

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

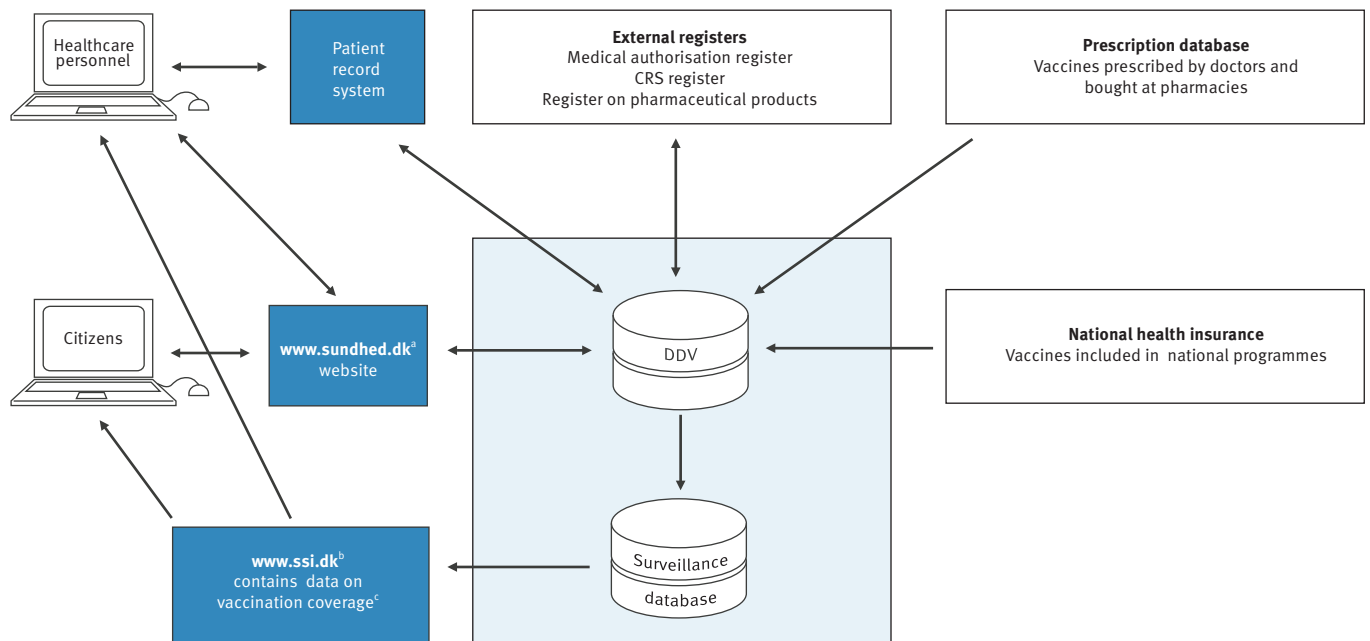
Differences between the childhood vaccination database and the Danish vaccination register

	The childhood vaccination database (CVD) ^a	The Danish vaccination register (DDV) ^b
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"> • Date of vaccination • Type of vaccine • Personal identifier of vaccinee • Name of vaccinator • Organisation of vaccinator 	<ul style="list-style-type: none"> • Date of vaccination • Type of vaccine • Personal identifier of vaccinee • Personal identifier of vaccinator • Product name • ATC code • Dosage • Batch number • Organisation of vaccinator
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.

^a In existence since 2000.

^b Will be implemented in 2012-14.

FIGURE 1**Architecture of the Danish vaccination register**

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

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

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

^c 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, 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

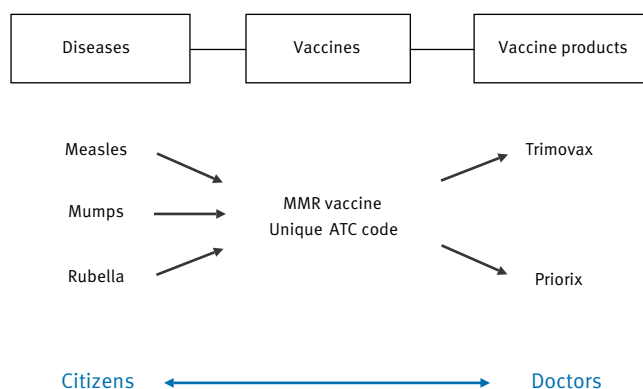
In the DDV, healthcare personnel can register both newly administered vaccinations, and vaccinations administered previously by another doctor in Denmark or in another country. Medical doctors can delegate their rights to register vaccinations to their assistants.

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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