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# Vaccine registers – experiences from Europe and elsewhere

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In this special issue, published in two parts, *Eurosurveillance* has presented a series of articles from countries in Europe, Australia and Canada, describing their various experiences with the introduction of vaccine registers [2-11]. Vaccine registers are population-based systems that contain core individual-level information on the population, together with information on immunisation status – usually for the childhood vaccination programmes. These systems are linked to a variety of programme management, surveillance and research tasks [1].

The lessons outlined in this special issue of *Eurosurveillance* illustrate the many potential opportunities of such systems and some of the challenges and the alternatives that may be available (Table).

There are a series of core attributes for any successful national vaccine register. Firstly, accurate and up-to-date ascertainment of individual-level demographic data of the population of interest is needed, as these constitute the denominator for calculation of coverage data. A small number of countries illustrate how this has been achieved through access to their national administrative population or universal healthcare registers based on personal identifiers/health numbers (2-4,7). Some of the systems presented are able to electronically transfer this population data in real-time and can automatically take into account new births, families moving address, children dying etc. Such innovations can help to minimise some of the traditional denominator problems of ghosting and unregistered populations. Secondly, information on vaccine status (numerator data) on this population needs to be both accurate and complete. Examples are provided of vaccine programmes using barcodes on vaccine vials, which can be used to record information on vaccine dose, batch number and name, thus reducing data entry time and errors [6,11]. Thirdly, register systems need to be flexible as national vaccine programmes are continuously evolving, with the introduction of new vaccines and changes in current childhood immunisation programmes. The registers are able to adapt to

such changes. Finally, as personal identifiable data are required, which is highly sensitive, the importance of developing robust data security and confidentiality mechanisms to protect these systems are highlighted by L Trogstad et al. [2].

The articles illustrate how vaccine registers can be used both as a management tool and for surveillance purposes. As a management tool, countries show how they have used registers to deliver their immunisation programmes. Examples are provided how they can be used to purchase vaccines and monitor supply [3,8]; how they can function as patient call-recall systems – producing invitation and reminder letters [3,5-8]; how they can provide certificates of vaccination for patients [2] and also how they can be linked to incentive schemes for health practitioners [7].

Vaccine registers can also be used as important surveillance tools to monitor national immunisation programmes. Data from such systems can be used to monitor vaccine uptake from national through to local level. This can identify unvaccinated sub-populations (whether by age, geography or particular risk group) and to ensure vaccine uptake is optimal in these pockets. The availability of unique personal identifiers provides the opportunity to link vaccine registers to disease registers and thus identify specific health outcomes. This provides the ability to evaluate the vaccine effectiveness and to investigate vaccine safety signals of existing and new vaccine programmes. Finally, there are examples of these systems being used to answer specific research questions, seeking informed consent from individuals on the national register to take part in vaccine trials or questionnaire surveys [3].

The challenges of developing such national systems are outlined. Firstly, the development of such systems is a significant undertaking, not least from the IT perspective, requiring substantial investment and careful planning. Secondly a number of countries have decentralised health structures, which create difficulties in establishing such a national register. Some

TABLE

## Characteristics of immunisation registers in six European countries, Australia and Canada

| Country                    | Register name                                         | Start date                              | Level of information available                                                   | Description of register                                                                                                                                                                                                      | Use                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------|-------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Denmark [4]                | Danish vaccination register                           | 2000 <sup>a</sup>                       | National                                                                         | Covers programme vaccinations in children (planned for all vaccinations in children and adults)<br>Based on unique civil registration number and national population register                                                | <ul style="list-style-type: none"> <li>• Call-recall (planned)</li> <li>• Vaccine coverage</li> <li>• Vaccine effectiveness</li> <li>• Vaccine safety</li> <li>• Patient access to vaccine record (planned)</li> <li>• Patient research</li> </ul>                                                                                                               |
| England [5]                | Child Health Information Systems (CHISs) <sup>b</sup> | Mid -1980s                              | Local                                                                            | Covers population up to 18 years <sup>c</sup> of age based on birth health registration<br>Computerised clinical record systems for child health prevention programmes                                                       | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine coverage</li> <li>• Vaccine safety</li> <li>• Vaccine effectiveness</li> <li>• Outbreak investigation and response</li> <li>• Child health screening</li> </ul>                                                                                                                   |
| Italy [8]                  | Computerised immunisation register                    | Not available                           | Local                                                                            | Regional-level computerised systems (15/21 regions)                                                                                                                                                                          | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine supply</li> <li>• Vaccine coverage</li> <li>• Management of the high-risk group target</li> </ul>                                                                                                                                                                                 |
| the Netherlands [3]        | Præventis                                             | 2005                                    | National and subnational                                                         | Covers all children and adolescents<br>Linked to population register<br>Continuously updated (birth, death, change of address)                                                                                               | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine supply</li> <li>• Vaccine coverage and vaccine status at individual child level</li> <li>• Additional research (on vaccine safety, vaccine effectiveness, acceptance of the national immunisation programme, etc.)</li> <li>• Other mother-child prevention programmes</li> </ul> |
| Norway [2]                 | SYSVAK                                                | 1995                                    | National                                                                         | Covers all children<br>Covers adult vaccinations since 2011<br>Based on unique personal identification number<br>Vaccination is entered once in the Electronic Patient Record system and transferred automatically to SYSVAK | <ul style="list-style-type: none"> <li>• Vaccine coverage</li> <li>• Vaccine safety</li> <li>• Vaccine effectiveness</li> <li>• Research</li> <li>• Link to other data systems</li> <li>• Healthcare personnel access to vaccine records</li> <li>• Vaccinee access to vaccine record</li> </ul>                                                                 |
| Spain – Murcia [6]         | Computerised vaccinations register                    | 1991                                    | Regional                                                                         | All children and adults<br>Uses population register and is updated (deaths, change of address) real-time<br>Developed vaccine barcode use                                                                                    | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine coverage</li> <li>• Linked to other public health programmes</li> </ul>                                                                                                                                                                                                           |
| Spain – Navarre [10]       | Computerised medical record                           | 2000–2004                               | Regional                                                                         | Covers all the residents and all vaccines for children and adults<br>Represents a subsection of the computerised medical record                                                                                              | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine coverage</li> <li>• Vaccine effectiveness</li> </ul>                                                                                                                                                                                                                              |
| Australia <sup>d</sup> [7] | Australian Childhood Immunisation Register            | 1996                                    | National                                                                         | Covers information on all children up to seven years of age based on the health insurance scheme<br>Data updated daily                                                                                                       | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine coverage (including risk groups)</li> <li>• Vaccine safety</li> <li>• Payments to parents and vaccination providers</li> </ul>                                                                                                                                                    |
|                            | National Human Papillomavirus Vaccination Register    | 2008                                    | National                                                                         | Covers details on HPV vaccinations given to eligible females                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Call-recall system</li> <li>• Vaccine coverage</li> <li>• Potential to link with a disease register of cervical cancer screening</li> </ul>                                                                                                                                                                             |
| Canada [11]                | Various depending on province/territory               | Various depending on province/territory | Various (regional/ local to provincial/territorial) depending on specific system | Provincial level computerised systems (covers 6/13 provinces)<br>Creating and adopting national standards<br>Promoting interoperability between registries<br>Developing vaccine barcode use                                 | <ul style="list-style-type: none"> <li>• Vaccine coverage (as part of an integrated public health surveillance system in some provinces/territories)</li> </ul>                                                                                                                                                                                                  |

<sup>a</sup> Covers data on childhood vaccinations from 1996; system under reorganisation, changes planned to be implemented in 2012-14.

<sup>b</sup> Multiple CHISs exist in England, provided by different suppliers.

<sup>c</sup> Sometimes up to 16 years only.

<sup>d</sup> In addition to the two national immunisation registers, a variety of jurisdiction-based registers and primary care practice software systems exist in Australia, which interact with the national registers; there is also a Q fever vaccination register (industry-based register).

countries have overcome this problem, at least to a certain extent, by regions/provinces creating register networks. Such networks require common national standards and issues can remain around ensuring an accurate denominator. Thirdly, some countries have strict information governance regulations which do not allow personal identifiable data to be kept at national level [9]. Finally, the role of the private sector in vaccine delivery in some settings (as opposed to the central purchase of vaccine by the public sector) can provide a challenge to properly estimating the numerator.

The special issue highlights some of the future directions of travel. Countries which already have national vaccine registers are now extending these to whole life and teenage and adult vaccine programmes. The potential for synergy (and efficiencies) with other public health programmes such as maternal screening/neonatal screening is being explored. There is an increasing automation of operational processes from patient reminders through to scanning barcoded vaccine products. These need to be more standardised and at least for the latter, buy-in from the vaccine manufacturers is required. The full surveillance and research potential of such systems (under appropriate governance) is only just being realised, particularly through linkage to other electronic health records and through direct contact with patients. For some countries, there are important operational, financial and governance challenges to their establishment, for example decentralised health systems or concerns about data confidentiality. Alternative solutions need to be found, and some countries have tried to collect vaccine uptake data in other ways – such as by the use of telephone surveys [9]. Despite these challenges, national vaccine registers can play a key role in the delivery of national immunisation programmes in many countries and make important contributions to achieving national and international control and elimination targets.

Acknowledgments

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# The Danish vaccination register

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Immunisation information systems (IIS) are valuable tools for monitoring vaccination coverage and for estimating vaccine effectiveness and safety. Since 2009, an advanced IIS has been developed in Denmark and will be implemented during 2012–14. This IIS is based on a database existing since 2000. The reporting of all administered vaccinations including vaccinations outside the national programme will become mandatory. Citizens will get access to data about their own vaccinations and healthcare personnel will get access to information on the vaccinations of their patients. A national concept of identification, a national solution combining a personal code and a card with codes, ensures easy and secure access to the register. From the outset, the IIS will include data on childhood vaccinations administered from 1996 and onwards. All Danish citizens have a unique identifier, a so called civil registration number, which allows the linking of information on vaccinations coming from different electronic data sources. The main challenge will be to integrate the IIS with the different electronic patient record systems currently existing at general practitioner, vaccination clinic and hospital level thereby avoiding double-entry. A need has been identified for an updated international classification of vaccine products on the market. Such a classification would also be useful for the future exchange of data on immunisations from IIS between countries.

## Background

Since the year 2000 Denmark has had a national childhood vaccination database with information on all vaccinations administered to children below the age of 18 years in the framework of the national childhood vaccination programme. The information in the register allows for the data on vaccinations to be attributed to a person, hence the data is person-based.

The Danish childhood vaccination database (CVD) consists of data derived from a state-managed administrative register on services offered by general practitioners, who are electronically reimbursed from the national health insurance system. Hence the data in the CVD is the same as in the national health insurance system. Data sets are validated and imported regularly but there is a delay of up to two months from the date of vaccination to entry in the database.

The CVD includes information on date of vaccination, the unique identifier of the recipient, the so-called civil registration system (CRS) number, a vaccination code, and name and address of the vaccinator. The CVD has been a valuable data source for research studies and has contributed immensely to the knowledge on effectiveness [1–4] and safety [5–10] of childhood vaccinations. Furthermore, it has been used for providing precise estimates of vaccination coverage of childhood vaccinations by birth cohort and region in Denmark. [11–13]. The register does not include information on product name or batch number of the vaccine. The Department of Infectious Disease Epidemiology at Statens Serum Institut is the only authority which has had direct access to the CVD. They can provide healthcare personnel with information on vaccinations registered for a patient by telephone, email or fax if they receive a written consent form from the patient.

In 2007, Danish National Board of Health published a health technology assessment report about human papillomavirus (HPV) vaccination [14]. This report recommended that HPV vaccination should be included in the childhood vaccination programme for girls as a three-dose programme at the age of 12 years. Furthermore, it was recommended to establish a national HPV vaccination register with data on all administered HPV vaccinations including those given outside the HPV programme to recipients at their own cost, for instance to males or females above the age of 15. Such a register was considered a prerequisite for estimating the impact of the HPV vaccination programme on the incidence of HPV-related diseases in the future.

At the same time, there was an increased demand from the healthcare sector to get direct access to the data on vaccinations available in the CVD in order to validate the vaccination status of their patients.

Furthermore the delay of the data entry in the CVD and the lack of information on product name and batch number limited its use for studying potential side effects of vaccinations.

Taking the above considerations into account, there was a need for a new more advanced vaccination register than the CVD.

## Organisation of the Danish vaccination register project

In 2008, the Danish government decided that a national vaccination register including data on all administered vaccinations as well as vaccinations administered outside the national childhood vaccination programme should be established.

Approximately 3 million EUR were allocated to Statens Serum Institut to develop and implement a new Danish vaccination register (DDV), within a three year period. The development of this register started in 2009.

The project was managed by a steering committee with participants from the Danish Ministry of Health, the National Board of Health, the National Board of Health Information Technology, the Danish Medicines Agency, the Danish Regions, the General Practitioners Organisation and the Statens Serum Institut.

The project group included a project manager, an epidemiologist, a secretary and an information technology

(IT) developer. The development of the system was outsourced to a private company, whereas the internal IT developer was responsible for developing the database for the surveillance of vaccination coverage and vaccine failures.

A simplified version of the system was used to register pandemic influenza vaccines in 2009/10. The final version of the DDV was finished in the summer of 2011 after a two month pilot phase. Because of an organisational restructure of health IT in the national administration in 2011, the responsibility of implementing the DDV in the healthcare sector and the responsibility for maintenance and support of the system were placed in the newly established National Board of Health IT. This reorganisation has delayed the implementation process of the system, but the DDV will be rolled out to general practitioners, vaccination clinics, hospitals and citizens during 2012-14.

**TABLE**

Differences between the childhood vaccination database and the Danish vaccination register

|                                                                 | The childhood vaccination database (CVD) <sup>a</sup>                                                                                                                                                             | The Danish vaccination register (DDV) <sup>b</sup>                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Registered vaccinations                                         | Only childhood vaccinations and influenza vaccinations given as part of a national programme                                                                                                                      | All vaccinations including those given outside a national programme                                                                                                                                                                                                                                                    |
| Variables included                                              | <ul style="list-style-type: none"> <li>• Date of vaccination</li> <li>• Type of vaccine</li> <li>• Personal identifier of vaccinee</li> <li>• Name of vaccinator</li> <li>• Organisation of vaccinator</li> </ul> | <ul style="list-style-type: none"> <li>• Date of vaccination</li> <li>• Type of vaccine</li> <li>• Personal identifier of vaccinee</li> <li>• Personal identifier of vaccinator</li> <li>• Product name</li> <li>• ATC code</li> <li>• Dosage</li> <li>• Batch number</li> <li>• Organisation of vaccinator</li> </ul> |
| Registration                                                    | Vaccinations only registered from existing administrative electronic registries                                                                                                                                   | By healthcare personnel real-time on date of vaccination and also through retrospective data-capture from existing administrative registries in case of non-entry on vaccination date                                                                                                                                  |
| Timeliness                                                      | Up to two months delay                                                                                                                                                                                            | Real-time registration                                                                                                                                                                                                                                                                                                 |
| Mandatory reporting                                             | No                                                                                                                                                                                                                | Mandatory reporting of all given vaccines                                                                                                                                                                                                                                                                              |
| Access                                                          | Only Statens Serum Institut                                                                                                                                                                                       | Healthcare personnel, citizens and Statens Serum Institut                                                                                                                                                                                                                                                              |
| Accessibility                                                   | Not applicable                                                                                                                                                                                                    | Either through a web-based system or by integration with an existing electronic patient record system                                                                                                                                                                                                                  |
| Informed consent from patient                                   | No                                                                                                                                                                                                                | No                                                                                                                                                                                                                                                                                                                     |
| Data retrieval and linkage allowed for surveillance or research | Yes                                                                                                                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                    |
| Other characteristics                                           | A simple database                                                                                                                                                                                                 | An advanced IT-system with user interfaces, which support healthcare workers in decision making                                                                                                                                                                                                                        |

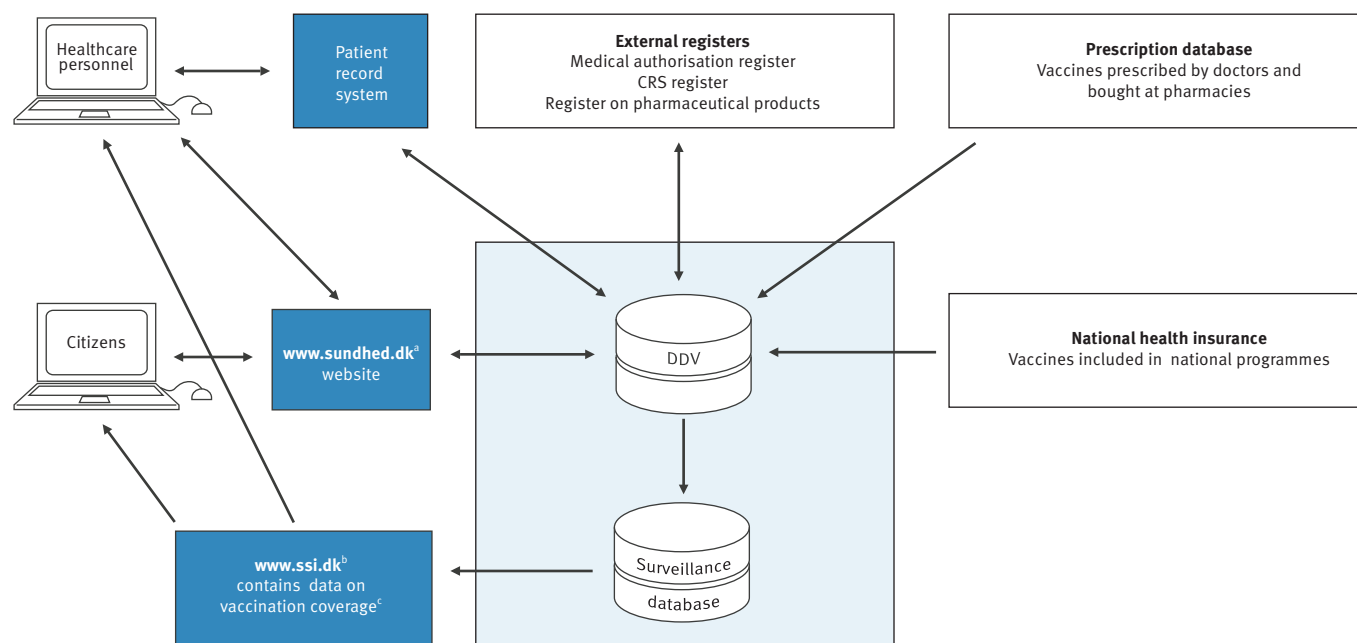
ATC: anatomical therapeutic chemical.

<sup>a</sup> In existence since 2000.

<sup>b</sup> Will be implemented in 2012-14.

**FIGURE 1**

## Architecture of the Danish vaccination register



CRS: civil registration system; DDV: Danish vaccination register.

<sup>a</sup> www.sundhed.dk is the official website of the public Danish healthcare services and enables patients and healthcare professionals to find information and communicate.

<sup>b</sup> www.ssi.dk is the webpage of Statens Serum Institut, which is responsible for the control and prevention of infectious diseases.

<sup>c</sup> Vaccination coverage of vaccines administered in the framework of the DDV, presented real-time in an interactive website by birth cohort, sex, region or municipality.

## The aims of the Danish vaccination register

The aims of the register are to:

- provide access for healthcare personnel to information on vaccinations for their patients, through user-friendly interfaces;
- provide access for citizens to data on their own vaccinations, through user-friendly interfaces;
- improve the surveillance of childhood and influenza vaccination coverage and all other vaccinations;
- improve the quality of the data that can be used for measuring vaccine effectiveness and estimate the overall impact of national vaccination programmes on the incidence of vaccine-preventable diseases;
- improve the quality of the data for studying potential side effects of vaccinations.

Reporting all administered vaccinations to the register will be mandatory. The DDV will differ from the current system, the CVD, in several ways (see Table).

## Description of the Danish vaccination register

### Import of data from existing sources

Data will continuously be imported from the following electronic data sources: (i) the prescription database, and (ii) the national health insurance system. Furthermore, the DDV captures relevant information from a wide range of other administrative registers with information on the vaccinator, the vaccinee or the vaccine used (see Figure 1).

The prescription database contains real-time data on vaccinations prescribed by doctors and delivered at pharmacies. The database includes variables such as date of delivery, type of vaccine, personal identifier of recipient, name of the prescribing doctor, product name, anatomical therapeutic chemical code and dosage.

From the outset the DDV will comprise data on childhood vaccinations from 1996 and onwards, imported

from the national CVD and data from the prescription database, from 2006 and onwards.

### Access to the Danish vaccination register

After identifying themselves, healthcare personnel can get access to information on vaccinations for their patients either (i) by entering an online web-based system (ii) by integration of their local electronic patient record system with DDV web services from a central platform, or (iii) by integration of a so called 'Smart Frame' in the local patient record system. The Smart Frame is an embedded browser that allows the exchange of data between the browser and the patient record system. Integration with the existing patient record systems with web services or Smart Frame is the preferred choice in order to avoid double entry of vaccinations in both the DDV and the patient record system.

Healthcare personnel identify themselves by a digital signature. Citizens can access their own data on the official website for the public Danish healthcare services that enables patients and healthcare professionals to find information and communicate. The website, [www.sundhed.dk](http://www.sundhed.dk), also contains person-based information on e.g. laboratory results, medication and hospitalisations. The concept of identification is the so called NEMID which is a national solution combining a personal code and a card with codes. This concept of identification is also used by all Danish banks and Danish authorities, which means that the concept is widely known and used in the population.

### Data in the Danish vaccination register

The DDV has access to several external registers. The CRS is an administrative register which includes information on all citizens in Denmark such as civil registration number, date of birth, name and address. The medical authorisation register is used to identify healthcare personnel. The register of pharmaceutical products contains names and ATC codes of all medical products, including vaccines, sold at pharmacies in Denmark. This register has proven to be insufficient for the DDV as many vaccines are not sold at pharmacies but delivered exclusively from Statens Serum Institut. As it is possible also to report vaccinations given previously in Denmark or in other countries, the database on vaccines has had to be expanded with information about a wide range of historical vaccinations and vaccine products. This database is currently administered by the Statens Serum Institut.

Healthcare personnel enter information on administered vaccinations in real time but because of a delay in the importing of data from the other registries, specific matching criteria are set up to avoid duplicates. The variables that they enter in the register include: CRS number of the recipient, date of vaccination, product name and/or vaccine type, dosage and batch number. Other variables are captured automatically through the identification procedure for healthcare personnel such

as the CRS number of the vaccinator or the assistant and the place of vaccination.

### Functionalities

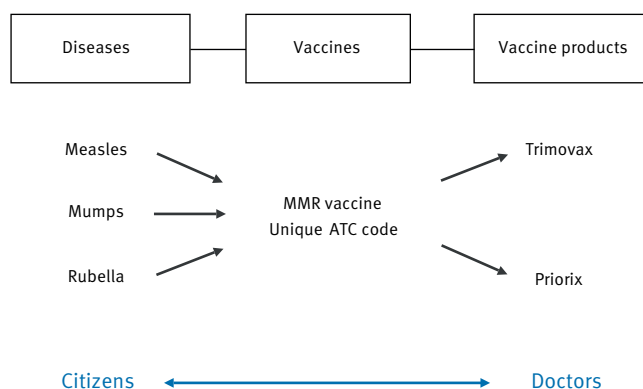
In the DDV, healthcare personnel can register both newly administered vaccinations, and vaccinations administered previously by another doctor in Denmark or in another country. Medical doctors can delegate their rights to register vaccinations to their assistants.

The system supports the healthcare workers in decision making. All vaccinations foreseen in the childhood vaccination programme will automatically appear in the system for all registered newborn children and the healthcare personnel only have to tick a box to register the vaccinations. If a vaccination is given too late in the programme, the system will automatically adjust the dates of the following vaccinations to secure minimal intervals between vaccinations. For a vaccination programme or a series where there is need for a booster dose, the system will automatically provide the duration of the protection by vaccine.

After identifying themselves, citizens have access to a list of vaccinations that they already received and a list with dates of vaccinations that have been planned for the future. They can register previously administered vaccinations, which after validation by a doctor will be registered on the immunisation chart. The data model ensures that the system can handle different levels of specificity of vaccinations registered by the citizen and the healthcare worker (Figure 2). A citizen may only report a disease for which they have been vaccinated whereas the healthcare worker will tend to report a vaccine product administered.

**FIGURE 2**

The relation between vaccination against diseases, vaccines, and vaccine products in the Danish vaccination register using the example of measles-mumps-rubella vaccine



ATC: anatomical therapeutic chemical; MMR: measles-mumps-rubella.

Healthcare personnel and citizens can print an updated immunisations chart. In the future the system can provide the data for generating recall reminders automatically.

### **Surveillance of vaccination coverage and vaccine failures**

Vaccination coverage of childhood vaccinations and influenza vaccinations given to people >65 years will be calculated automatically in real time by sex, birth cohort, region and municipality and presented on an interactive website of the Statens Serum Institut. The denominator is calculated on the basis of information from the CRS including information on age, sex, and address of every individual living in Denmark. The absolute number of influenza vaccinations given to risk groups will be presented on the website by sex, region and municipality. Notifications on mandatory notifiable vaccine-preventable diseases will automatically be linked with the DDV to identify vaccine failures. Vaccine effectiveness and safety studies will be conducted ad hoc.

### **Experiences during the development of the Danish vaccination register**

#### **Advantages**

Compared with other countries Denmark has had several advantages in the process of developing the new IIS. First of all Danish citizens have a unique identifier which makes it possible to match information on vaccinations coming from different electronic data sources, similar to Norway [15]. In the majority of European countries this is not possible. Secondly, Denmark has previously had only one register of childhood vaccinations and therefore did not have the challenge of integrating different existing systems to one new system. The electronic person-based data on childhood vaccinations administered from 1996 and onwards that is available from the Danish CVD means that the DDV will be of value for healthcare personnel and citizens as soon as it becomes available for use.

There has been political, economical and legislative support from the Ministry of Health for the development and implementation of the DDV in the healthcare sector. It will be mandatory to report all given vaccinations to the register, which is crucial for the completeness of the DDV. Finally the national concept of identification, the NEMID, results in an acceptable and secure access to the register for both healthcare personnel and citizens.

With permission from the Danish Data Protection Agency it is possible to carry out register linkage studies using a unique identifier given to all Danish citizens without obtaining informed consent from the participating individuals. This means that the data from the DDV can be used for surveillance and research projects at the national level on vaccine effectiveness and safety, which is not the case in many other European

countries. In Denmark, informed consent from the patient is not required for the registration of any vaccinations, as is the case in Norway for most vaccinations given outside a national programme [15].

### **Challenges**

In Denmark, there are at least 14 different medical record systems in use by general practitioners and several different electronic patient record systems in use at hospitals. This means that IT developers from a wide range of different companies have to integrate the vaccination register into their existing system. Furthermore, a wide range of private vaccination clinics with less mature health record systems may have problems with integrating DDV into their electronic patient record system.

There has been some debate regarding the workload of mandatory reporting which has to be dealt with in agreements with the stakeholders. We have identified a need for a classification system of vaccine products on the market. The ATC classification system is not specific enough. If the data on vaccinations has to be used to study potential side effects of vaccinations, it is necessary that information on the specific product used is available in a standardized format. A standardised classification of vaccine products will also promote future exchange of data between countries.

### **Conclusions**

The Danish CVD has been a valuable tool for surveillance of vaccination coverage and for estimating vaccine effectiveness and safety since 2000. With the new IIS, to be implemented in 2012-14, citizens and healthcare personnel will benefit by getting access to an up-to-date overview of the vaccination status of themselves or of their patients. Mandatory real-time registration of all administered vaccinations will allow us to also estimate the effectiveness and safety of vaccinations not included in the national programme. According to experience it is crucial that resources are allocated to (i) development of the system (ii) integration and implementation of the system into existing electronic patient record systems, and (iii) support of the users of the system after the system has implemented. The main challenge in Denmark is to integrate the IIS with the wide range of existing different patient record systems, which has required close collaboration between the IT companies that develop and maintain the patient record systems. It is important that the IIS will ease the daily procedures regarding immunisations for the healthcare workers and eventually support decision making to encourage the use of the DDV. We have experienced that access to a continuously updated international classification of international vaccine products would be useful, also in case of future exchange of data on immunisations from IIS between European countries.

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# Præventis, the immunisation register of the Netherlands: a tool to evaluate the National Immunisation Programme

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Vaccination coverage is an important performance indicator of any national immunisation programme (NIP). To monitor the vaccination coverage in the Netherlands, an electronic national immunisation register called 'Præventis' was implemented in 2005. Præventis has a link with the population register and can produce letters of invitation for the NIP, register and validate administered vaccinations. The database is used to monitor the vaccination process, produce reminder letters, control the stock of vaccines and provides information used for paying the fees to the different executive organisations involved. Præventis provides a crucial tool for the evaluation of the NIP by producing (sub)national vaccination coverage estimates with high accuracy and allowing additional research: identifying populations at high risk for low coverage based on existing data, conducting specific studies where individuals included in the immunisation register are approached for further research, using vaccination coverage data for the interpretation of (sero)surveillance data, and linking the immunisation register with disease registers to address vaccine safety or vaccine effectiveness. The ability to combine Præventis data with data from other databases or disease registers and the ability to approach individuals with additional research questions offers opportunities to identify areas of priority for improving the Dutch NIP.

## Introduction

The Dutch National Immunisation Programme (NIP) started in 1957. Today, the immunisation schedule includes vaccination against diphtheria, tetanus, polio, pertussis, infection with *Haemophilus influenzae* type b, measles, mumps, rubella, meningococcal C disease,

pneumococcal disease (10 serotypes), cervical cancer (human papillomavirus type 16/18) and hepatitis B (Table 1). In the Netherlands, vaccinations within the NIP are administered free of charge and voluntary. The overall direction of the NIP rests on the programme manager at the Centre for Infectious Disease

**TABLE 1**

Immunisation schedule of the National Immunisation Programme, the Netherlands, 2011

| Age                  | Vaccination-dose                         |
|----------------------|------------------------------------------|
| At birth (<48 hours) | HepB-o <sup>a</sup>                      |
| 2 months             | DTaP-IPV-Hib-HepB-1 <sup>b</sup> + PCV-1 |
| 3 months             | DTaP-IPV-Hib-HepB-2 <sup>b</sup> + PCV-2 |
| 4 months             | DTaP-IPV-Hib-HepB-3 <sup>b</sup> + PCV-3 |
| 11 months            | DTaP-IPV-Hib-HepB-4 <sup>b</sup> + PCV-4 |
| 14 months            | MMR-1 + MenC                             |
| 4 years              | DTaP-IPV-5                               |
| 9 years              | DT-IPV-6 + MMR-2                         |
| 12–13 years          | HPV-1 + HPV-2 + HPV-3 <sup>c</sup>       |

DTaP: diphtheria-tetanus-acellular pertussis vaccine; HepB: hepatitis B vaccine; Hib: *Haemophilus influenzae* type b vaccine; HPV: human papillomavirus vaccine; IPV: inactivated polio vaccine; MenC: meningococcal C-conjugate vaccine; MMR: measles-mumps-rubella vaccine; PCV: pneumococcal conjugate vaccine.

<sup>a</sup> Only for children whose mother tested positive for hepatitis B surface antigen (HBsAg).

<sup>b</sup> From August 2011 all newborns have received vaccination against hepatitis B; before August 2011 this vaccination was only offered to risk groups.

<sup>c</sup> Only for girls; three doses with vaccination scheme 0-1-6 months.

Source: [1].

Control of the National Institute for Public Health and the Environment (RIVM). She is responsible for implementing the ministry's vaccination policy in the NIP and defines the operational conditions. The execution of the NIP is coordinated operationally by the department Regional Coordination of Programmes/Purchase, Storage and Distribution (RCP/IOD). Five local offices of RCP/IOD coordinate the execution of the NIP in their own region. Vaccinations are administered at local level by the network of Child Health Clinics (CHC) and by Public Health Services (PHS). The Epidemiology and Surveillance (EPI) unit is responsible for evaluation of the NIP through surveillance and epidemiological research of the impact of (future) target diseases including vaccination coverage.

With regard to evaluation of the NIP, vaccination coverage is an important performance indicator. To be able to monitor the Dutch vaccination coverage, an electronic national immunisation register called 'Præventis' was implemented in 2005 and is managed by RCP/IOD. Before the introduction of Præventis, different regional immunisation registers were in place, producing invitation letters and reminders and registering vaccinations. Præventis has these functionalities and moreover includes an algorithm to validate administered vaccinations. The database is used to monitor the vaccination process, to produce reminder letters and to control the stock of vaccines, and it provides information used for paying the fees to the different executive organisations involved in the vaccination process. Thus Præventis provides a crucial tool for the evaluation of the NIP by producing vaccination coverage reports and allowing additional research. In this paper we describe this in more detail.

### **The immunisation register Præventis**

All children under the age of 19 years eligible for the NIP are registered in the national immunisation register Præventis (files are stored for a period of 15 years, until the age of 34 years). Through a link with the population register (gemeentelijke basisadministratie, GBA), Præventis receives continuous updates on all newborn and deceased children and on changes in the address of children (due to movement within the country or immigration/emigration). In general, these GBA updates are processed automatically with the use of the personal public service number (burgerservicenummer, BSN) as a unique identifier; only in case of a problem with processing an update, manual validation takes place by an employee of RCP/IOD. For each newborn or immigrated child a new NIP record with a unique client number is automatically created in Præventis. Therefore, Præventis includes a record for each child, irrespective of participation in the NIP. Præventis is used as the national immunisation register but is also the database to facilitate other collective preventive programmes such as maternal screening for hepatitis B, syphilis, infection with human immunodeficiency virus (HIV), blood group and irregular antibodies, as

well as neonatal screening for congenital diseases such as inborn errors of metabolism.

### **Vaccination process through Præventis: from invitation to registration**

The letters to invite parents to get their child(ren) vaccinated according to the NIP are automatically created in Præventis and sent by RCP/IOD for all children at the age of one month, around four years, and around nine years, as well as for girls around 12 years. This invitation includes personalised vaccination cards that parents need to bring along at each vaccination (Table 1) of their child. Vaccinations are administered by the CHC for children up to the age of four years and by PHS for school-aged children. Subsequently, administered vaccinations (vaccine characteristics, dose, date of administration, executive organisation) as well as possible principal objections to vaccination are registered on the vaccination cards. The CHC and PHS return the vaccination cards by post to one of the five local offices of RCP/IOD, where the data are entered in Præventis with a barcode reader. Alternatively, the CHC and PHS can choose to enter the data directly in Præventis through an internet application 'RVP Online' (i.e. NIP online), which is increasingly used. Parents of children that do not respond to the initial invitation to get their child(ren) vaccinated within a certain time limit receive a reminder by letter by the RCP/IOD centrally or on request at regional level by one of the local executive organisations.

### **Validation**

RCP/IOD is responsible for managing the registration process in both Præventis and RVP Online. The local organisations are only allowed to make corrections in their own regional data. Præventis includes criteria to judge the validity of each vaccination within the current NIP guidelines. This means that in some cases administered vaccinations are registered in Præventis but automatically rejected, for example because they are not administered at the right moment (the time interval between two vaccinations was too short) or with a deviant vaccine product. If needed, the parents of the concerned child receive a new invitation for additional vaccination.

### **Authorisation and confidentiality**

Access to Præventis is only allowed to people who need to administer or register vaccinations and to the medical advisors and regional managers of the NIP. The data are saved on the level of the individual (i.e. they are not anonymous) but are only accessible at individual level for people who need to register vaccinations or assess the immunisation status of a particular child. All data requests made for the purposes of additional research through Præventis are assessed by a multidisciplinary team, specifically with regard to privacy aspects.

Residents do not have access to Præventis but they are able to request information on their vaccination history at the local organisation responsible for the

execution of the NIP in their own region. Furthermore, there is no connection between healthcare records of clinicians and Præventis but a link with the electronic youth health files that are used by the CHC and PHS to monitor the child's health on different aspects, is being developed.

## Tool to evaluate the National Immunisation Programme

Besides a powerful tool to facilitate the daily delivery of the NIP with high quality, Præventis is also a very useful tool to evaluate the coverage of the NIP. The information in the register enables evaluation by various approaches. Here we describe these approaches and present our experiences with the immunisation register.

### To measure (sub)national vaccination coverage

Monitoring vaccination coverage is important in order to follow the progress towards goals for controlling and/or eliminating vaccine-preventable diseases. Præventis does not include a standard threshold to indicate low vaccination coverage. An additional reporting tool, 'Præmis', was developed to be able to compose different reports on vaccination coverage. At central level, the RIVM determines annually the national vaccination coverage for specific birth cohorts. On individual level and at different moments in life we determine if, according to the NIP guidelines, sufficient vaccinations have been given before a fixed age. Table 2 gives an overview of the different ages at which the vaccination coverage is determined for each of the (combination of) vaccines.

Besides determination of the national vaccination coverage it is also important to have insight into the vaccination coverage at subnational level since a high

national vaccination coverage is no guarantee for a high vaccination coverage at subnational level and consequently no guarantee against outbreaks of vaccine-preventable diseases [3-6]. Annually, the vaccination coverage is reported by province (n=12) and by municipality (n=415 on 1 January 2012).

The data on (sub)national vaccination coverage are disseminated in the form of an annual RIVM report that is publicly available [2]. Through this annual report we inform not only the Ministry of Health and other organisations such as the European Centre for Disease Prevention and Control and the World Health Organization but also the CHC and PHS. With the subnational data in this report the latter are able to evaluate their local efforts to reach high vaccination coverage in their own region. An example of the standard geographical presentation in the annual report of the vaccination coverage by municipality is presented in the Figure. These maps are also available online through the Dutch National Atlas of Public Health [7]. This website shows the current and historical vaccination coverage in each municipality simply by clicking on one of the municipalities. If needed the five local offices of RCP/IOD are also able to break down the regional vaccination coverage at a lower level, such as the four-digit postcodes. Furthermore, they are able to produce more timely management information at any time during the year to be able to monitor the progress in regional participation more closely than through the annual report.

### To identify populations at high risk for low vaccination coverage based on existing data

Understanding reasons for a low vaccine uptake is important to provide recommendations to improve vaccination coverage and to determine which aspects

**TABLE 2**

Individual age at which vaccination coverage is determined per (combination) vaccine, the Netherlands, 2011

| Newborns<br>3rd day of life | Infants<br>1 year | Toddlers<br>2 years | Preschool children<br>5 years | School children<br>10 years | Adolescent girls<br>14 years |
|-----------------------------|-------------------|---------------------|-------------------------------|-----------------------------|------------------------------|
|                             | DTaP-IPV-3        | DTaP-IPV-4          | DTaP-IPV-5                    | DT-IPV-6                    |                              |
|                             | Hib-3             | Hib-4               |                               |                             |                              |
|                             | PCV-3             | PCV-4               |                               |                             |                              |
|                             |                   | MMR-1               |                               | MMR-2                       |                              |
|                             |                   | MenC                |                               |                             |                              |
|                             |                   |                     |                               |                             | HPV-3                        |
| HepB-o <sup>a</sup>         |                   | HepB-3/4            |                               |                             |                              |

■ primary immunisation    
 ■ basic immunity    
 ■ revaccinated    
 ■ fully immunised

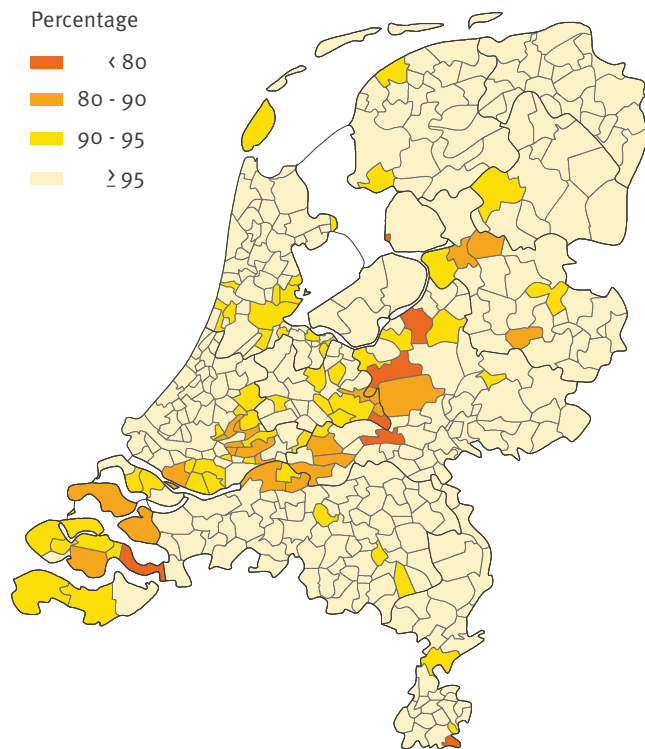
DTaP: diphtheria-tetanus-acellular pertussis vaccine; HepB: hepatitis B vaccine; Hib: *Haemophilus influenzae* type b vaccine; HPV: human papillomavirus vaccine; IPV: inactivated polio vaccine; MenC: meningococcal C-conjugate vaccine; MMR: measles-mumps-rubella vaccine; PCV: pneumococcal conjugate vaccine.

<sup>a</sup> Only for children whose mother tested positive for hepatitis B surface antigen (HBsAg).

Source: [2].

## FIGURE

Vaccination coverage for the first measles-mumps-rubella vaccination in birth cohort 2008 (determined at the age of two years), by municipality, the Netherlands, 2011



Source: [8].

future studies should focus on. Besides data on vaccination history, some background characteristics are also available on individual level through Præventis (sex, age, country of birth of the parents). Since Præventis includes all children in the Netherlands, these data can be used to determine whether there are differences in background characteristics between vaccinated and unvaccinated children so as to identify risk groups.

Præventis also makes it possible to combine immunisation data with other existing databases, even if these data are not available on an individual level. An example of this is a study on human papillomavirus (HPV) vaccination coverage: voting data for two political parties (Reformed Political Party (SGP) with predominant orthodox reformed adherents and Christen Union (Christen Unie) with Christian adherents) by municipality from Statistics Netherlands and socioeconomic status data by postcode from the Netherlands Institute for Social Research were incorporated in the analysis of possible determinants of HPV vaccination coverage since information on religion and socioeconomic background was not available in Præventis [9]. A similar analysis was conducted for other vaccinations (data not shown).

### Future research areas

In the future we would like to determine vaccination coverage per school to identify risk schools that need

priority attention during an outbreak situation. This is important for the Dutch situation since people belonging to the orthodox Protestant minority and anthroposophists, who more often object to vaccination, tend to cluster at school level [10]. At first, possible privacy issues with regard to combining data from Præventis with data from schools (who is going to which school?) need to be explored. Another future research area is to find out if premature newborns follow the NIP guidelines in the same way as the rest of the newborns by combining data from Præventis with data on pregnancy duration from neonatal screening. Based on literature the hypothesis is that premature newborns receive their first vaccination somewhat later than full-term children [11,12] and could therefore be more at risk for vaccine-preventable diseases.

### To approach individuals included in the immunisation register for further research

Participants of studies aimed at evaluating the NIP can be recruited through the immunisation register: Præventis enables the inclusion of both vaccinated and unvaccinated individuals. These individuals are asked by post whether they are willing to participate in a specific study. Such studies include questionnaire studies (e.g. on hepatitis B vaccination acceptance [13]), vaccination trials (e.g. pneumococcal disease), studies with focus groups (e.g. acceptance of the NIP) and vaccine effectiveness studies (e.g. mumps outbreak [14]). Individual vaccination records are regularly used for this kind of studies. When informed consent is obtained from participants in a specific study, their vaccination history can be checked in Præventis. Thus information on immunisation status can be obtained that is more reliable than self-reported vaccination history. In the nationwide serum collection [15] used to evaluate the NIP and in a mumps outbreak study [14] this information was retrieved from Præventis for all participants.

### To use vaccination coverage data for the interpretation of (sero)surveillance data

With reliable nationwide data on vaccination coverage we can interpret observations from other surveillance sources on the occurrence of particular diseases and on immunity profiles. The screening method can be used to estimate vaccine effectiveness using the proportion of cases vaccinated [14,16]. This proportion is compared to the nationwide vaccination coverage. To prevent bias in this method, it is essential that the cases' vaccination history as well as the nationwide data are reliable. This method is particularly suitable to study changes in vaccine effectiveness over time and was used in the Netherlands to interpret the re-emergence of pertussis [17]. Also to interpret sero-profiles measuring the immunity in the population by assessing specific antibodies, vaccination coverage is needed, since the immunity of the population reflects the result of the level of vaccination coverage, vaccine effectiveness and occurrence of natural infection.

## To link the immunisation register with disease registers to address vaccine safety or vaccine effectiveness

Secondary use of healthcare data may advance medical knowledge especially with regard to disease aetiology and outcome. Extending linkages between databases will create a useful tool for knowledge discovery in the area of disease aetiology and outcome. In the Netherlands we plan to link Præventis to a large, well-established population-based medical record database, IPCI (Interdisciplinary Processing of Clinical Information [18]). The linkage itself will be done by a trusted third party (TTP). This TTP will store the linkage file that comprises the patient identifier of Præventis, the IPCI identifier and a matching weight which indicates the probability that record pairs may be accepted as links. The researchers will receive a study file with data from the linked databases but without patient identifiers.

At present, we are performing a study on the validity of the linkage of Præventis and IPCI. The association between measles-mumps-rubella (MMR) vaccination with febrile convulsions (true positive association) and fractures (true negative association) will be tested. Based on the results of this study future linkage studies can be performed to monitor effectiveness and safety of vaccination.

Another example is an ongoing study to estimate the association between the HPV vaccination status of daughters and the participation of their mothers in cervical cancer screening. The aim of this study is to identify risk groups for inclusion in (educational) campaigns in order to increase participation in cervical cancer prevention programmes. It uses data from Præventis combined with data from the cervical cancer screening, which was also linked by a TTP [19].

## Discussion

A survey on vaccination coverage assessment among the countries in the Vaccine European New Integrated Collaboration Effort network (VENICE) in 2007 showed that 15 countries in Europe had national or local computerised immunisation registers in place and five countries had future plans to develop such a register [20]. The VENICE survey on functional standards for computerised immunisation registers in Europe revealed that in a number of countries such as Belgium, Spain, Italy, Ireland and the United Kingdom (UK), the register does not consist of one national immunisation register, such as in the Netherlands since 2005, but of different local immunisation registers [21].

An important advantage of Præventis is that it is one registration system with a central database that covers the whole country. Therefore, there are almost no linkage and definition problems between local regions any more compared to the period before 2005 when different regional immunisation registers were in place. Having one national immunisation register also

simplifies evaluation of the NIP, since the data can be extracted from the register at a central level instead of combining several data sets extracted at regional level. In the Netherlands, the vaccination coverage in the NIP is evaluated annually and published in an RIVM-report. In the UK, the vaccination coverage is evaluated quarterly by COVER (Cover of Vaccination Evaluated Rapidly), which might allow earlier detection of changing trends [22]. However, in the Netherlands the vaccination coverage has been very stable for a long time [2,23] and the five local offices of RCP/IOD are able to produce timely management information at any time during the year to be able to monitor the progress in regional participation more closely than through the standard annual report. Furthermore, in specific situations such as during the introduction of HPV vaccination, the national participation is evaluated ad hoc and more frequently than annually.

Another advantage of Præventis is that it is continuously updated by data from the population register (GBA) and can therefore produce an accurate figure of the denominator for calculating vaccination coverage. This in contrast to some other immunisation registers such as in the UK where the denominator is based on a combination of general practitioner registration and place of residence for unregistered patients, and where children can sometimes be registered more than once because they are not always removed from a system when they move to a different area [22].

Because only one immunisation register has been in place since 2005, the system is also vulnerable. Different operations such as regular backups are established to guarantee the continuous accessibility of Præventis. Regular changes in the NIP require regular adjustments of Præventis. These changes in the software carry certain risks for the continuation of the registration process. Good standard procedures, for example standard procedures for implementing changes and test reports are necessary and have been formulated and implemented for Præventis. At this moment, only vaccinations included in the NIP are registered in Præventis. Certain vaccinations are therefore not registered, for example seasonal influenza vaccination which is covered by a separate programme (vaccinations administered by the general practitioners), travel related vaccinations, and all other vaccinations that are administered outside the NIP.

## Conclusion

The Dutch immunisation register Præventis does not only support the daily delivery of the NIP but allows the assessment of vaccination coverage with high accuracy at both national and subnational level. The ability to combine Præventis data with data from other databases or disease registers and the ability to approach individuals with additional research questions depending on their vaccination history offers opportunities to explore areas of priority to improve the Dutch NIP.

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# Immunisation registers in Canada: progress made, current situation, and challenges for the future

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Immunisation registers have the capacity to capture data on the administration of vaccine doses at the individual level within the population and represent an important tool in assessing immunisation coverage and vaccine uptake. In 1999, the National Advisory Committee on Immunization recommended that a network of immunisation registers be established in Canada. The Canadian Immunization Registry Network (CIRN) was established to coordinate the development of standards and facilitate the sharing of knowledge and experience to develop a national network of such registers. In 2003, the National Immunization Strategy identified immunisation registers as an important component in improving national immunisation surveillance. In addition, there has been consistent public and professional interest in a national immunisation register being available and considerable progress has been made in developing technologies to facilitate the capture of immunisation-related data. More specifically, the automated identification of vaccines, through the use of barcodes on vaccines, will facilitate collection of data related to administered vaccine doses. Nevertheless, challenges remain in the implementation of immunisation registers in all Canadian provinces and territories such that Canada still does not currently have a fully functional network of immunisation registers with the capacity to be interoperable between jurisdictions and to allow for data to be captured at the national level.

## Introduction

In Canada, several millions doses of vaccines are administered every year. According to the immunisation schedules recommended by the National Advisory Committee on Immunization (NACI), the national committee tasked with making scientific recommendations on the use of vaccines in Canada, a child will receive 18 vaccinations to protect against 13 diseases by the age of two years, and 26 vaccinations by the age of 19 years [1]. These figures do not include seasonal influenza immunisation whereby the seasonal influenza vaccine may be received on an annual basis. In addition, several vaccines may be administered during a single immunisation visit. During each immunisation event,

a healthcare provider must manually record details of the immunisation event in the patient's health record as well as in the patient's personal immunisation card or hand-held immunisation record.

Thus, information related to each immunisation event should become part of an individual's permanent health record. Access to this information is critical in the event of a vaccine recall, vaccine failure or of suspected adverse event following an immunisation (AEFI). Hand-held immunisation records can contain information such as antigen, brand name of vaccine, dose, date of immunisation, vaccine lot number, expiry date, route of administration, and injection site. Unfortunately, surveys conducted across Canada have shown that as many as 30% of parents have misplaced their child's immunisation record by the time their child is seven years old, 15% of immunisation records are incomplete, and 24% contain data entry errors [2]. Incomplete immunisation records result in up to 10% of the population being re-immunised needlessly, delays in the appropriate follow-up of AEFI, and vaccine supply issues. These issues result in increased costs to the health system and may potentially result in adverse health outcomes for vaccine recipients.

Reliable immunisation records at the individual level are essential to ensure that immunisations are provided according to the recommended immunisation schedules such that optimal protection against vaccine-preventable diseases (VPD) can result from immunisation [3]. At the population level, reliable and complete data from immunisation records are necessary for the assessment of vaccine uptake and coverage, vaccine effectiveness [4] and vaccine safety. Accurate and readily accessible immunisation records are also crucial in the event of a lot recall or vaccine failure because they can provide information necessary to track down potentially affected individuals.

Immunisation registers are information or software applications that have the capacity to perform the scheduling of immunisation appointments, the management and recording of immunisation events, notify

when immunisations are due. These functions of immunisation registers allow them to serve as a tool to assess immunisation coverage. These population-based databases have the potential ability, depending on the specific system used, to accurately assess, in real time, vaccine uptake at the national and regional levels, and personal immunisation status for individuals residing within a jurisdiction. Immunisation registers can also assist with the timely reporting of vaccine coverage, assessment of vaccine supply, identifying populations with low coverage, monitoring immunisation programmes designed to achieve specific target immunisation rates [5], as well as generating reminders to patients and recalls for immunisation visits. As a result, immunisation registers are considered to be one of the most effective strategies for improving coverage irrespective of provider [6]. Immunisation registers can also provide basic data to conduct vaccine effectiveness studies [7-9] as well as contribute to monitoring existing and new immunisation programmes. A number of countries have been successful in building and utilizing national population-based immunisation registries [4]. The Australian Childhood Immunization Register (ACIR) was the first complete national immunisation register and has been operational since 1996 [10].

The usefulness and power of a population-based immunisation register depend on the quality and quantity of the information it contains [8,9]. Keeping the records up-to-date and ensuring comprehensive use by all providers is important to warrant accurate projections for immunisation eligibility, vaccine supply and assessment of uptake. In some settings such as in Australia, monetary incentives have been supplied to providers for entering their patient immunisation data and for using immunisation registers to monitor their patient immunisation history and background [11].

In 1999, NACI recognised the importance of reliable, accessible, and standardised electronic immunisation records by passing a resolution recommending that a network of immunisation registers be established across Canada. A network of immunisation registers from the jurisdictions was proposed instead of a national immunisation register due to the fact that immunisation programme delivery is a provincial/territorial mandate in Canada. The goal of this resolution was to facilitate the maintenance of accurate immunisation records and the improvement of the management of vaccine supply.

The Canadian Immunization Registry Network (CIRN) was established to coordinate the development of standards and facilitate the sharing of knowledge and experience to develop a national network of immunisation registers [12]. CIRN is a Canadian immunisation committee working group made up of immunisation programme experts from all 13 Canadian provinces and territories involved in the development of immunisation registers as well as monitoring vaccine uptake in their respective jurisdictions. While CIRN members

from the provinces and territories volunteer their time to the working group, the secretariat for CIRN is currently housed in the Centre for Immunization and Respiratory Infectious Diseases at the Public Health Agency of Canada (PHAC) where employees provide support to the working group. In addition, the working group has two co-chairs; a provincial/territorial co-chair and a federal co-chair. The mandate of CIRN is to guide the provinces and territories in the development of a national network of compatible immunisation registries. CIRN works with Canadian provinces and territories to develop and agree upon national standards for immunisation registers as well as immunisation coverage assessment and provides input and expertise in the development of the national immunisation coverage surveys.

### Immunisation registers in Canada

The 2003 National Immunization Strategy (NIS) identified the importance of coordinating common approaches to immunisation registers. One of the five key components of the NIS was to 'improve national surveillance and the transfer of (and access to) individual immunisation records, by establishing and maintaining a comprehensive, compatible national immunization registry network' [13]. Also in 2003, during the follow-up to the Severe Acute Respiratory Syndrome (SARS) outbreak in Canada, the 'Naylor Report' recommended CAD 100 million (approximately EUR 77 million) 'in incremental federal funding on new vaccines as well as improving the information systems to ensure that Canada meets an articulated health goal (and international norms) as regards vaccination coverage' [14].

In March 2004, responding to the lessons learned from the SARS outbreak, the federal government tasked Infoway with the development, in partnership with the Canadian provinces and territories, of a country-wide public health surveillance system. Infoway is a not-for-profit organisation created and funded by the federal government to accelerate the use of electronic health records (EHRs) in Canada through collaboration with the Canadian provinces and territories, health-care providers and technology solution providers [15]. While CIRN and Infoway are two separate entities, the two groups are currently collaborating by the participation of some CIRN members in Infoway's Standards Collaborative Working Group [16] in developing agreed-upon standards to be used in EHRs. The public health surveillance system developed through the partnership with Infoway was eventually called Panorama. Initially, a CAD 100 million (approximately EUR 77 million) fund was provided to support application software development. This funding initiative required the Canadian provinces and territories to provide the resources for training, equipment and implementation of the surveillance system. In 2008, an additional allotment of CAD 100 million was provided to advance the development and the implementation of Panorama [17]. Initially, Panorama had seven modules which were to be developed using existing commercially-available software

applications, and which could be modified to respond to specific provincial and territorial needs. Two of the modules, the immunisation management and inventory management modules, were envisioned to provide the basis for a national network of immunisation registers. These modules were to be developed to include nationally agreed-upon functional and data standards. Moreover, the modules were to eventually provide each jurisdiction access to a standardised electronic immunisation register and an inventory management system to better manage immunisation events and vaccine supply, and assess immunisation coverage in their jurisdictions, as well as report standardised vaccine uptake data nationally. Panorama allows healthcare workers to view the immunisation history for individuals and particular groups in the population. In addition, lists of clients who are eligible and overdue for immunisation can be displayed by antigen, demographic or particular risk factors.

While the original scope of Panorama was to include, among other things, a Pan-Canadian approach to immunisation registers, some individual provinces and territories have developed and are currently using other immunisation register systems. These systems vary between jurisdictions in their availability to immunisation providers as well as to the extent of the data which they capture. Variability also exists between jurisdictions in validation procedures for immunisation register data as well as for the specific information contained in the register. For example, the currently available registers differ between jurisdictions in terms of the age groups for which information is captured. While data linkage between immunisation registers and clinical outcome databases is highly desirable, the capacity to link immunisation status to clinical outcome remains an issue in some contexts.

### **Role of the federal government in immunisation registers**

Although Canadian provinces and territories are responsible for immunisation programme delivery and for implementing immunisation registers within their jurisdiction, the federal government is considered to provide leadership to the development of a national network of immunisation registers across Canada. Through NIS and CIRN, the federal government has provided leadership and coordination by supporting the development of national data and functional standards to guide immunisation register development and technologies such as the automated identification of vaccines. Automated identification of vaccines, or the use of scanners and barcodes on vaccine products, enhances considerably the quality and accuracy of the data captured in electronic registers by reducing the amount of time required by immunisation providers to create and maintain immunisation records and also reduces the possibility of errors related to data entry. The federal government has also contributed funds for the development of Panorama.

### **Vaccine coverage assessment in Canada**

As is the case for other countries, Canada reports national vaccine coverage information to the World Health Organization. However, in order to compensate for the lack of a national network of immunisation registers to facilitate the accurate assessment of vaccine uptake, the PHAC currently uses telephone surveys to assess immunisation coverage in the Canadian population. The Childhood and Adult National Immunization Coverage Surveys are conducted approximately every two years to assess routine childhood immunisations and adult selected vaccines [18,19]. Cross-sectional vaccine coverage data are obtained for a selected set of age milestones for children and target groups for adults. Results from these surveys are used to monitor progress towards national targets, to report immunisation coverage estimates to international organisations, to improve planning for pandemic influenza, and to develop appropriately-targeted public education strategies.

These surveys are conducted using random-digit dialling or pre-existing sampling frames to contact households where eligible respondents might reside. Among the drawbacks associated with this current methodology are the facts that it is expensive and results in small sample sizes which do not permit for provincial and territorial vaccine coverage estimates, or the identification of under-served or under-immunised populations. The sample size selected for the national immunisation coverage surveys allows for immunisation coverage estimates with a 5% margin of error for each group. The use of surveys also precludes performing most studies related to immunisation programme effectiveness or evaluation. Finally, the use of telephone surveys introduces a responder bias as it is also becoming increasingly difficult to recruit representative samples, due partly to the increase in the use of cell phones, and in the number of cell-phone-only households and changing lifestyles.

While national immunisation coverage estimates are obtained through surveys, provinces and territories use different methods to assess immunisation coverage within their jurisdiction depending on the availability of registers and other methods of collecting coverage data. To facilitate the collection of vaccine coverage data from the provinces and territories, PHAC and CIRN have developed national immunisation coverage reporting standards [20]. However, while these standards provide guidance to jurisdictions in reporting vaccine coverage, the standards have yet to be adopted. This is due to the fact that PHAC does not have the mandate to collect surveillance data from the jurisdictions. Thus, the adoption of a standardised methodology to estimate coverage remains problematic. Therefore, the PHAC will continue to implement national immunisation coverage surveys to estimate vaccine uptake nationally until a national network of immunisation registers is fully functional in all jurisdictions across Canada.

## Challenges to the implementation of immunisation registers across Canada

Despite overwhelming demand and clear support for a national network of immunisation registers [21,22], and approximately a decade after the NACI recommendation, only six of the 13 provinces and territories have developed centralised electronic immunisation registers that conform to national functional and data standards. Although Panorama was initially scheduled to roll out to the provinces and territories in 2009, it is substantially behind schedule and now will provide only a partial solution towards a national network of immunisation registers as some jurisdictions consider using other systems. While progress has been made, Panorama continues to face serious challenges due to cuts in scope and escalating costs leading to important delays. As a result, several provinces and territories have decided to opt out of using Panorama. The cuts in scope mean that several important agreed-upon national functional standards will not be included in Panorama. These include, but are not limited to, interoperability, or the ability to electronically share immunisation records between jurisdictions, and inclusion of automated identification technology.

## Public versus non-public immunisation providers

In Canada, vaccines can be administered by immunisation providers that operate either in the public or in the non-public setting, depending on the jurisdiction where some provinces/territories deliver vaccines either through public health clinics or private physician's offices or a combination of both. The majority of immunisation registers in Canada currently capture information obtained only from public immunisation providers. These differences in immunisation delivery methods create considerable data completion issues in the larger Canadian provinces such as Ontario, Quebec, and British Columbia where physicians in private clinics administer most of the immunisations given in these jurisdictions.

## Acceptance of registers and 'knowledge, attitudes and beliefs' information

The development, implementation and use of immunisation registers are well accepted amongst stakeholders and healthcare providers in Canada. However, beyond the development and implementation challenges previously discussed, and given the provincial and territorial mandate for immunisation programmes and delivery, data sharing agreements need to be developed and in place for jurisdictional level data to be shared with the federal government and included as part of national immunisation coverage estimates. Moreover, each province and territory needs to assess and deal with potential issues related to requirements regarding privacy for the use of such data before the implementation of an immunisation register or a public health surveillance system within a jurisdiction. While the use of immunisation registers to obtain coverage information represents an important tool to assess

immunisation programmes, information on knowledge, attitudes, and behaviours/beliefs related to immunisation in the general population will need to be collected separately from coverage data obtained from immunisation registers thus making it impossible to assess the relationship between different knowledge, attitudes, behaviours/beliefs and vaccine uptake and to use this information to develop outreach and education programmes.

## Vaccine barcoding and automated identification technology

To reduce the errors occurring from clinic staff manually entering vaccine name, lot number and expiry date into inventory and client records, NACI issued a recommendation in 1999 that barcodes be placed on all vaccine products manufactured in Canada to facilitate the automatic entry of scanned vaccine data [23]. A pilot project implemented with front-line immunisers in Alberta and Manitoba showed a 48% to 69% reduction in the time to record data and a 33% reduction in immunisation errors using peel-off, tagged and direct barcodes instead of manual entry [24]. In light of these findings and in support of NACI's recommendations, the Automated Identification of Vaccines Project Advisory Task Group (AIVP ATG) was founded, including representation from the vaccine and clinical software industries, healthcare professional organisations, and standard setting organisations [25].

In 2008, the AIVP ATG developed a five-year strategic plan. One of the first tasks was to perform an independent cost benefit analysis for the adoption and implementation of barcoding of vaccine products in Canada. Six different implementation options - varying in technical detail and the relative costs and benefits anticipated - were selected by the AIVP ATG for consideration. The study concluded that barcodes on vaccine products would be very beneficial and that these benefits would increase over time as technology advanced and new vaccines were introduced [26].

In 2009, AIVP ATG reached a consensus on vaccine barcode standards in Canada, including the placement of a Global Trade Identification Number (GTIN) - a unique product identifier - and lot number on primary packaging, with expiry date as an optional addition [25]. Canadian vaccine manufacturers have committed to adhering to these new standards over the next several years [25], and PHAC has developed the Vaccine Information Database System (VIDS), a web-based repository of information on all vaccines approved in Canada [27]. Vaccine manufacturers provide data (including GTIN, lot number, expiry date) for all of their products to the database (GS1) and transfer the data to PHAC, who is responsible for entering this information as well as lot number and expiry date into VIDS. Thus, when the barcode on a vaccine vial is scanned, the information is downloaded into the electronic immunisation or inventory record, eliminating the need for manual entry or paper-based recording.

Vaccine manufacturers in Canada committed to voluntarily adopt the barcode standards and to include GTIN, lot number and expiry date on vaccine packages. By 2016, all vaccine products in Canada will be required to adhere to the agreed upon standards. Some vaccine labelling lines in Canada and the United States are currently able to print two-dimensional (2D) barcodes, and these vaccine products are shipped all over the world. Products manufactured in Europe will be the last to have the 2D barcodes as manufacturers have not yet agreed to the standards. A 2D barcode (such as the DataMatrix symbology from GS1, a barcode standard setting organisation) consists of printed squares or dots, spiralling outwards from the centre of the symbol. The 2D barcode includes a 14-digit Global Trade Identification Number (GTIN), expiry date and lot number [25]. Including the expiry date in the barcode is an optional labelling requirement, as the expiry date can be determined through lot number. Lot number and expiry date will continue to appear in human readable form on vaccine primary packaging as per Canadian labelling requirements.

The AIVP ATG is working with Canadian provinces and territories to encourage both public and private health-care professionals to include barcoding in their software applications as well as to encourage the purchase of scanners required to read barcodes. With the numerous different applications used in healthcare across the country, support to this community is essential in ensuring that barcodes on vaccine products are used to their fullest potential and that entering barcodes into immunisation registers results in reliable and timely immunisation and inventory records.

To support the use of barcodes in Canada, the AIVP ATG has committed to supporting early adopters of barcode technology, both in private and public health-care settings, at point of vaccine administration as well as at the vaccine inventory level. Previous studies implementing barcode scanning on medications have employed linear barcodes containing a product identifier only [28-30]. However, placing a vaccine's GTIN and variable data (lot number and expiry date) on the limited space of a small vial requires a 2D matrix barcode.

To facilitate future adoption of barcode scanning technology, barcode readability and the incorporation of scanning the primary packaging into vaccination clinic workflow need to be examined. As the adoption of a new system can encounter user resistance, especially if it is unable to integrate into user workflow [31-32], it is important to understand how potential users perceive barcode scanning of vaccines and to identify aspects of the process requiring modification before its implementation in vaccination settings.

PHAC, in partnership with the PHAC/CIHR Influenza Research Network (PCRIN) and the Ontario Niagara Region, studied the integration of automated identification of vaccine products into inventory recording

during seasonal influenza vaccination campaigns across Canada. Results demonstrated the readability of barcodes and positive user perceptions of this technology. While barcoding scanning was perceived to be beneficial in reducing errors, individual vial scanning for high volume clinics was found to be time consuming and may hinder adoption of this technology in these clinical settings [33]. These results highlight the importance of reviewing workflow processes and encouraging efficient practices specific to vaccination setting. . It is possible that the benefits of barcode scanning may be more apparent in settings where multiple vaccines and lot numbers are used [33].

Two early adoption studies are currently in the planning stages and will examine the use of barcode technology in a public or private health care setting where multiple vaccines are administered. A second study (in progress) examines the benefits of barcode technology in inventory management at the provincial depot level. Results from these studies are expected to be available and published in 2012.

## Conclusion

Progress has been made in the last decade to develop a national network of immunisation registers. The federal government has contributed considerably through funds and leadership to this initiative. However, considerable challenges remain to the development and adoption of immunisation registers in all provinces and territories and even with the adoption of Panorama as a public health surveillance system or other immunisation registers, the vision of a national network of immunisation registers will not be realised unless innovative cost-efficient solutions are developed and the issue of interoperability between jurisdictions is resolved. Nevertheless, while several challenges need to be overcome for a fully operational network of immunisation registers to be available, several areas related to immunisation registers have made substantial progress. These include the development of standards and the automated identification of vaccine products through the barcoding of vaccines. While there have been challenges in the development of immunisation registers in Canada, other countries and regions with different immunisation surveillance systems in place such as in Europe have dealt with similar issues related to the need for homogeneous systems to provide comparable immunisation-related data across a region [34]. Nevertheless, other federated countries such as Australia have been successful in setting up a national immunisation register and benefit from an operational national immunisation register to provide immunisation coverage data and vaccine safety data [35,36]. Finally, the upcoming years will most likely see greater developments in the availability of immunisation registers and in the accessibility of the relevant public health data.

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# Estimating vaccination coverage in the absence of immunisation registers – the German experience

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Immunisation registers are regarded as an appropriate solution to measure vaccination coverage on a population level. In Germany, a decentralised healthcare system and data protection regulations constrain such an approach. Moreover, shared responsibilities in the process of immunisation and multiple providers form the framework for public health interventions on vaccination issues. On the national level, those interventions consist mainly of conceptualising immunisation strategies, establishing vaccination programmes, and issuing recommendations. This paper provides an overview on sources and methods for collecting appropriate coverage data at national level and their public health relevance in Germany. Methods of data collection and available information on immunisations are described for three approaches: school entrance health examination, population surveys and insurance refund claim data. School entrance health examinations allow regional comparisons and estimation of trends for a specific cohort of children and for all recommended childhood vaccinations. Surveys deliver population based data on completeness and timeliness of selected vaccinations in populations defined by age or socio-demographic parameters and on knowledge and attitudes towards vaccination. Insurance refund claim data inform continuously on immunisation status (e.g. of children aged two years) or on vaccination incidence promptly after new or modified recommendations. In a complex healthcare system, the German National Public Health Institute (Robert Koch Institute, RKI) successfully compiles coverage data from different sources, which complement and validate one another. With the German approach of combining different data sources in the absence of immunisation registers, it is possible to gain solid and reliable data on the acceptance of vaccination programmes and target groups for immunisation. This approach might be of value for other countries with decentralised healthcare systems.

## Introduction

Germany has a population of 82 million people living in 16 federal states. Health legislation with regard to communicable diseases is national and recommendations on vaccination are released annually by the German Standing Committee on Vaccination (STIKO) [1,2]. STIKO recommendations are not legally binding but are usually closely complied with or complemented by the official recommendations of the federal states. The official recommendation is necessary for receiving compensation in case of adverse events following immunisation. STIKO recommendations are the basis for the decision by the Joint Federal Committee (self-governing body of physicians and health insurance funds), whether the costs of vaccinations are covered by the statutory health insurances. In Germany, health insurance is obligatory. The majority (85%) of people living in Germany are members of a variety of statutory health insurances, all of which provide a basic healthcare plan by statute and are funded by fixed fees paid by the members and their employers. The remaining 15% are mainly insured with private health insurance companies.

STIKO recommendations do not include specific vaccines but antigens and refer to specific target groups (defined by age, risk etc.). Beyond recommendations, all licensed vaccines can be administered, but have to be paid by the patients at their own expense.

Vaccination is voluntary in Germany. People are not only free to decide whether or not they get vaccinated but also which physician they want to consult.

Private physicians administer about 90% of all vaccinations and may choose from all available vaccines that are licensed. The remaining 10% are given in public health clinics, schools, or day care centres through special programmes of the federal states or by occupational health physicians [3]. Every vaccination has to be documented in the vaccination card of the vaccinee. Documentation includes antigen, brand name, batch number, and application date. The administering

physician enters the same information into his patient file. Vaccination cards and files are not centrally registered.

The decentralised healthcare system together with data protection regulations which emphasise everyone's right to a self-determined use of personal data [4], are strong constraints for national registers. In only one German federal state, all vaccinations of children up to the age of seven are to be reported to the local public health services by law. However, informed consent of the parents is required prior to reporting and regulations concerning how these data should be registered and processed are lacking [5].

As vaccinations affect health at individual and population level, the assessment and evaluation of trends and of regional and demographic differences in vaccination coverage are major public health tasks. At the level of the federal states, the commitment to these tasks and their prioritisation vary and range from state campaigns and intensive monitoring of immunisation to leaving all action to the capacities and responsibility of the local health offices.

At national level, the development of immunisation strategies, the establishment of vaccination programmes, and the evaluation of recommendations are the main tasks requiring reliable and representative data on vaccination coverage. The Robert Koch Institute (RKI) as the German National Public Health Institute in the portfolio of the German Ministry of Health is responsible for collection and analysis of these data. This paper provides an overview on sources and methods used by the RKI for collecting appropriate coverage data at national level in the context of the German healthcare system and with regard to their public health relevance.

## Methods

The RKI uses primary and secondary data to monitor the uptake of vaccines and to evaluate vaccination programmes. While primary data refer directly to the immunisation status as measured in, documented for or remembered by the respective individual, secondary data are obtained from sources with an original purpose different from assessing immunisation status or coverage. Primary data on vaccination coverage are gathered by the assessment of vaccination cards of children prior to school entry or by population surveys [6]. Secondary sources of information on vaccinations are data originating from physicians' refund claims from health insurances [6].

### School entrance health examination

The Communicable diseases Law Reform Act (Infektionsschutzgesetz, IfSG) [7] requires to collect the vaccination status at school entry and to send aggregated coverage data to the RKI. Health examinations are carried out as a precondition for school entrance and concern children whose age varies from four to six

years, depending on the federal state. The school entry cohort includes children, who should have completed their primary vaccination courses. Part of the examination is to check the completeness of recommended childhood vaccinations as documented in the vaccination card and give individual catch-up reminders where necessary. The school entrance health examinations (SEE) are carried out locally, vaccination data are aggregated at county level and sent to the federal state. Data are then transferred to the RKI once a year and include the number of investigated children, the number of children presenting the vaccination cards and the number of fully and of partly vaccinated children by defined antigens per federal state. Vaccination coverage of the respective school entry cohort is calculated based on children presenting their vaccination cards and the results, stratified by federal states, are published by the RKI in the Epidemiological Bulletin annually [8].

### Population surveys

The RKI regularly conducts health examination surveys and health interview surveys, which are described in more detail below. These surveys both include cross-sectional and longitudinal components in subsequent follow-ups, and are periodically carried out. The study population is geographically and socio-economically representative for the German population [9]. According to pre-defined sampling procedures, people are invited either to present to dedicated study units (for health examination and face-to-face interview) or to be interviewed by phone only (interview survey). Both forms – health examination including health interview as well as health interview only – are alternately conducted.

Vaccination status is included into these surveys as one of multiple core indicators of the population's health status. It is assessed for selected antigens on the basis of either vaccination cards or reports by the subjects themselves. In the health examination surveys, data is complemented by serological testing for specific antibody.

The health examination and interview surveys for children and adolescents are conducted separately from that for adults. The nationwide representative 'German Health Interview and Examination Survey for Children and Adolescents' (KiGGS) was carried out between May 2003 and May 2006. KiGGS was based on a sample of 17,641 children and adolescents aged 0–17 years with main residence in Germany. The 'German Health Interview and Examination Survey for Adults' (DEGS) is the respective representative survey for adults conducted by the RKI, succeeding previous adult surveys, the last of which was in the late 1990s. The DEGS was carried out from November 2008 until November 2011 in a total of 180 cities and municipalities all over Germany and included 7,988 adults aged 18–79 years. Like in KiGGS, in DEGS vaccination cards and serological tests are used to assess the immune status.

The examination survey is periodically accompanied by the 'German Health Update' (GEDA) by waves of telephone surveys which started in July 2008 and involved already 25,000 and 23,000 people aged 18 years and over in 2008–09 and in 2009–10, respectively. Questions on vaccination status for influenza, tetanus and pertussis were included into the interviews [10].

Additional sporadic and smaller surveys for defined research questions are conducted by the RKI to gather information on knowledge, attitude and behaviour towards vaccination in the general population or in defined groups. For example, during the 2009/10 influenza season, uptake of seasonal and influenza A(H1N1) pdm09 vaccines as well as acceptance and progress of the pandemic influenza vaccination campaign was monitored by consecutive representative surveys. The RKI commissioned a professional market research agency to carry out computer assisted telephone interviews (CATI) by experienced interviewers [11].

### Insurance refund claim data

Statutory Health Insurance Funds are billed by the Associations of Statutory Health Insurance Physicians (ASHIP) on the basis of quarterly reports on medical services, including vaccinations, delivered by physicians. ASHIPs are regionally organised, mostly one ASHIP per federal state. In 2004, the RKI established an ongoing project together with ASHIPs using their insurance refund claim data for epidemiological assessment of vaccine preventable diseases and vaccination coverage. The methods of the project, including a detailed description of quality assurance have been described elsewhere [12]. Pseudonymised data are quarterly transmitted from the ASHIPs to the RKI and include demographic characteristics of the vaccinees (month and year of birth, sex, county of residence), information on the vaccination (vaccine, date of vaccination), and information on medical contacts (medical specialisation of physician, county of physician's office).

According to the public health question of interest, different applications of these data are possible for monitoring vaccination coverage, i.e. follow-up of birth cohorts and vaccination incidence. Information on distinct individuals can be tracked over time for receiving vaccinations. Thus, birth cohorts can be followed-up and compared by vaccination status at a certain age (i.e. 24 months) and by ASHIP region [13].

Vaccination incidence is defined as the number of vaccinated individuals in relation to the number of insured individuals of the same age and per time. Taking into account that the number of vaccinated persons accumulates over time, the cumulative vaccination incidence by a defined age and year can be calculated.

We used the insurance refund claim data and the methods described to determine varicella vaccine coverage. Varicella vaccination is part of the recommended childhood immunisation schedule since 2004. It was

therefore not included in KiGGS and firstly recorded at SEE in 2008.

## Results

In the following sections only selected results of the above described methods are shown as example of their feasibility and practical use.

### School entrance health examination

With more than 90% in total, the vast majority of children had vaccination cards available at SEE 2009. While the percentage of children having their vaccination cards has increased over time, the range between the federal states' highest and lowest value has decreased, however the minimum was still below 90% in 2009.

SEE for 2009 showed, that vaccination coverage of children fully immunised against diphtheria, tetanus, polio (>95% each) and *Haemophilus influenzae* type b (Hib, 94%) was high [8]. Figure 1 shows the vaccination coverage for selected antigens. Immunisation gaps existed particularly for hepatitis B (90% coverage) and for the second dose of measles (90%). Moreover, increasing vaccine uptake was visible in recent years, especially for the second dose of vaccines containing measles antigens. Data on varicella vaccination in 2009 were available from 15 federal states and varied between 15% and 71%. For almost all vaccinations, SEE-data analysis also revealed a higher coverage in eastern federal states (Saxony, Brandenburg, Saxony-Anhalt, Thuringia, Mecklenburg-West Pomerania, n=5) than in western federal states (North Rhine-Westphalia, Bavaria, Baden-Württemberg, Hesse, Lower Saxony, Rhineland-Palatinate, Berlin, Hamburg, Schleswig-Holstein, Saarland, Bremen, n=11).

### Population surveys

According to KiGGS, the average prevalence of completed immunisation series for tetanus, diphtheria and polio as well as the coverage for the first dose of measles vaccination was above 90% in children aged 2–17 years. Primary courses were often not completed at the recommended age of two years. Vaccination coverage for pertussis, Hib and hepatitis B was higher in younger children than in adolescents [14]. Multivariate analyses revealed predictors for not being vaccinated or for negative serology i.e. regarding measles, such as born abroad and critical attitudes of parents towards vaccination [14,15]. Children not presenting the vaccination cards were more likely to be seronegative.

First results of GEDA revealed immunisation gaps for tetanus of more than 25% in the adult population [16].

About 1,000 randomly selected German speaking persons aged 14 years or older, living in private households, were included in each of the consecutive bi-weekly telephone surveys on the influenza A(H1N1) pdm09 vaccine, during the influenza season 2009/10, so that by week 53 in 2009, a total of 4,003 people had

been interviewed. Vaccination coverage was shown to be low reaching only 8% at the end of December 2009 (Figure 2) [11].

### Insurance refund claim data

For one dose of varicella vaccine, coverage at two years of age was 34% for birth cohort 2004 and differed regionally between 13 examined ASHIPS [13]. Children of birth cohort 2005 were the first to be vaccinated with two doses of a combined vaccine against measles, mumps, rubella and varicella (MMRV) at two years of age. The varicella coverage for birth cohort 2005 was 51%, including 5% of children who received two doses of MMRV. For birth cohort 2007, preliminary analysis of data from six ASHIPS showed a further increase of coverage with one dose of varicella vaccine at two years of age to >80% (unpublished data).

Annual vaccination incidence for one dose of varicella vaccine was highest in one year old children and increased here from 4% in 2004 to 50% in 2006 (Figure 3). Cumulative vaccination incidence for the age group comprising four to six year-olds increased from 1% to 47% between 2004 and 2009.

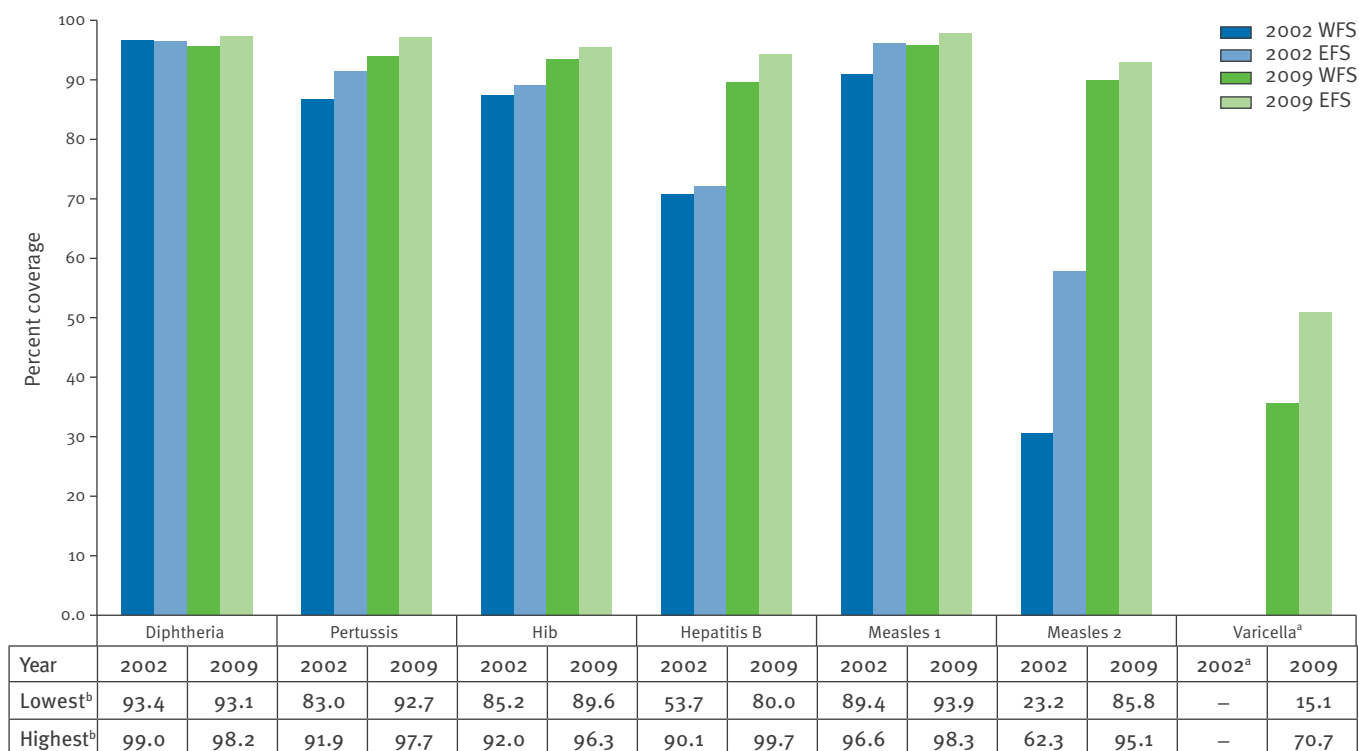
## Discussion

For the estimation of vaccination coverage at national level vaccination data as retrieved at SEE are the only routine data required by law (IfSG) in Germany [7]. Based on SEE coverage across regions can be compared and trends for complete cohorts can be assessed by all recommended childhood vaccinations. Thus, representativeness, completeness and validity are high. However, shortcomings of this approach are that timeliness of vaccination cannot be assessed at national level and that vaccinations which are newly introduced into the childhood immunisation schedule are eligible for assessment at school entry only several years thereafter. For example, since its recommendation in 2004, varicella vaccination coverage was still not available from all federal states for the school-entry cohort 2009 for publication in 2011.

Data from SEE cover only a limited children's age group and vaccination status at other ages is not routinely collected in all federal states. Thus, they do not provide data for high interest target groups such as children at two years of age and adults for longitudinal analysis at national level.

**FIGURE 1**

Vaccination coverage by selected vaccinations, at school entry, in western (n=11) and eastern (n=5) federal states, Germany, 2002 and 2009



Hib: *Haemophilus influenzae* type b; WFS: western federal states; EFS: eastern federal states.

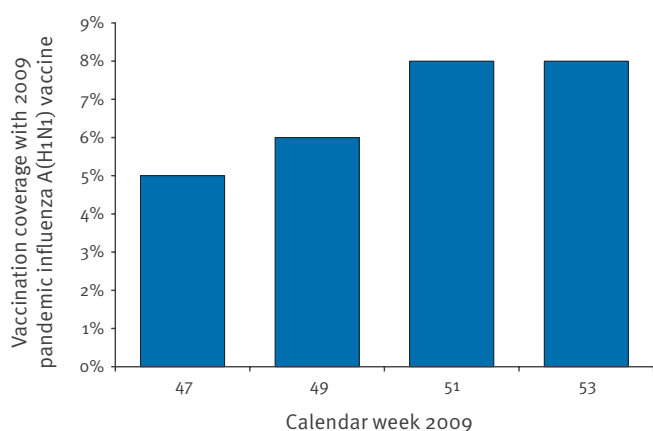
Vaccination coverage is given by vaccinated children per children presenting vaccination cards at school entry.

<sup>a</sup> Varicella vaccination was not yet recommended in 2002. In 2009, data on varicella vaccination were available from 15 federal states.

<sup>b</sup> Lowest and highest federal state vaccination coverage values [8].

**FIGURE 2**

Real-time monitoring of coverage with monovalent influenza A(H1N1)pdm09 vaccine by countrywide telephone interviews of individuals aged 14 years or older, Germany, 16 November–29 December 2009 (n=4,003)



The calculated coverage from SEE based on children presenting their vaccination cards is probably overestimated. Children not presenting the cards were less likely to have been vaccinated in an outbreak investigation [17] and had a higher prevalence of seronegativity in KiGGS [18] as compared to children with vaccination cards.

Coverage as assessed by KiGGS was comparable to that of data from SEE in the same age groups, thus the respective results are validating each other. The huge benefits of examination surveys such as DEGS or KiGGS are their socio-demographic representativeness. This allows population based information on completeness and timeliness of vaccination in different groups defined by age and social status. By comparing documented vaccinations with serological results and socio-demographic parameters, risks for not being vaccinated can be predicted and essential information for composing prevention strategies is gained.

However, regular examination surveys are expensive, laborious, and complex and do not allow to estimate for recently recommended vaccinations. These shortcomings are partly overcome by telephone interview surveys. They are fast and flexible methods for collecting data and enable decision makers, for instance, to respond quickly to inadequate immunisation rates. In addition, information on perceptions on vaccination issues can easily be gained. The balance between practicability and representativeness according to the aim of the survey may lead to limitations. A general shortcoming of interviewing people for their vaccination status might be the reliability of information as compared to the documented vaccinations in official documents [19].

Insurance refund claim data may compensate the limitations of data from SEE. Moreover, if continuously collected, they can fill the gaps remaining between discrete population surveys.

ASHIP data were the only available population based source for calculating vaccination coverage by age group and region shortly after introduction of varicella vaccines into the childhood immunisation programme in July 2004. Besides a growing acceptance of the recommendation and increasing coverage particularly in the recommended age group, the data showed that a considerable amount of vaccinations were given later than recommended and that the availability of vaccines as well as the reimbursement influenced the vaccine uptake [13]. In 2009, cumulative varicella vaccination incidence for children aged 4–6 years was in the same range as coverage calculated by SEE. Moreover, based on ASHIP data the vaccination coverage for children at two years of age will be routinely assessed and indicate whether the primary courses of immunisation are completed as recommended.

ASHIP data have been available since 2004, but vaccinations were also administered before that time, so only incident vaccinations per year since the time data collection started can be analysed. This leads to an underestimation of the true coverage, particularly in older age groups. Vaccination coverage, however, can be estimated for birth cohorts since ASHIP data collection. These data are particularly useful to monitor uptake of vaccines which are newly introduced or recommended for other age groups than before.

ASHIP data may be of limited representativeness for the total population as they are only related to statutory health insured persons, while vaccination coverage of privately health insured persons may differ. Availability, validity and reliability of coverage estimates based on data sources with an original purpose different from assessing vaccination status or coverage are highly dependent on a stable database and data structure.

ASHIP data so far have been primarily used to answer specific questions that could not be answered by other data sources. Currently, these data are being established as the official vaccination coverage of children aged 24 months in Germany. In addition, a comparison between data sources is being done to validate results whenever possible.

In summary, the described methods are of different public health relevance. Data from SEE allow to continuously analyse trends and regional differences in vaccination coverage related to childhood immunisation. With population surveys, target groups of immunisation can be defined by age or socio-demographic characteristics, and insight on the acceptance of specific vaccines can be gained. In addition, vaccination programmes and campaigns can be assessed and

attitudes and behaviour towards vaccination examined. ASHIP data give rapid information on the compliance with vaccination schedules but also about the general acceptance of immunisation programmes, in terms of vaccination coverage by region and age, and thus are helpful for identifying target age groups for (supplementary) immunisation.

The exploitation of further primary and secondary data sources for retrieving information on vaccination coverage has been tested by the RKI with limited public health relevance.

Immunising physicians were asked for the number of administered first and second doses of varicella and measles vaccines per month in a network of private doctors (sentinel). As the sentinel is not population based, coverage could not be calculated but trends in vaccine uptake were detected and related to different physician groups, regions and availability of vaccines [20]. As the documentation workload is high, attempts are ongoing to retrieve data automatically from the software systems used by physicians, but limiting factors are the variety of those systems together with data protection.

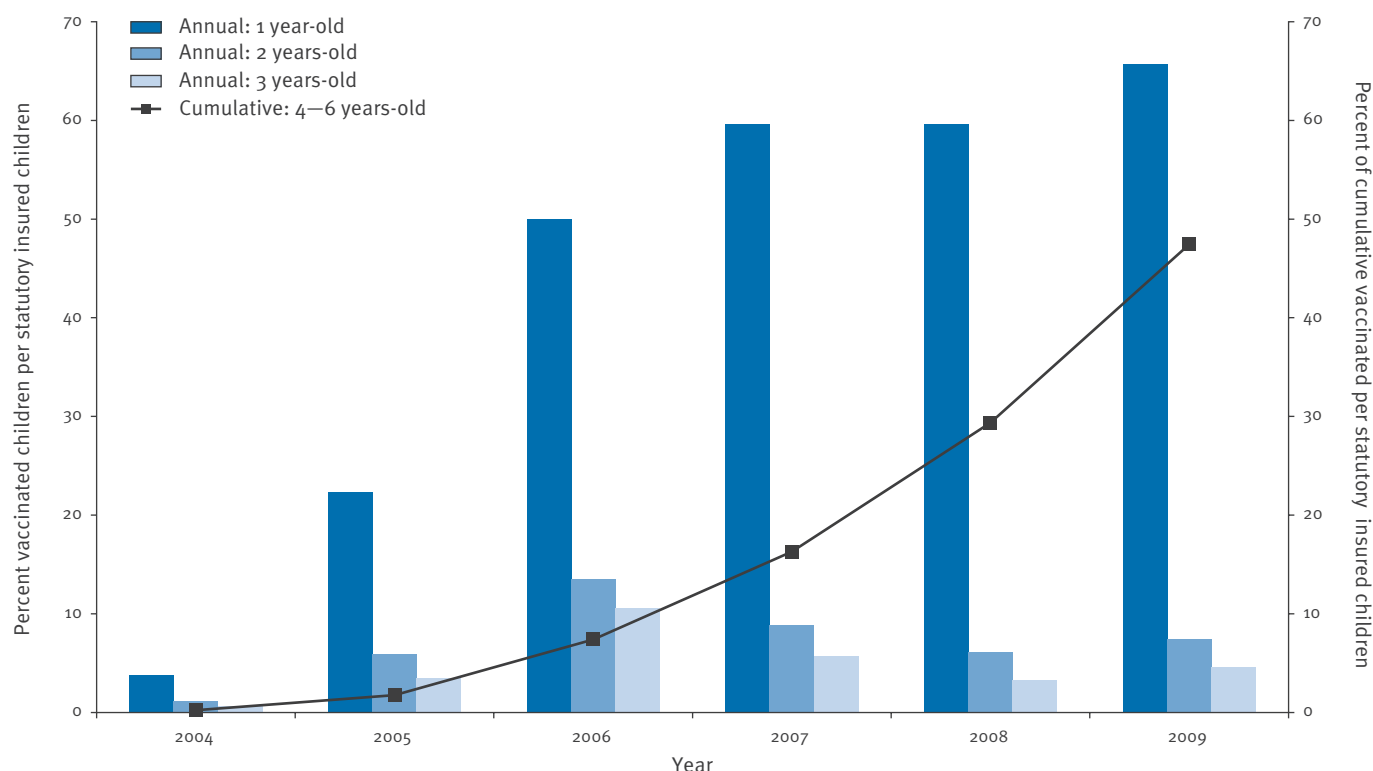
Commercial data on sale or prescription figures deliver trends in number of sold or prescribed vaccine doses over time by brand name, region and physician's speciality. Trend comparisons by region and by physicians' speciality are possible. Moreover, with different vaccines available, insight is gained on preferred vaccine brands. These data show trends in vaccine uptake in total but not the coverage, as the number of immunised persons remains unknown. The completeness of individual vaccination series cannot be assessed, particularly if multiple doses are needed.

In conclusion, complex health systems require complex approaches to gain data on vaccination coverage or on other vaccination issues.

In the absence of immunisation registers several primary and secondary data sources have been explored by the RKI for assessing nationwide vaccination status and coverage. Different approaches for the utilisation of the various sources, either routinely or on specific demand, have been successfully implemented. Each of them has its strengths and limitations and they complement one another, thus validating the information retrieved from different sources.

**FIGURE 3**

One-dose varicella vaccination, annual rates for children aged one, two and three years, and cumulative rates for children aged from four to six years, Germany, 2004–2009



The proportion statutory insured children who are vaccinated is according to data from nine of 17 Associations of Statutory Health Insurance Physicians (ASHIP).

The German experience with collecting vaccination coverage data at national level in a decentralised healthcare system, dominated by the private sector and in the absence of immunisation registers, might be of value for other countries with federal or otherwise decentralised healthcare systems.

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# Immunisation registers in Italy: a patchwork of computerisation

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In Italy, the 21 regional health authorities are in charge of organising and implementing their own vaccination strategy, based on the national vaccine plan. Immunisation coverage varies greatly among the regions for certain vaccines. Efforts to increase childhood immunisation coverage have included initiatives to develop and implement computerised immunisation registers in as many regions as possible. We undertook a cross-sectional online survey in July 2011 to provide an updated picture of the use, heterogeneity and main functions of different computerised immunisation registers used in the Italian regions and to understand the flow of information from local health units to the regional authorities and to the Ministry of Health. Comparing current data with those obtained in 2007, a substantial improvement is evident. A total of 15 regions are fully computerised (previously nine), with 83% of local health units equipped with a computerised register (previously 70%). Eight of the 15 fully computerised regions use the same software, simplifying data sharing. Only four regions are able to obtain data in real time from local health units. Despite the progress made, the capacity to monitor vaccination coverage and to exchange data appears still limited.

## Introduction

Childhood vaccination services in Italy are usually provided by vaccination centres in local health units (LHUs). To date, there are 157 LHUs in the 21 Italian regions. Since the decentralisation of the Italian national health system in 2001 [1], regional health authorities were charged with organising, coordinating and implementing their vaccination strategy, based on the national vaccine plan [2]. The plan was prepared by the Ministry of Health in collaboration with the National Institute of Health (Istituto Superiore di Sanità, ISS), scientific societies, experts and regional health authorities. In March 2012, a new national vaccine plan for 2012 to 2015 was released [3].

Currently, all the LHUs in Italy estimate vaccine coverage using the administrative method – with the number of vaccinated people as numerator and the local population, obtained from the administrative database or from the health system database, as denominator. The Ministry of Health collects annual data from all the regions on immunisation coverage and on the number of doses administered for most vaccines. The data are collected on paper and the form used is currently under revision to include all the vaccines recommended in the national vaccination schedule.

Even though immunisation coverage in Italy for vaccinations included in the 2005–2007 national vaccination plan is higher than 90%, there are still concerns about the coverage at subnational level (e.g. coverage at age 24 months for diphtheria-tetanus-acellular pertussis-inactivated polio vaccine at the national level is 96%, whereas it ranges from 88% to 98% among the regions). Pockets of lower vaccination coverage still exist in certain geographical areas and among hard-to-reach population groups, as highlighted by the current resurgence of measles in the country [4]. Furthermore, conjugate pneumococcal, meningococcal C and varicella vaccines are offered by some regions to all children and by others only to people in at-risk groups, leading to variations in coverage rates [5]. However, since the new vaccine schedule adopted in the recently approved national vaccination plan includes human papillomavirus, pneumococcal and meningococcal C vaccines for all newborns and postpones the introduction of mass immunisation against varicella to 2015, it is likely that the differences between regional vaccination coverage will decrease.

Childhood vaccines included in the national vaccination plan are bought by the LHUs and are administered free of charge in the vaccination services. The vaccination services' personnel are in charge of keeping individual records of the administered vaccine doses and

enter the data into the computerised register, if there is one.

Efforts to increase childhood immunisation efficiency have included initiatives to develop and implement computerised immunisation registers in as many regions as possible. Such registers allows public health personnel to evaluate whether an individual's immunisation history is complete and up to date. This functionality is used to identify individuals who are in need of further immunisation, to generate recall/reminder notifications for immunisations and to produce immunisation coverage reports, which can be used to evaluate immunisation programmes [6,7]. The register should be a confidential, population-based, computerised database that records all immunisation doses administered by participating providers to persons residing within a given geopolitical area [8]. In addition, such registers can facilitate the monitoring of larger areas and evaluation of the impact of the vaccine strategies and also permit a fast and reliable exchange of data.

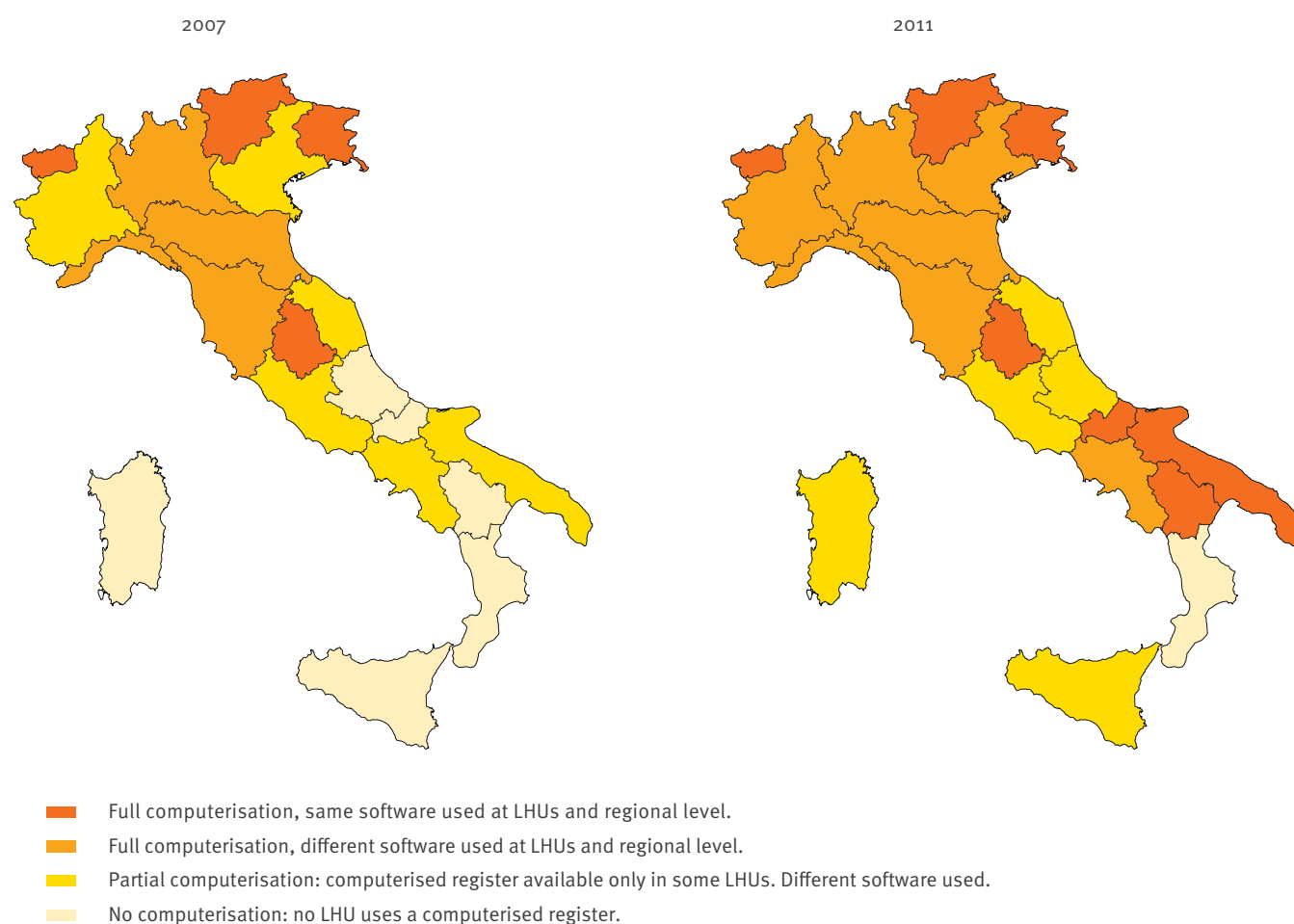
Implementation of a computerised register was first identified as a priority in Italy in 2003, in the first

national plan for the elimination of measles and congenital rubella [9] and use of such registers has been endorsed in subsequent national plans [3,10,11]. Within the framework of a larger project named 'MATTONI', funded by the Italian Ministry of Health [12], an inter-regional working group in 2007 defined a common minimum set of variables to be included in local computerised registers, to enable the development of a national system capable of aggregating data from all the Italian regions. Furthermore, a recommended information flow from local vaccination centres to the national level was described. The metadata identified included information on a single individual that could facilitate local logistic management and also allow vaccination coverage to be more precisely estimated. It also includes information that allows the vaccination register to be linked with other relevant demographic databases.

At the national level, the aim of the MATTONI project is to feed a centralised information system able to support monitoring of vaccine coverage, evaluation of vaccination strategies and assessment of vaccine effectiveness by collecting aggregated data from the LHUs. This would allow areas with pockets of

## FIGURE

Existence of computerised immunisation registers in Italy, by region, 2007 and 2011



LHU: local health unit.

Source of 2007 data: [13].

susceptible individuals to be identified and would create a link between vaccine coverage and incidence data and identify vaccine failures.

A survey conducted in 2007 to assess the existence of computerised immunisation registers in Italy showed that 70% (126/180) of LHUs were using such registers and that only nine of the 21 regions were fully computerised [13]. The present study aims at providing an updated picture of the use, heterogeneity and main functions of different computerised immunisation registers adopted in the regions and to understand the flow of information from the LHUs to the regional health authorities and to the Ministry of Health.

## Methods

In July 2011, we undertook a cross-sectional survey on the level of computerisation of immunisation registers in the 21 Italian regional health authorities. All regional coordinators for infectious diseases and vaccinations were contacted and asked to fill in a standardised

online questionnaire. It included 20 questions about the number of computerised LHUs, use of different or the same software in the LHUs that were computerised, the name and basic characteristics of the software used. In order to explore the flow of information between LHUs and the regions, we also asked about the method and the frequency of data collection (i.e. shared data, transmission of individual or aggregated data). Availability of vaccine coverage for vaccines not included in the national immunisation plan in 2011 (i.e. pneumococcal, meningococcal, varicella and rotavirus vaccines) and for high-risk children was also requested. The questionnaire also asked whether regions with no computerisation or those using more than one such register were planning any changes in the coming years.

Regional coordinators who reported having a single computerised regional register were asked by email or telephone about the characteristics of the software used in the register, confidentiality issues,

**TABLE 1**

Computerisation of immunisation registers in Italy and data management at regional level, 2011

| Degree of computerisation                                                             | Number of regions | Proportion of LHUs using computerised register | Proportion of regions that automatically calculate immunisation coverage | Frequency of submission from computerised LHUs to regional health authorities | Regions that have access to computerised individual data         |
|---------------------------------------------------------------------------------------|-------------------|------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------------------------------------------------|
| Full (same software)<br>Same software used at LHUs and at regional level              | 8                 | 21/21                                          | 5/8                                                                      | Real time (n=3)                                                               | Direct access to LHU individual data in real time (n=3)          |
|                                                                                       |                   |                                                |                                                                          | Quarterly (n=1)                                                               | Access after periodic individual-data transmission by LHUs (n=1) |
|                                                                                       |                   |                                                |                                                                          | Every six months (n=4)                                                        | No access to individual data (n=4)                               |
| Full (different software)<br>Different software used at LHUs and at regional level    | 7                 | 84/84                                          | 1/7                                                                      | Real time (n=1)                                                               | Direct access to LHU individual data in real time (n=1)          |
|                                                                                       |                   |                                                |                                                                          | Every six months (n=3)                                                        | Access after periodic individual-data transmission by LHUs (n=1) |
|                                                                                       |                   |                                                |                                                                          | Yearly (n=3)                                                                  | No access to individual data (n=5)                               |
| Partial<br>Computerised register available only in some LHUs. Different software used | 5                 | 25/46                                          | 0/5                                                                      | Quarterly (n=2)                                                               | No access to individual data (n=5)                               |
|                                                                                       |                   |                                                |                                                                          | Every six months (n=1)                                                        |                                                                  |
|                                                                                       |                   |                                                |                                                                          | Yearly (n=2)                                                                  |                                                                  |
| None<br>No LHU uses a computerised register                                           | 1                 | 0/6                                            | 0/1                                                                      | —                                                                             | —                                                                |

LHU: local health unit.

perspectives for future development and any aspects to be improved.

The information obtained was compared with results from the previous survey conducted in 2007 [13].

## Results

Information was collected for all 21 regions, which included a total of 157 LHUs. As shown in the Figure, to date, 15 of the regions and 130 (83%) of LHUs are fully computerised, five regions are partially computerised and one does not use a computerised register (Figure, Table 1).

Among the 15 fully computerised regions, eight use the same software in all LHUs, while the remaining seven use different software (Table 1). In the five regions not fully computerised, the proportion of LHUs that are computerised ranges from 25% to 92% of the LHUs.

LHUs must transmit data to the regional level. Individual data are accessible in only six of the 15 fully computerised regions (Table 1); in the remaining nine, individual data are stored in each LHU and only aggregate data on vaccine coverage are sent to the regional level, as in the regions with partial or no computerisation.

Eight of the 21 regions receive data every six months from the LHUs, four receive data in real time, three receive them quarterly and five yearly (Table 1). The capacity of the different systems to manage vaccination coverage data at regional level is very heterogeneous: of the 15 regions that are fully computerised, only six

are able to calculate vaccine coverage automatically. Of these six, only three can calculate the coverage using individual data available in real time from the LHUs. From the regional level, vaccination coverage data are forwarded to the Ministry of Health once a year.

The main features of the immunisation registers used in the eight fully computerised regions using the same software are presented in Table 2.

The findings of the survey highlight that for paediatric vaccinations not included in the national vaccination plan in 2011, coverage data for children at risk are available at regional level in eight regions for pneumococcal, in seven for meningococcal C, in six for varicella and in three for rotavirus vaccines.

In some of the fully computerised regions, an evolution of the software is already scheduled; in particular, three regions have planned to shift to a web-based system, which is easier and faster than the current computerised register.

All regions not yet fully or not at all computerised are planning to extend the system to the entire region or implement one in the coming years.

## Discussion

In Italy, estimation of vaccine coverage and assessment of vaccination status are always based on individual records for each vaccinated child. There is a large variability in the type of registers used (paper or electronic) but basic information, such as date of vaccination, number of dose, brand and vaccine lot, is always collected. The quality of collected data is good and comparable with those provided by a national cluster sampling survey performed every five years to estimate vaccination coverage with an alternative method [14]. There is, however, considerable variability in the methods used to manage the list of children to call for vaccination, the kind of call (i.e. active versus passive) and in the ability to calculate the vaccine coverage. Extensive use of computerised immunisation registers could help to increase vaccination coverage, but because of the decentralisation of the Italian health system, a single national immunisation register seems to be difficult to realise. This situation appears to be common in Europe: a survey conducted by the Vaccine European New Integrated Collaboration Effort (VENICE) network in 2007 found that only four countries in Europe have a national computerised immunisation register [15] and many countries, as in Italy, have regional systems. A new survey conducted by VENICE in 2011 showed that five countries have a national register and six have subnational ones [16].

As Italy has a fragmented health system, it seems reasonable that all the existing computerised immunisation registers in the regions could adopt the common minimum dataset proposed by the MATTONI project [12]. These metadata include demographic information

**TABLE 2**

Main features of the immunisation registers at local health unit level in the fully computerised regions using the same software, Italy (n=8)

| Feature                                                    | Number of regions |
|------------------------------------------------------------|-------------------|
| Capacity to list the persons to be invited for vaccination | 8                 |
| Calculation of vaccination coverage for risk groups        | 8                 |
| Printing of invitation letters                             | 8                 |
| Managing vaccination appointments                          | 7                 |
| Collecting information on reason for missed vaccinations   | 6                 |
| Managing vaccine storage                                   | 6                 |
| Producing a list of vaccination delays                     | 5                 |
| Management of the high-risk group target                   | 5                 |

on the individuals, history of all the administered vaccines (who administered them, when, what and where) and information about non-administration of scheduled vaccinations (including the reasons). All this information should allow a better management of the vaccine centre's activities and a faster calculation of vaccine coverage. Furthermore, using the same meta-data, individual-based data exchange among LHUs and regional and national authorities should be facilitated.

A great heterogeneity among regions about health matters has emerged in Italy, sometimes with differences even within the same region [17]. An optimal situation is present only in four regions (with a population equal to 18% of the total Italian population), where individual data on vaccination history collected at LHUs is shared in real time with the regional level. However, comparing the findings of our survey with those obtained in 2007, it is evident that there has been some improvement. Currently, of the 15 fully computerised regions, eight use the same software in all their LHUs. These regions are relatively small (all but one have fewer than 1,500,000 inhabitants): it may be that in small regions (with therefore a small number of LHUs), it is easier to reach a consensus on a common tool.

Although the percentage of LHUs with computerised immunisation registers increased from 70% in 2007 to 83% in 2011, there are still important geographical differences and some regions have not yet covered all their territory. Only one region, in the south, does not yet have any of its LHUs equipped with a computerised register. Moreover, there is considerable difficulty in guaranteeing the transmission of individual data from local to regional level, as only six regions have access to individual vaccination histories.

All the regions with a unique immunisation register that covers all their LHUs agreed that the most important advantages of the register are the simplification of the management of the vaccination centres and the timely availability of coverage data. However, the capabilities of the systems adopted can still be improved – such as the management of the appointments, collection of information on the reasons for missed vaccinations, management of vaccine storage, calculation of vaccine coverage for specific target groups or birth cohorts, management of adverse events, recording linkages between the vaccine register and notification database of communicable diseases and transmission of data to the regional level – are all powerful tools of computerised immunisation register but are not present in all the registers in the eight fully computerised regions that have the same software (Table 2).

Increasing the current frequency of annual vaccination coverage assessment seems currently not feasible: data on the vaccination coverage for HPV is collected by the National Institute of Health every six months and it is perceived as an excessive workload in some regions (data not shown). Although there are

difficulties at regional level, there are some improvements that should be introduced at national level: aggregated coverage data for recently introduced vaccines are still not routinely collected and there is still no technical document that describes how to send electronic vaccine coverage data from the regions to the Ministry of Health.

In conclusion, this study shows progress has been made towards a more extensive use of computerised immunisation registers in Italy. The adoption of such registers all over the country should improve the management of the vaccination services and the control, at local level, of vaccine-preventable disease. Notwithstanding, the patchy situation in the Italian LHUs, in terms of systems adopted, even within the same region, does not allow an easy transmission of data from the periphery to the centre. The existence of metadata recommended by the MATTONI project is not enough because many regions still do not have access to the individual records present in the LHUs. Furthermore, the Ministry of Health does not require the aggregated data to be sent electronically.

A reasonable objective for the next three years is to have vaccine coverage data at national level for all vaccinations using exclusively electronic data management and transmission from each level (from LHUs to regional health authorities and from there to the Ministry of Health). This will provide more complete and timely data that can be used for monitoring the national vaccination strategies. A flexible and standardised data format should be decided upon for exchange of data among different systems. Furthermore, the new paper form prepared by the Ministry of Health for the collection of regional data should be substituted by a web-based version, in line with the pilot experience of the European Centre for Disease Prevention and Control (ECDC) in collecting vaccine coverage data from European Union Member States at subnational level. In this pilot experience, data entry or file transmission are accepted [18].

Finally, more effort should be made to calculate vaccine coverage for specific target populations (i.e. risk groups or health professionals), as is done for influenza vaccination in Italy and in many other European countries [19]. The new Italian national vaccination plan – with the specific objective of a countrywide diffusion of computerised immunisation registers and a new vaccination schedule for all the diseases common to all the regions – should accelerate the process of computerisation. This should make it easier to identify and actively call unvaccinated children, thus leading to a better control of vaccine-preventable diseases at local level and a better planning of resources and strategies at regional and national level.

## Regional coordinators for infectious diseases and vaccinations

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# Use of the vaccination register to evaluate influenza vaccine coverage in seniors in the 2010/11 influenza season, Navarre, Spain

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People aged 65 and older have a high risk of suffering from complications of influenza, therefore it is recommended that they receive annual influenza vaccination. However, vaccination coverage falls far short of the target of 75%. In this study we use the vaccination register to evaluate the coverage of influenza vaccine in non-institutionalised persons aged 65 and over in Navarre, Spain, in the 2010/11 season (104,427 persons). Vaccination coverage was 58.6%, lower than the 62.7% coverage in the 2009/10 season. In the multivariate analysis, lower coverage was associated with being female, age under 80 or over 94 years, immigrant status and hospitalisation in the previous year. In contrast, persons with major chronic conditions, high level of dependence or those with more visits to the general practitioner in the previous year had higher vaccination coverage. Influenza vaccination in the previous season was a strong predictor of vaccination in the current season (odds ratio: 37.0, 95% confidence interval: 35.7–38.4). The vaccination register has been shown to be useful to monitor the coverage of influenza vaccination in seniors and may help guide strategies to improve coverage.

## Introduction

Computerised vaccination records have been shown to be useful in reducing the frequency of missed opportunities for immunisation, facilitating reminder notices, preventing over-immunisation, and providing information about immunisation delivery and documentation on a population level [1,2]. Vaccination records can also be useful tools for clinicians and public health officials, for monitoring immunisation coverage and for providing feedback to clinicians, patients and case management workers [3,4].

Seasonal influenza can cause serious complications in the elderly and in subjects with chronic health conditions. Annual vaccination against influenza is the most

effective measure for reducing morbidity and mortality associated with this disease [5-7]. In Spain, the recommendations for preventing seasonal influenza include annual vaccination of all people aged 65 and over, but the coverage reached in this population is far from the 75% target proposed by the World Health Assembly for 2010 [8]. This highlights the importance of monitoring the vaccination coverage and identifying possible ways to improve it.

The present study aims to explore the utility of a population-based vaccination register to quantify seasonal influenza vaccine coverage and to describe its determinants in non-institutionalised subjects aged 65 and older.

## Methods

### Vaccination register

The Regional Health Service of Navarre, Spain, provides free healthcare to approximately 97% of the population of the region (642,051 inhabitants). All Navarre residents at birth are registered into the healthcare computerised system and people who change their residence to Navarre are registered at the first visit to a healthcare centre. From 2000 to 2004 the computerised medical record was implemented throughout the whole Navarre Health Service, in both hospitals and primary care. A specific section in the computerised medical record is provided to register vaccinations. Whenever health professionals administer a dose of vaccine they must register online the type of vaccine, dose number, brand, batch, date of administration, person who administers it and possible incidents. The type and brand of vaccine are registered using predefined codes to avoid errors and make it easier to consult the information recorded. Software filters are applied to ensure valid data entry. The same registration system is used for all vaccines, both those administered in childhood

or adult vaccination programmes and all other vaccines that are not included in these programmes. The information in this register is available to the physician and is part of each patient's computerised medical record. It provides an alert about the doses required to complete the vaccination schedules and performs the functions of the vaccination record, regardless of whether the patient retains a paper copy.

The information contained in the vaccination register is exported weekly to an individual-level database. In this format, the information from the vaccine register can be linked to other databases (as described below) with complementary data, such as data on demographics or data on incidence of vaccine-preventable diseases. The combined data can be used to monitor the coverage of each vaccine, to plan improvements in coverage, to detect vaccine failures and to evaluate the effectiveness of different vaccines.

### Influenza vaccination campaign

In the 2010/11 season, the influenza vaccination campaign in Navarre took place from 11 October to 26 November, following a system similar to that used in previous seasons [9]. The trivalent inactivated vaccine was used, with the composition recommended by the World Health Organization [10]. In Navarre, the vaccine was indicated for all persons aged 60 and over, and for persons with chronic diseases that increase the risk of influenza complications [9]. The vaccines for this programme were purchased centrally by the regional government and were distributed to all primary healthcare centres. Before the vaccination campaign began, an information campaign focusing on the target population was carried out by means of posters in the healthcare centres and notices in the media to let people know the population groups for whom the vaccine was indicated and where they could go to be vaccinated. Physicians and nurses in primary care centres were sent a detailed protocol of the programme with the objectives, dates, indications, logistics, instructions on how to register the doses administered, and phone numbers for further information [9]. Healthcare staff in the healthcare centres took advantage of all contacts with patients to remind them of the benefits of being vaccinated against influenza.

### Study population and variables

Using computerised databases of physicians, we selected all non-institutionalised persons aged 65 and older who were covered by the Navarre Health Service at the beginning of the vaccination campaign. According to the national and regional protocols all subjects in this study population had indication for influenza vaccination [9]. From the computerised database of primary healthcare, we obtained the following baseline variables: sex, age, migrant status, district of residence, major chronic conditions, high level of dependence (Barthel's index <40), number of outpatient visits during the previous 12 months and hospitalisation in the previous 12 months. Residence in municipalities

**TABLE 1**

Characteristics of the population aged 65 and older and respective 2010/11 seasonal influenza vaccine coverage, Navarre, Spain (n=104,427)

| Characteristic                              | Number of people (%) | Number of vaccinated people (%) |
|---------------------------------------------|----------------------|---------------------------------|
| Total                                       | 104,427 (100)        | 61,195 (58.6)                   |
| Sex                                         |                      |                                 |
| Male                                        | 45,712 (43.8)        | 27,201 (59.5)                   |
| Female                                      | 58,715 (56.2)        | 33,994 (57.9)                   |
| Age group, years                            |                      |                                 |
| 65–69                                       | 27,543 (26.4)        | 12,605 (45.8)                   |
| 70–74                                       | 21,995 (21.1)        | 12,715 (57.8)                   |
| 75–79                                       | 22,353 (21.4)        | 14,289 (63.9)                   |
| 80–84                                       | 17,220 (16.5)        | 14,289 (63.9)                   |
| 85–89                                       | 10,291 (9.9)         | 6,905 (67.1)                    |
| 90–94                                       | 3,749 (3.6)          | 2,426 (64.7)                    |
| 95–99                                       | 1,081 (1.0)          | 601 (55.6)                      |
| ≥ 100                                       | 195 (0.2)            | 61 (31.3)                       |
| Number of major chronic conditions          |                      |                                 |
| 0                                           | 45,049 (43.1)        | 22,750 (50.5)                   |
| 1                                           | 33,767 (32.3)        | 21,204 (62.8)                   |
| >1                                          | 25,611 (24.5)        | 17,241 (67.3)                   |
| Major chronic conditions                    |                      |                                 |
| Liver cirrhosis                             | 2,214 (2.1)          | 1,320 (59.6)                    |
| Diabetes                                    | 20,827 (19.9)        | 13,545 (65.0)                   |
| Heart disease                               | 21,333 (20.4)        | 14,261 (66.8)                   |
| Haematological cancer                       | 1,026 (1.0)          | 629 (61.3)                      |
| Non-haematological cancer                   | 16,806 (16.1)        | 10,539 (62.7)                   |
| Immunological disease                       | 838 (0.8)            | 525 (62.6)                      |
| Pulmonary disease                           | 15,038 (14.4)        | 10,101 (67.2)                   |
| Renal diseases                              | 8,590 (8.2)          | 5,814 (67.7)                    |
| Dementia                                    | 4,429 (4.2)          | 2,926 (66.1)                    |
| Stroke                                      | 6,848 (6.6)          | 4,516 (65.9)                    |
| Rheumatic disease                           | 1,800 (1.7)          | 1,117 (62.1)                    |
| Morbid obesity (BMI ≥40 kg/m <sup>2</sup> ) | 1,962 (1.9)          | 1,197 (61.0)                    |
| Visits as outpatient in the previous year   |                      |                                 |
| 0–3                                         | 36,670 (35.1)        | 16,928 (46.2)                   |
| 4–7                                         | 31,403 (30.1)        | 19,415 (61.8)                   |
| >7                                          | 36,354 (34.8)        | 24,852 (68.4)                   |
| Seasonal influenza vaccine                  |                      |                                 |
| 2009/10                                     | 64,245 (61.5)        | 55,700 (86.7)                   |
| 2008/09                                     | 62,385 (59.7)        | 53,604 (85.9)                   |
| 2007/08                                     | 58,607 (56.1)        | 50,332 (85.9)                   |
| Vaccinated in all three previous seasons    | 49,247 (47.2)        | 44,699 (90.8)                   |
| Place of residence                          |                      |                                 |
| Rural area                                  | 50,341 (48.2)        | 30,010 (59.6)                   |
| Urban area                                  | 54,086 (51.8)        | 31,185 (57.7)                   |
| Immigrant                                   | 1,699 (1.6)          | 542 (31.9)                      |
| High level of dependence                    | 858 (0.8)            | 621 (72.4)                      |
| Hospitalisation in the previous year        | 12,191 (11.7)        | 7,772 (63.8)                    |

BMI: Body mass index.

with more than 10,000 inhabitants was considered urban and any other was defined as rural. The major chronic conditions were defined according to the International Classification of Primary Care, version 2 [11], and included: heart disease (K71, K74-77, K81-K84, K99), lung disease (R79, R95, R96, R99), renal disease (U99), cancer (A79, B72-B74, D74-D78, F74, H75, K72, L71, N74, N76, R84, R85, S77, S79, T71, T73, U75-U77, U79, W72-W73, X75-X77, X81, Y77-Y79), diabetes (T89, T90), liver cirrhosis (D97), dementia (P70), stroke (K90, K91), immunodeficiency or transplants (B78, B79, B90, D28, K28, U28), rheumatic disease (L88) and morbid obesity (body mass index of 40 kg/m<sup>2</sup> or greater).

From the vaccination register we obtained information on influenza vaccination in the 2010/11 season, as well as influenza vaccination in the three previous seasons. Individuals with no information on vaccination status were considered unvaccinated.

The Navarre Ethical Committee for Medical Research approved the study protocol.

## Analysis

This study was conducted in Navarre after the 2010/11 influenza vaccination campaign was concluded. The distribution of the baseline covariates in the population

was evaluated. Age was categorised in 5-year groups, and number of outpatient visits in the previous year was categorised in tertiles.

Influenza vaccine coverage in the 2010/11 season was quantified as the percentage of people vaccinated in each population group. This data was compared with coverage in the previous seasons which was calculated the same way as for 2010/11. Possible determinants of influenza vaccine coverage in the 2010/11 season were investigated using univariate and multivariate logistic regression models. The analyses were conducted using SPSS 18.

## Results

### Characteristics of the population

A total of 104,427 non-institutionalised individuals aged 65 or older were included in the analysis. They represented 94.4% of the population in this age group in the region. The 5.6% remaining were those who were institutionalised or people without coverage by the public healthcare service of Navarre. Some 32,536 (31%) were aged 80 or older, 58,715 (56%) were women, and 59,378 (57%) presented at least one major chronic condition, most frequently, heart disease (21,333, 20%)

**TABLE 2**

Determinants of 2010/11 seasonal influenza vaccine coverage, Navarre, Spain (n=104,427)

| Factor                                    | Crude odds ratios<br>(95% confidence interval) | Adjusted odds ratios<br>(95% confidence interval) <sup>a</sup> | P      |
|-------------------------------------------|------------------------------------------------|----------------------------------------------------------------|--------|
| Female vs. male                           | 0.94 (0.91–0.96)                               | 0.91 (0.88–0.93)                                               | <0.001 |
| Age group (in years)                      |                                                |                                                                |        |
| 65–69                                     | Reference                                      | Reference                                                      |        |
| 70–74                                     | 1.62 (1.57–1.68)                               | 1.56 (1.50–1.62)                                               | <0.001 |
| 75–79                                     | 2.10 (2.03–2.18)                               | 1.91 (1.84–1.98)                                               | <0.001 |
| 80–84                                     | 2.44 (2.35–2.54)                               | 2.18 (2.09–2.27)                                               | <0.001 |
| 85–89                                     | 2.42 (2.31–2.53)                               | 2.17 (2.07–2.28)                                               | <0.001 |
| 90–94                                     | 2.17 (2.02–2.33)                               | 2.03 (1.89–2.19)                                               | <0.001 |
| 95–99                                     | 1.48 (1.31–1.68)                               | 1.50 (1.32–1.70)                                               | <0.001 |
| ≥100                                      | 0.54 (0.40–0.73)                               | 0.66 (0.48–0.90)                                               | 0.008  |
| Major chronic conditions                  |                                                |                                                                |        |
| None                                      | Reference                                      | Reference                                                      |        |
| 1                                         | 1.65 (1.61–1.70)                               | 1.41 (1.36–1.45)                                               | <0.001 |
| >1                                        | 2.02 (1.96–2.09)                               | 1.50 (1.45–1.55)                                               | <0.001 |
| Visits as outpatient in the previous year |                                                |                                                                |        |
| 0–3                                       | Reference                                      | Reference                                                      |        |
| 4–7                                       | 1.89 (1.83–1.95)                               | 1.79 (1.74–1.85)                                               | <0.001 |
| >7                                        | 2.52 (2.45–2.60)                               | 2.19 (2.12–2.27)                                               | <0.001 |
| Immigrant vs. Spanish citizen             | 0.33 (0.29–0.36)                               | 0.40 (0.36–0.45)                                               | <0.001 |
| Residence in urban area vs. rural area    | 0.92 (0.90–0.95)                               | 1.00 (0.98–1.03)                                               | 0.836  |
| High level of dependence                  | 1.86 (1.60–2.16)                               | 1.27 (1.09–1.49)                                               | 0.003  |
| Hospitalisation in the previous year      | 1.28 (1.23–1.33)                               | 0.89 (0.85–0.93)                                               | <0.001 |

<sup>a</sup> Logistic regression model including all the variables listed in the table.

or diabetes (20,827, 20%), and 12,191 (12%) had been hospitalised in the previous year (Table 1).

### Influenza vaccine coverage in the 2010/11 season

Overall influenza vaccine coverage reached 58.6% of the study population. The coverage was slightly higher in men (59.5%) and differed by age group, with the highest vaccine coverage observed for the 85 to 89 year age group (67.1%) and the lowest for subjects older than 99 years (31.3%) or aged 65 to 69 years (45.8%).

Subjects with major chronic conditions were more likely to be vaccinated, and an upward trend was seen with increasing number of diseases. People with renal (67.7%), pulmonary (67.2%) and heart diseases (66.8%) had the highest vaccination rates.

The proportion of vaccinated people increased with the number of visits as outpatient in the previous year,

from 46.2% in subjects with zero to three visits to 68.4% in those with more than seven visits.

The highest influenza vaccine coverage was observed in subjects who had been vaccinated in all three previous seasons (90.8%). Vaccination coverage was also high in subjects who had been vaccinated against influenza in the 2009/10 season (86.7%).

Similar coverage was observed among persons with urban or rural residence. Immigrants had the lowest vaccination rates (31.9%) (Table 1).

### Determinants of seasonal influenza vaccine coverage

Multivariate analyses showed that having at least one major chronic condition, more than three visits as an outpatient in the previous year, and high level of dependence were associated with greater vaccination uptake. Age was significantly associated with vaccine uptake, especially in the age group 85 to 89 years (odds ratio (OR): 2.18, 95% confidence interval (CI): 2.09–2.27) and 80 to 84 years (OR: 2.17, 95% CI: 2.07–2.28) as compared with those aged 65 to 69. On the other hand, being female, being older than 99 years of age, being an immigrant or having been hospitalised in the previous year were associated with a lower seasonal vaccination uptake. Residence in an urban area was not significantly associated with differences in seasonal influenza vaccine coverage (Table 2).

When each type of major chronic condition was considered separately after adjusting for all other covariates, vaccination rates were found to be higher among people with pulmonary disease (OR: 1.25, 95% CI: 1.20–1.30), diabetes and heart disease (OR: 1.18, 95% CI: 1.14–1.22 for both diseases). Non-haematological cancer and renal disease were also associated with significantly higher influenza vaccine coverage. The other chronic conditions evaluated were not associated with vaccination uptake (Figure).

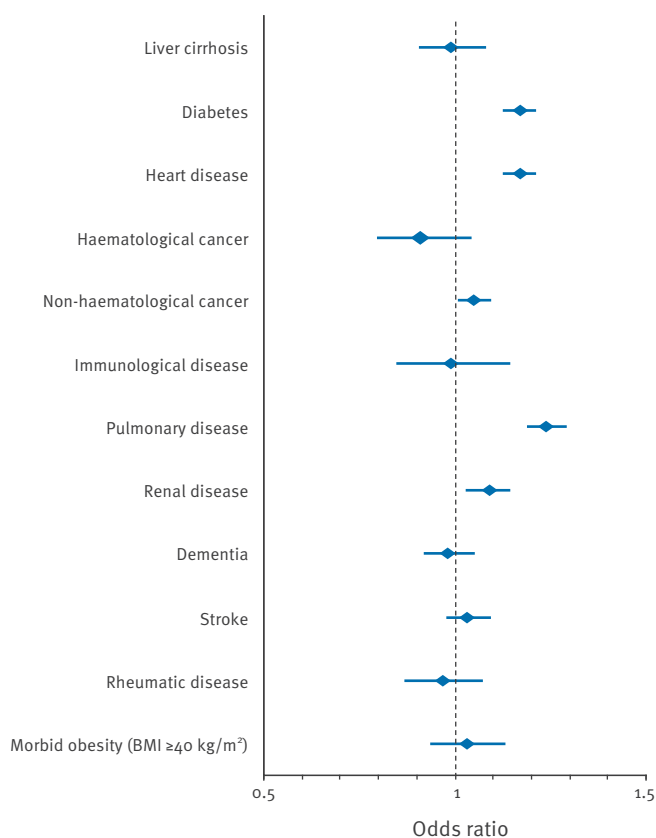
When influenza vaccination in the previous season was introduced in the adjusted model, it was found to be a strong predictor of vaccination in the current season (OR: 37.0, 95% CI: 35.7–38.4). Having been vaccinated in all three previous seasons improved the predictive value (OR: 55.8, 95% CI: 53.5–58.2) (Table 3).

### Time trends in vaccine coverage

The vaccine register made it possible to obtain estimates of influenza vaccination coverage in seniors in the most recent seasons using comparable criteria. In 2006 influenza vaccine coverage in non-institutionalised persons aged 65 or over was 59.9%, rising to 61.3% in 2007 and peaking at 62.7% in the 2008/09 and 2009/10 seasons. The coverage achieved in the 2010 campaign (58.6%) represents a decline with respect to coverage in the previous campaign ( $p < 0.001$ ) and breaks the previous upward trend.

### FIGURE

Major chronic conditions as determinants of 2010/11 seasonal influenza vaccine coverage, Navarre, Spain (n=104,427)



BMI: Body Mass Index.

Odds ratios obtained from a logistic regression analysis adjusted for sex, age, outpatient visits in the previous 12 months, immigrant status, urban/rural residence, level of dependence and hospitalisation in the previous 12 months.

## Discussion

Our results show the utility of the vaccination register in monitoring the coverage of influenza vaccination in seniors in Navarre and in identifying factors that affect this coverage.

Vaccination registries have been shown to be useful in clinical assessment and in estimating coverage [12]. In Navarre, the vaccine register is used primarily so that physicians and nurses can consult the vaccine status of their patients at any time and to programme the dates to administer the doses of the vaccine schedule. This register allows more rigorous research, because it contains individual-level information that can be used to conduct population-based studies to measure the impact of vaccination programmes, to evaluate vaccine effectiveness, and to monitor vaccine safety [13-21].

Although the completeness and accuracy of the vaccine register have not been evaluated in Navarre, there are multiple data that support it. The number of doses registered is very close to the number of doses distributed from the regional vaccination programme, and the small differences can be explained on the basis of stock, expired doses, cold chain failure or other incidents. No discrepancies have been detected in healthcare or public health practice between the vaccination data in the register and the information in patients' vaccination records. The person who administers the vaccine documents it at the same time. Furthermore, one of the indicators used in quality assurance of primary care in Navarre is the vaccination coverage in people for whom the vaccine was indicated, which serves as an incentive for physicians to record all doses administered.

Vaccination registries make it possible to evaluate coverage continually in the whole population in a way that is comparable over time. Vaccination coverage has also been studied through surveys in population samples [22-24]. Although the coverage of influenza

vaccination in our study (58.6%) is within the range of what other authors have reported [22-24], it is far from the programme objective and leaves considerable margin for improvement [8]. Vaccination coverage in Navarre had increased in recent years through efforts to improve information and vaccine uptake. However, coverage fell appreciably after the influenza A(H1N1) pdm09 pandemic in 2009. Women had lower vaccination coverage than men, and people with chronic conditions were more likely to be immunised, in particular those with pulmonary disease, diabetes or heart disease. All these results are consistent with what has been described in the literature [22,25]. However, coverage in persons with major chronic conditions could still be improved. Hospitalisation in the previous year was associated with a lower probability of vaccination, which suggests that in these patients' primary care, measures like vaccinations may be forgotten, despite the fact that their potential benefit in these persons may be even greater.

Influenza vaccination in previous seasons was a strong predictor of vaccination in the current season, which shows that efforts to improve vaccine uptake may be rewarded by increased commitment to the programme in successive seasons. It is likely that people's objections to and reservations about the vaccine are largely overcome after being vaccinated for the first time.

Although influenza vaccination is considered an effective measure against influenza, the decision whether or not to accept the vaccine is influenced by many factors. Low immunisation coverage is usually attributed to a combination of patient characteristics, beliefs and attitudes about vaccines, and barriers to access [22]. In this study we only evaluated factors depending on the subject, even though some healthcare factors may also influence the vaccination coverage achieved. Some authors have pointed out that the single most important factor is the recommendation of a healthcare

**TABLE 3**

Previous seasonal influenza vaccinations as determinants of 2010/11 seasonal influenza vaccine uptake, Navarre, Spain (n=104,427)

| Vaccination status                                          | Crude odds ratios<br>(95% confidence interval) | Adjusted odds ratios (95%<br>confidence interval) <sup>a</sup> | p      |
|-------------------------------------------------------------|------------------------------------------------|----------------------------------------------------------------|--------|
| Analysis 1                                                  |                                                |                                                                |        |
| Not vaccinated in 2009/10 season                            | Reference                                      | Reference                                                      | -      |
| Vaccinated in 2009/10 season                                | 41.2 (39.7–42.7)                               | 37.0 (35.7–38.4)                                               | <0.001 |
| Analysis 2                                                  |                                                |                                                                |        |
| Not vaccinated in 2009/10 season                            | Reference                                      | Reference                                                      | -      |
| Vaccinated in 2009/10 but not in all three previous seasons | 17.4 (16.6–18.2)                               | 16.2 (15.5–17.0)                                               | <0.001 |
| Vaccinated in 2009/10 and in all three previous seasons     | 62.0 (59.5–64.7)                               | 55.8 (53.5–58.2)                                               | <0.001 |

<sup>a</sup> Logistic regression model adjusted for sex, age, major chronic conditions, outpatient visits in the previous 12 months, immigrant status, urban/rural residence, level of dependence and hospitalisation in the previous 12 months.

professional [24]. When vaccination in elderly people has been explored, perceptions of enjoying good health and the feeling of not being susceptible to influenza were the reasons most frequently mentioned for non-compliance. It was also associated with the opinion that the complications of influenza were not dangerous [25].

Our results demonstrate the need to improve influenza vaccination coverage in Navarre. Activities should be directed to increasing awareness of those who belong to high-risk groups, encouraging healthcare workers to proactively propose influenza vaccination, promoting the use of patient reminders, and developing effective communication and education campaigns [6,26].

## Conclusion

The Navarre vaccine register has been shown to be a useful tool in determining vaccine coverage in the population, its evolution over time, and the influence of different factors. This information has made it possible to detect possible ways to improve coverage and may aid the design of more efficient measures to achieve this objective.

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# Ten years polio-free: anniversary in the World Health Organization European Region

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In 2002, the World Health Organization (WHO) European Region was declared polio-free [1]. This week, 21-27 April 2012, the seventh European Immunization Week highlights the ten-year anniversary of the polio-free status [2]. In spite of a large outbreak of imported wild poliovirus in Tajikistan in 2010, the Region has retained its polio-free status, as confirmed by the European Regional Certification Commission for Poliomyelitis Eradication in August 2011 [3].

It was on 23 April 2010 that the WHO announced the confirmation of wild poliovirus serotype 1 (WPV1) in seven samples obtained from children with acute flaccid paralysis (AFP) in Tajikistan. Genetic sequencing determined that the poliovirus was most closely related to virus from Uttar Pradesh, India. In total 136 (80%) of the AFP cases were in children aged under five years (age range 0-17 years). Cases were mainly reported from districts bordering Afghanistan and Uzbekistan [4].

While remaining polio-free is an achievement to celebrate and a good example of how immunisation can control the spread of disease, the 2010 outbreak was a poignant reminder of the need to stay vigilant. Due to ongoing threats in countries bordering or nearby the European region such as China and Pakistan, polio continues to be a threat [5].

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