

Immunisation registers – important for vaccinated individuals, vaccinators and public health

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Vaccines save lives, protect against disability and improve health. Diseases such as smallpox, tuberculosis, poliomyelitis, diphtheria, tetanus, pertussis, invasive diseases related to *Haemophilus influenzae* type b and *Neisseria meningitidis* group C infection, that only half a century ago were all communicable disease threats to Europeans, are now rare entities or, as in the case of smallpox, eradicated [1]. Consequently, some of them are almost forgotten by the younger general public. However, despite the availability of safe and effective vaccines against measles and rubella and the considerable decline in the number of cases in the last decades, Europe is still struggling to eliminate them. In 2011 alone, over 30,000 cases of measles and more than 3,000 cases of rubella were reported in the European Union (EU) [2]. To help improve coverage with recommended vaccines in the childhood and other age or risk group-specific immunisation programmes and assess their impact, immunisation registers have been or are being developed in a number of countries. In a special issue of *Eurosurveillance*, published in two parts in this and the following week, country-specific experiences with established immunisation registers are shared in a series of articles [3-11].

During the upcoming European Immunization Week, the measles and rubella elimination 2015 goal for Europe will be advocated by EU Member States, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) through activities such as (i) communication packages [12], (ii) a video produced in collaboration between the ECDC and the European news channel Euronews that presents the severe complications that can occur following measles infections and (iii) a number of national conferences. While this creates awareness, it is also essential to continue the development of technical support to the immunisation programmes. One example of such technical development are immunisation registers, providing a repository of information for vaccinated individuals and vaccine providers. In addition, public health will benefit from this tool when assessing impact of vaccination programmes as recently

highlighted during the large immunisation campaigns following the 2009 pandemic. A need for accurate and rapid information on vaccine coverage by target group was identified and individual-level data were requested by stakeholders assessing pandemic vaccine safety and effectiveness.

Most established immunisation registers are able to at least (i) collect data on vaccines provided, (ii) generate reminders and recall vaccination notices for each client, (iii) provide official vaccination forms upon request for the individual, and (iv) allow vaccination coverage assessments. They are therefore also referred to as Immunisation Information Systems (IISs). Such systems are confidential, population-based and computerised systems that collect vaccination data about residents within a geographic area or with a healthcare provider. IISs are among the most important tools to strengthen and improve the performance of immunisation programmes by consolidating vaccination records of all immunisation clients from multiple vaccination providers. Access to complete records of all previous vaccinations makes it easier for the healthcare provider to ensure that individuals receive recommended vaccines. Systems can also be used to increase and sustain high vaccination coverage through identification of pockets of unvaccinated individuals or groups and serve as a basis for tailored vaccination campaigns.

Population-based electronic IISs are preferably created at birth if possible through linkage with electronic birth records. IISs can then be linked to health-outcome databases with clinical information and data on medical care provided by general practitioners or hospitals. Upon linkage of different data sources, anonymised data can be made available through newly-developed software that even permits sharing of data across national borders [13]. Linkage of such different data sources can establish brand-specific vaccine safety and effectiveness but also allow studies of programmatic issues such as optimising immunisation schedules.

The eight pandemic vaccines available in the EU for protection against the 2009 pandemic (Cantgrip, Celltura, Celvapan, Fluval P, Focetria, Pandemrix, Panenza, PanvaxH1N1) were closely followed and initial safety reports were provided regularly on the centrally authorised vaccines by the European Medicines Agency [14]. In August 2010, a safety signal was reported from Finland and Sweden and an association between the use of one of the adjuvanted vaccines Pandemrix and an increase in rates of narcolepsy was later confirmed in these two countries [15-18]. For the investigations of this safety signal, individual exposure data on who was vaccinated, with which vaccine (including batch number) and when the vaccination occurred were needed. In Sweden, investigations were facilitated by immunisation registers with information on vaccine exposure available for parts of the country (covering a population of more than 5 million persons). In Finland, data were available locally with each vaccinator, but had to be compiled at the national level in order to acquire an overview.

A key factor in the development of IISs is to ensure the integrity of the individual and collected information on health and access and use of data varies between countries. Many EU Member States have found difficulties in establishing electronic IISs due to strict data protection laws. However, regional or national IISs do exist in the EU and are compliant with national data protection laws in Denmark, Estonia, Finland, France, Iceland, Ireland, Italy, Norway, Scotland, the Netherlands, Portugal, Romania, Spain and Sweden. The European Commission now proposes a comprehensive reform of the data protection rules due to the fact that rapid technological and business developments have brought new challenges for the protection of personal data [19]. New technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities. A reform of the EU's 1995 data protection rules has been viewed needed, not only because the scale of data collection and sharing has increased dramatically, but also because the 27 EU Member States have implemented the 1995 rules differently, resulting in divergences in enforcement. Through this new proposal, there is hope that a single law will reduce the current fragmentation. It is currently unknown whether and how this single law will facilitate establishing ISSs in EU countries with strict data protection laws. It should be emphasised here that it is important to maintain public trust in such systems and to strike a balance between keeping a level of data protection high, while at the same time delivering the protection and promotion of health that the public rightly expects [20,21].

The Council of the EU have during the last three years adopted a Council recommendation on seasonal influenza vaccination (2009) and a Council conclusions on childhood immunisations: successes and challenges of European childhood immunisation and the way forward

(2011) [22,23]. Both documents highlight the importance of and encourage Member States to gather specific and comparable data at national level regarding the uptake rates of vaccines.

Following the general success of immunisation programmes during the last two centuries eliminating or significantly reducing a number of communicable diseases, new efforts have resulted in a number of novel vaccines for diseases against which immunisation was not available before, new combination vaccines (e.g. hexavalent vaccines for vaccination of infants during the first year of life) to reduce the number of injections and visits to vaccination clinics or new formulations of vaccines earlier available (e.g. intranasal influenza vaccine). Examples of vaccines made available on the EU market during the last decade are presented in the table.

TABLE

Newly-authorised vaccines in the European Union through the central procedure or through mutual recognition, aimed for the paediatric immunisation programmes, 2000–2011

Newly-authorised vaccine	Year of authorisation	Name of product
Combination vaccine against diphtheria, tetanus, pertussis, poliomyelitis, Hib, hepatitis B	2000	Infanrix hexa
Combination vaccine against diphtheria, tetanus, pertussis, poliomyelitis, Hib, hepatitis B	2000	Hexavac ^a
Vaccine against invasive infections caused by <i>Neisseria meningitidis</i> group C	2001	NeisVac-C
Combination vaccine against measles, mumps, rubella and varicella	2007	Priorix-Tetra
Vaccine against rotavirus-induced gastroenteritis	2006	Rotarix
	2006	RotaTeq
Vaccine against human papillomavirus-induced cervical cancer	2006	Cervarix
	2006	Gardasil
Vaccine against invasive infections caused by <i>Streptococcus pneumoniae</i>	2001	Prevenar 7
	2009	Synflorix
	2011	Prevenar 13
Vaccine against invasive infections caused by <i>Neisseria meningitidis</i> group A, C, W-135, Y	2010	Menveo
Intranasal trivalent influenza vaccine	2011	Fluenz

Hib: *Haemophilus influenzae* type b.

^a Suspended since 2005 as a precautionary measure due to concerns about the long-term protection against hepatitis B.

As of today, vaccines against 16 infectious diseases are available but no EU Member State has implemented all available paediatric vaccines in their recommended programmes. Changes in immunisation programmes need to be performed carefully and as much as possible rely on evidence-based decisions obtained through monitoring the impact of the implemented programmes. The use of linked ISSs to outcome databases to assess first safety and then effectiveness is the best tool in the initiation phase of a new vaccine but also in assessing long term performance.

A European Conference on Immunisation Information Systems was held in Stockholm in 2010 with support from the European Commission [24]. Conference conclusions included (i) a recommendation to develop a long term EU plan to support Member States to implement immunisation and information systems able to communicate across the EU and (ii) a request to vaccine industry to implement a standardised system for bar coding vaccines to facilitate recording of each vaccination encounter.

ECDC supports these recommendations and would like to add that setting a goal to include over 75% of all European children and if possible also other age groups in national immunisation information systems by 2020 would be valuable for monitoring of future EU vaccination programmes.

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