2 weeks

Yes No Don't know

Q7a3. Within 3 weeks

Yes No Don't know

Q7a4. Within 4 weeks (1 month)

Yes No Don't know

Q7a5. Other, please specify:

Q8. How is information submitted to?

Q8a. Electronically

Yes No Don't know

Q8b. Paper report form

Yes No Don't know

Q8c. Verbal report

Yes No Don't know

Q8d. Other, please specify:

Q9. Do the immunisation registry in your country has written confidentiality policy and procedures in place and implemented, including administrative and technical practices to protect health care information?

Yes No Don't know

Q10. Does the immunisation registry in your country have written security policies and procedures in place and implemented, including administrative and technical practices and physical safeguards to protect health care information?

Yes No Don't know

Q11. Does the immunisation registry in your country have a function for recover lost data (disaster recovery)?

Yes No Don't know

Q11a. If yes, please specify:

Q12. Does the immunisation registry in your country have an automated function, accessible at the provider level, that determines needed routine childhood immunisations, in compliance with current National Advisory Committee (or corresponding body) recommendations, given an individual's immunisation history to date?

Yes No Don't know

Q13. Does the immunisation registry in your country have an automated function that produces a list of individuals who, as of a given date, are due or late for immunisations according to the registry's algorithm?

- Yes No Don't know

Q13a. Does the output from this function give the ability to produce reminder or recall notices?

- Yes No Don't know

Q14. Does the system is able automatically produce immunisation coverage reports as of a given date for an individual provider's practice?

- Yes No Don't know

Q15. Does the system is able automatically produce immunisation coverage reports for the registry's entire catchment area?

- Yes No Don't know

Q16. Is the system able to automatically produce immunisation coverage reports for subgroups within a practice or the catchment area?

- Yes No Don't know

Q17. Does the registry have a function that allows authorised users to produce an individual's immunisation history that is accepted as an official immunisation record?

- Yes No Don't know

Q18. Has the registry developed and implemented a data quality protocol to combine all available information relating to a particular individual into a single, accurate immunisation record?

- Yes No Don't know

Q19. Can the immunisation registry in your country consolidate all immunisation records from multiple providers, using de-duplication and edit checking procedures to optimise accuracy and completeness?

- Yes No Don't know

Q20. Is the immunisation registry in your country able to record immunisation services in the registry through a variety of alternatives?

- Yes No Don't know

Q21. Is the immunisation registry able to allow parents or guardians of a child to opt out of the recall/ reminder scheme or to prevent any details from being released from the registry?

- Yes No Don't know

Q22. Does optional core data set include these data elements?

Q22a. Patient alias

- Yes No Don't know

Q22b1. Patient address

- Yes No Don't know

Q22b2. Phone number

- Yes No Don't know

Q22b3. Birthing facility

- Yes No Don't know

Q22c. Patient Social Security Number (or equivalent unique identifying number)

- Yes No Don't know

Q22d. Information on subgroups

Q22d1. Ethnicity

- Yes No Don't know

Q22d2. Country of birth

- Yes No Don't know

Q22d3. Marginal groups

- Yes No Don't know

Q22d4. Other, please specify

Q22e. Patient primary language

Yes No Don't know

Q22f. Patient birth order

Yes No Don't know

Q22g. Patient birth registration number

Yes No Don't know

Q21h. Patient medical insurance number

Yes No Don't know

Q22i. Mother's social security number (or equivalent unique identifying number)

Yes No Don't know

Q22j. Father's name

Yes No Don't know

Q22k. Father's social security number (or equivalent unique identifying number)

Yes No Don't know

Q22l. Vaccine dose number

Yes No Don't know

Q22m. Vaccine expiration date

Yes No Don't know

Q22n. Vaccine injection site

Yes No Don't know

Q22q. Vaccine provider

Yes No Don't know

Thank you very much for your time. If you have any questions in relation to this questionnaire, please contact Jolita Mereckiene or Suzanne Cotter by emails: jolita.mereckiene@hse.ie or suzanne.cotter@hse.ie

Appendix 2. Accompanying letter 1.

17 November 2008

Re: VENICE Functional Standards for Computerised Immunisation Registries in Europe, 2008

Dear VENICE Project Gatekeepers and Contact points,

VENICE Project WP3 conducting a survey on Functional standards for computerised immunisation registries (CIR) in Europe in 2008.

The objective of the survey is to describe the minimum set of core data for functional standards among those European countries those indicated having immunisation registries at the local and/ or national level in previous studies conducted by VENICE project.

As you know the VENICE workshop will be held in Rome, Italy on 1st - 3rd of December of 2008. We are under pressure to complete this in very short time frame but we would be grateful if you could respond to the survey by the deadline below.

We would kindly ask you to fill in questionnaire, which is attached by next Monday, 24th of November 2008. It will allow us to conduct analysis and to prepare preliminary data during the week after we will get back questionnaire and present preliminary data for meeting in Rome.

Please return completed questionnaire by fax.+353 18561299 or by e-mails: jolita.mereckiene@hse.ie and/or suzanne.cotter@hse.ie . If you have any questions filling in this questionnaire please contact myself or my colleague Dr.Suzanne Cotter by emails indicated above.

Thank you in advance for your participation.

Yours sincerely,
On behalf of Dr. Darina O'Flanagan

Jolita Mereckiene
VENICE Project
Work Package 3
Health Protection Surveillance Centre
25-27 Middle Gardiner Street
Dublin 1
Ireland

Appendix 2. Accompanying letter 2.

17 April 2009

Re: Survey on Functional Standards for Computerised Immunisation Registries in Europe 2008

Dear VENICE Project Gatekeepers and Contact points,

Thank you for participating in the survey regarding functional standards for computerised immunisation registries in Europe, 2008, which was undertaken in November 2008 before VENICE workshop (Rome, Italy on 1st - 3rd of December of 2008) in order to present data for this meeting.

I prepared a draft preliminary report "Survey on Functional Standards for Computerised Immunisation Registries in Europe 2008" which is attached to this email. I would like kindly to ask you to validate your country's data. Please look to each table and if you find that your country's data are not in correct place please provide the correct answer. Check-missing data and if you would be able to fill in these gaps please do it. I would appreciate if countries which did not complete the questionnaire would be able to fill in tables in this draft report.

I apologies for delay with data validation process due to other studies in particular hepatitis B survey.

Please send comments or corrected data **by 16th of April 2009 (Thursday)**. I would be very grateful if you could respond by this deadline. I will finalise the report as soon as I receive feedback from you.

Thank you for your participation in this study.

Kind regards,

Jolita Mereckiene

VENICE Project
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25-27 Middle Gardiner Street
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