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## **EDITORIALS**

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**Immunisation registers – important for vaccinated individuals, vaccinators and public health** 2

by K Johansen, PL Lopalco, J Giesecke

## **PERSPECTIVES**

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**Measuring childhood vaccine coverage in England: the role of Child Health Information Systems** 5

by G Amirthalingam, J White, M Ramsay

**The Norwegian immunisation register – SYSVAK** 11

by L Trogstad, G Ung, M Hagerup-Jenssen, I Cappelen, IL Haugen, B Feiring

**Computerised vaccination register for the Murcia region, Spain, 1991 to 2011** 18

by PJ Bernal-González, JA Navarro-Alonso, JJ Pérez-Martín

**Australian immunisation registers: established foundations and opportunities for improvement** 24

by LK Chin, NW Crawford, G Rowles, JP Buttery

# 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 <sup>a</sup>
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.

<sup>a</sup> 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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# Measuring childhood vaccine coverage in England: the role of Child Health Information Systems

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Child Health Information Systems (CHISs) are computerised clinical record systems which support a range of health promotion and prevention activities for children, including immunisation and screening. There are a number of different providers of CHISs in England. These systems are managed by child health departments in each local area and not all are interoperable. The establishment of systems which record and maintain accurate information on the entire population is critical to assess vaccination coverage at both national and local levels. These systems should have the flexibility to adapt to a continuously evolving immunisation programme, a mechanism to rapidly feedback to local public health teams for outbreak prevention and control, and the ability to mount a timely response to vaccine safety scares. The ability to schedule (call and recall) immunisation appointments has contributed to improvements in vaccination coverage both in England and elsewhere. While this has been achieved in England through multiple CHISs the development of a single national register would reduce the complexities of maintaining accurate and complete immunisation records for the entire population.

## Introduction

The ability to reliably measure vaccine coverage plays an essential role in evaluating the success of a vaccination programme, identifying susceptible populations for further interventions and informing future vaccine policy decisions. This is dependent on having an accurate estimate for the eligible population (denominator) and a robust method of ascertaining the number of those eligible individuals who have received a particular vaccine dose (numerator).

Data on vaccines administered in England are currently recorded on two computerised systems – general practitioner (GP) registers and population-based child health information systems (CHISs). Similar systems operate across the United Kingdom (UK) (in Scotland, Wales and Northern Ireland) which enables the production of UK-wide estimates of vaccine coverage. In England, while CHISs are generally used to estimate

vaccine coverage for the routine childhood immunisation programme, GP registers are often used to evaluate selective vaccination programmes for adults (e.g. seasonal influenza and pneumococcal polysaccharide vaccines). This paper will specifically focus on how data held on CHISs are used in England to assess the routine childhood immunisation programme in a timely and accurate manner.

The publication of the National Health Service (NHS) Health and Social Care Bill in 2011 marks a radical change to the organisational structure of the NHS in England [1]. The abolition of Primary Care Trusts (PCTs), currently responsible for maintaining CHISs, and changes to the responsibilities for the procurement of health services for local populations based on an assessment of their health needs are likely to have significant implications for the delivery and evaluation of national public health programmes including childhood immunisations. We also consider the challenges of collecting population-based vaccine coverage data through current systems in England, and of maintaining accurate collections in the newly structured NHS.

This paper focuses on how data held on CHISs have been used in England since the late 1980s to assess vaccine coverage in the routine childhood immunisation programme in a timely and accurate manner, and considers the challenges of maintaining accurate collections in light of the planned reorganisation of the English National Health Service. It also highlights the lessons learnt from an English perspective which will be of relevance to those European countries planning to implement population-based immunisation registers.

## Child Health Information Systems (CHISs)

CHISs are computerised clinical record systems which support a range of health promotion and prevention activities for children including screening and immunisation. There are a number of different providers of CHISs in England. These systems are managed by child health departments in each local area, previously in each district health authority and since the NHS



reorganisation of April 2002, in Primary Care Trusts (PCTs).

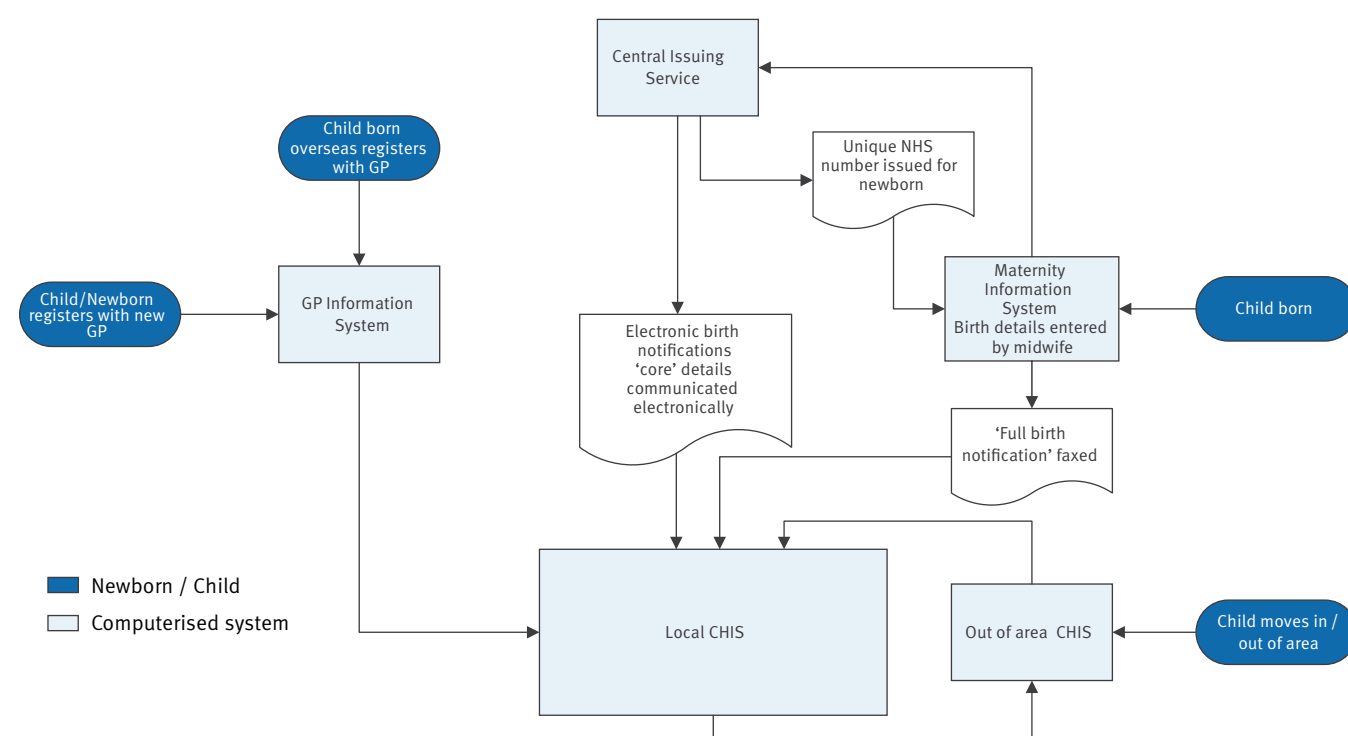
They hold data on all children in the responsible population for that PCT. The PCT responsible population is defined as all children registered with a GP whose practice forms part of the PCT, regardless of where the child is resident, plus any children not registered with a GP who are resident within the PCT's statutory geographical boundary. Note that children resident within the PCT geographical area, but registered with a GP belonging to another PCT, are the responsibility of that other PCT. Thus CHISs can provide a complete and accurate denominator for estimating vaccine coverage. Children are entered onto the local CHIS at birth or when they move into the local area. Much of the data required to start the child health record is already collected as part of the mother's maternal record stored in the local maternity information system. All new births are registered electronically by the attending midwife using the Central Issuing Service (CIS). This 'birth notification' automatically generates a unique NHS number within a few hours of delivery. An electronic copy of the birth notification containing core demographic information on the newborn and mother as well as GP registration details are sent from the CIS to the relevant Child Health department for entry onto the local CHIS. In addition, a paper record of the complete birth notification is faxed by the midwife to the local CHIS (Figure 1).

Records are transferred to the relevant CHIS for children moving into the area from other parts of the UK. When a child moves, he/she will register with a local GP who will request that all the child's health records (including their immunisation history) are transferred. Furthermore this practice will inform the local Child Health department managing the local CHIS of the newly-registered patient. A request is made to the former Child Health department to transfer their CHIS records. This transfer of information is either electronic or paper-based depending on the inter-operability of the different systems. For those children born outside the UK, a new record is created which includes all available data on vaccines that have been administered previously. Regular updating to take account of newborns and children moving in and out of the area is therefore essential. It is the responsibility of the PCT to ensure the accuracy of the data held on their local CHIS (Figure 1).

One of the primary functions of CHISs is to manage the local immunisation programme, scheduling appointments, recording data on vaccines administered and sending out reminders for those who fail to attend. Invitations for immunisation are either sent to parents / guardians from their registered GP or directly from the local CHIS. Information held on CHISs can be extracted to provide age-specific vaccine coverage estimates at local, regional and national levels. In addition, data held on CHISs are important for

**FIGURE 1**

Data flow to child health information system, England



CHIS: child health information system; GP: general practitioner; NHS: National Health Service.

predicting and responding to community outbreaks of vaccine-preventable diseases (VPD) where local catch-up programmes can be targeted at cohorts with poor coverage.

The majority of routine childhood immunisations are delivered to pre-school children by GPs in primary care although some selective programmes e.g. neonatal hepatitis B and Bacille Calmette Guérin (BCG) vaccines may be delivered in a combination of primary and secondary care settings. The contribution of vaccines delivered in the private sector currently is negligible. Vaccines administered in any of these settings are recorded electronically in the child's GP record and on the local CHIS. In addition, a paper copy of the children's vaccination record is held by the parent in the personal child health record (PCHR). Frequent exchange of information between CHISs, primary care and other providers is required to ensure assessment of vaccine coverage is based on accurate numerator and denominator estimates.

### Generating vaccine coverage data from CHISs: COVER Programme

Historically, long-term trends in childhood vaccine coverage in England were estimated by individual health authorities and published annually by the Department of Health (DH) [2]. Initially, the denominator was the number of live births in each district health authority, but in 1988, following the increasing use of computerised child health systems (CHISs), the denominator became all resident children in the district (Körner returns) [3]. Numerator data on the number of these eligible children receiving each of the recommended vaccines was also obtained from CHISs - providing, for the first time, a genuine measurement of total population coverage. Since 1995, annual vaccine coverage has been monitored by the Health Protection Agency (HPA) (previously Public Health Laboratory Service) on behalf of the DH.

In addition to the annual collection, a quarterly collection was developed in the late-1980s to provide more rapid feedback and enable changes in vaccine coverage to be detected quickly [4]. This data collection system, known as the COVER programme (Cover of Vaccination Evaluated Rapidly) exploited the role of district immunisation co-ordinators as contacts and used standardised programmes to extract aggregate data from CHISs [4]. For a number of years, there has been a mandatory requirement for all local areas within the NHS to provide quarterly and annual returns to the HPA [5].

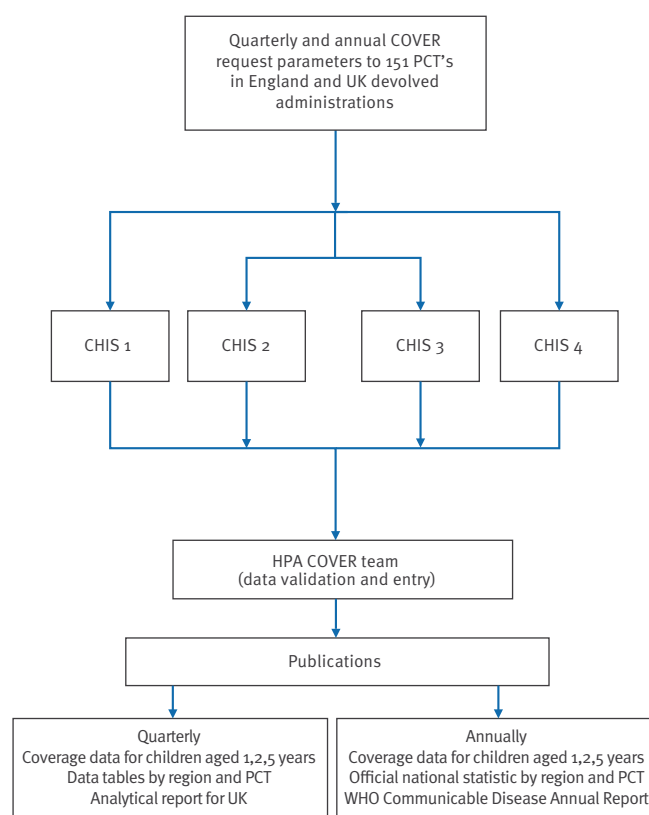
While the extraction processes may vary between the different CHISs, all system suppliers are provided with a specification detailing the 'request parameter's [6]. A quarterly request is made to each PCT Child Health department to provide computerised reports for these COVER parameters [7]. Information is requested for all children in the PCT responsible population who reach their first, second and fifth birthdays during a particular evaluation quarter. These data are aggregate

returns and will include the number of eligible children in each cohort and the numbers and proportion vaccinated for all routine vaccinations offered according to the current national immunisation schedule (Figure 2).

The UK immunisation programme is constantly evolving. The addition of new vaccines and changes to the schedule requires CHISs to have the flexibility to incorporate these changes in a timely manner. At the time of planning the introduction of a new vaccine or change to the routine immunisation schedule, the DH works with all the CHIS suppliers to ensure that the systems can schedule and record data on new vaccines / schedule changes ahead of their implementation. These are communicated to the system suppliers through Dataset Change Notices (DSCNs). This in turn allows for the timely collection of vaccine coverage data on the first and subsequent cohorts eligible for the new schedule. Coverage data on the first eligible cohort following the introduction of the seven-valent pneumococcal conjugate vaccine to the primary infant schedule in September 2006 was published in December 2007 [7,8].

**FIGURE 2**

Vaccine coverage data flows from Child Health Information Systems to the Health Protection Agency COVER programme, United Kingdom



CHIS: Child Health Information System;  
COVER: Cover of Vaccination Evaluated Rapidly;  
HPA: Health Protection Agency;  
PCT: Primary Care Trust;  
UK: United Kingdom;  
WHO: World Health Organization.

## Data quality requirements for vaccine coverage collections

The following section summarises the minimum data quality requirements for the collection of vaccine coverage data and the risks / implications if these requirements are not met.

### Accuracy and validation

To ensure accuracy, precise definitions for the denominator (eligible population) and the numerator (number of individuals in the eligible population who have received a given vaccine(s) within a given time) are required. For the routine childhood immunisation programme, these parameters are published on the HPA website prior to each quarterly collection [6]. A number of checks are made as part of the data quality assurance process for each submission. These include verifying the evaluation period and comparing the denominator from the current evaluation quarter with the previous submissions to identify discrepancies. For example, unless there have been boundary changes, the denominator figures are unlikely to have changed significantly between evaluation periods. Significant variation in coverage estimates ( $\pm 5\%$ ) from previous evaluation periods are also compared and investigated. Given that policy decisions and public health interventions at national and local level are informed by coverage data, inaccuracies in these data may result in inappropriate actions and the misuse of resources such as offering vaccines as part of a catch-up programme or a local outbreak response to individuals who are already fully protected.

Once the data has been collected, they are validated ('sense checking') prior to publication, within agreed timelines. This is essential to identify anomalies resulting from changes to the (i) national immunisation schedule (ii) Child Health Information Systems (CHISs) and (iii) vaccine preparations in use. There have sometimes been unexpected or temporary changes to vaccines offered due to vaccine shortages [9]. Awareness of these issues is imperative to understand the data and for the correct interpretation of current and future coverage estimates. In addition, variations in vaccine coverage for particular cohorts may result from national and local catch-up campaigns. This 'sense-checking' process requires historical knowledge and expertise of the UK immunisation schedule, an understanding of the complexities of CHISs and close working relationships with NHS staff providing these data.

### Completeness

In contrast to sentinel systems, assessment of childhood vaccine coverage in England is a genuine measurement of total population coverage. In order to achieve this, data from each PCT are required and should be based on every eligible child. This is important to identify pockets of susceptible individuals who would benefit from targeted interventions.

### Timeliness (collection and publication)

In England, vaccine coverage data are fed back promptly (within three months from the last evaluation quarter) to local public health teams, as provisional estimates, through the publication of UK COVER reports. These reports provide detailed commentary on the most recent coverage estimates at regional, national and UK level. Additionally, individual PCT level data for all vaccines assessed at one, two and five years of age are published on the HPA website, which allow national policy makers as well as local public health teams to consider appropriate interventions in a timely manner.

### Flexibility

It may be necessary to undertake new /modified data collections in response to unexpected events. To assess the immediate impact of the adverse publicity surrounding the measles-mumps-rubella (MMR) vaccine in the UK, the COVER programme was able to set up a sentinel reporting system for monitoring MMR coverage from an earlier age and at more frequent intervals than routine collections [10]. This has provided a more timely indication of trends in MMR coverage, complementing the routine collections to inform vaccine policy decisions e.g. national MMR catch-up programme in 2008.

## Operational issues with CHISs

### IT issues

The number of system providers for CHISs and their functionality has expanded since their national roll-out in the 1980s, necessitating replacement and / or upgrading of existing systems. Some CHISs have suffered from data quality issues as a result of these upgrades and the replacement of existing IT services [11,12]. Furthermore, the migration of data from legacy systems has made this a particular issue for older cohorts of children. In the past, the combination of different CHISs operating across London coupled with high population mobility made it difficult to maintain accurate data on each local system and has contributed to the lower coverage reported in the capital [13]. However, during the last five years, London PCTs have moved to the same system provider and have focused efforts on increasing coverage both through improving vaccine delivery and data quality [14]. While efforts have been made to ensure the exchange of information between systems is timely and complete, there is a need to ensure all current and future systems are fully interoperable.

### Denominator issues

There is historic evidence to suggest that some CHISs were poorly maintained so that children who had moved away remained on the system. These 'ghosts' inflated the denominator and therefore led to an under-estimate of vaccine coverage. A review of eight unpublished audits of data held on CHISs in 1997 suggested that COVER data underestimated true uptake by between 1% and 9% in children assessed before



their third birthdays [15]. Discrepancies increase when measuring coverage at five years given the increasing likelihood of moving PCTs with time, and fewer scheduled interventions which provide opportunities to identify children who have moved away/into the PCT. The greatest underestimates occurred in areas with lowest reported coverage and the highest population mobility.

Historically, NHS re-organisation has temporarily impacted on the quality of vaccine coverage data extracted from CHIS. For example, the last re-organisation in 2002, which coincided with a change in the definition of the denominator (from resident to responsible population), was thought to contribute to a reduction in the quality of COVER returns. This resulted in an underestimate of the denominator when compared with equivalent mid-year Office of National Statistics (ONS) population estimates [16]. The lower denominator was partly explained by delays in including unregistered children who are less likely to access primary care services and have less opportunity to be vaccinated, leading to an overestimation of true coverage. Reassuringly, however, by 2003, data quality improved as CHISs had begun to incorporate the reorganisational and population definition changes correctly [16].

## Numerator issues

As the majority of routine childhood immunisations are delivered in GP, the accuracy of numerator data held on CHISs will be largely dependent on the accuracy and timeliness of the information supplied by GPs.

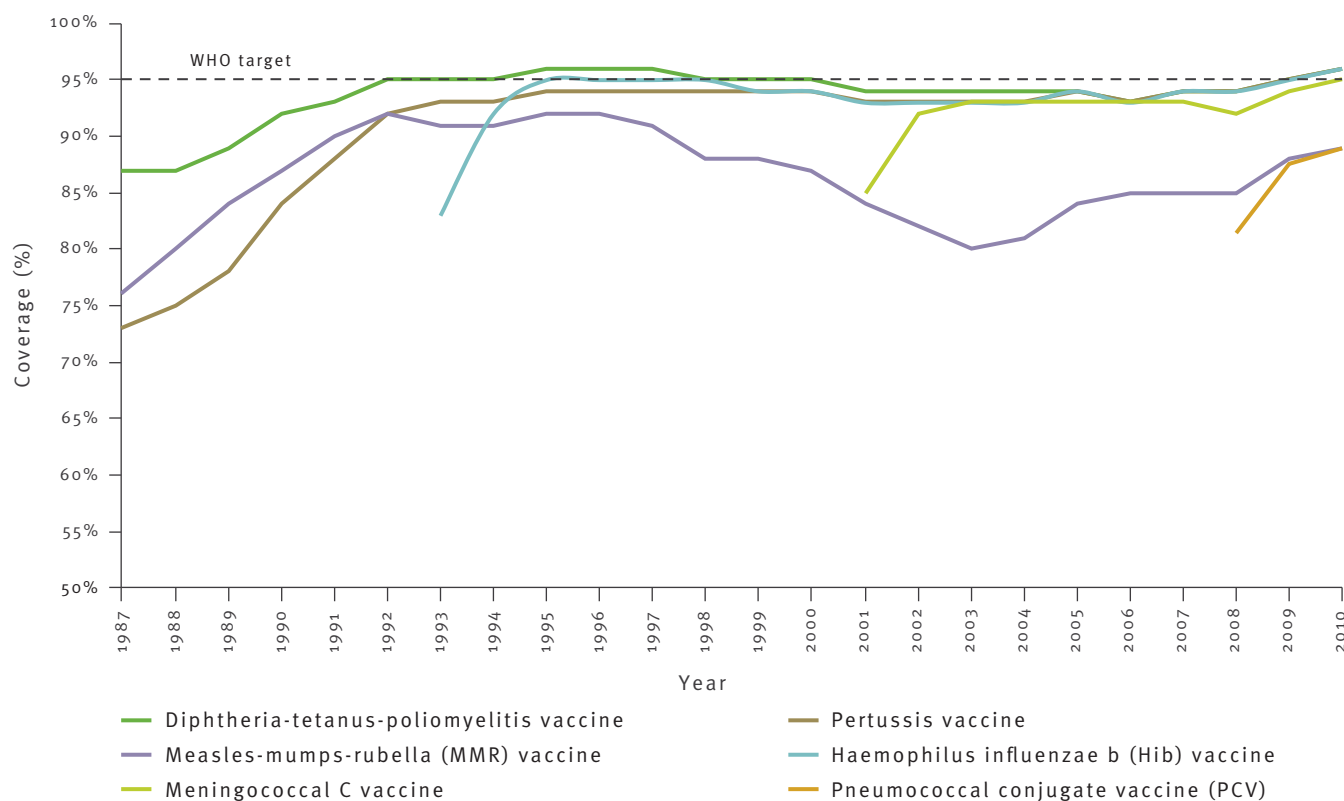
Although data held on CHISs are generally maintained until the age of 16 years, the accuracy of the numerator decreases with age given the reduced opportunities for older children and adolescents to routinely attend health services and for their records to be checked and updated. However, the introduction of the routine human papillomavirus (HPV) vaccination programme, targeting girls aged 12-13 years through a largely school-based programme, has provided a valuable opportunity to improve the accuracy of immunisation records for older children [17].

## Future considerations for monitoring vaccine coverage

The radical reorganisation of NHS structures in England with the reallocation of local public health teams from the NHS to local government will necessitate maintaining the timely transfer of public health data, including vaccine coverage, across increasingly complex organisational boundaries.

**FIGURE 3**

Annual vaccination coverage at 24 months, England, 1987–2010



WHO: World Health Organization.

MMR replaced single measles vaccine in 1988. Hib vaccine was introduced in 1992, meningococcal C vaccine in 1999 and PCV in 2006.

The abolition of PCTs and creation of Clinical Commissioning Groups (CCGs) with different geographical boundaries is likely to temporarily impact on the accuracy of denominator estimates and permanently impair the ability to compare trends in coverage data at a sub-national level. In addition, the potential increase in the number of non-NHS service providers will contribute to the challenges in maintaining accurate, up to date population based immunisation registers.

The challenge is to sustain the accurate and timely collection of vaccine coverage data to inform national policy decisions and local public health action. A programme of work led by the Department of Health, to address these issues, is currently underway with key stakeholders. This includes a proposal to agree a set of national minimum standards for CHISs that will deliver interoperable CHISs which can schedule appointments and communicate effectively with all provider systems.

### Implications for developing population-based immunisation registers in Europe

The UK has the longest running population-based child health registers in Europe that have contributed to a well organised and planned national immunisation programme. The system has survived many previous health service reorganisations in England, contributed to the achievement and maintenance of high vaccine coverage from the early 1990s and helped to minimise the impact of adverse publicity in the early 2000s (Figure 3).

Our experience has shown that there are a number of key requirements critical for success that may be relevant for European countries planning to introduce national immunisation registers. The establishment of a system which records and maintains accurate information on the entire population is critical to assess vaccination coverage at both national and local levels. These systems should have the flexibility to adapt to a continuously evolving immunisation programme, a mechanism to rapidly feedback coverage data to local public health teams for outbreak prevention and control, and the ability to mount a timely response to vaccine safety scares. The ability to schedule (call and recall) immunisation appointments has contributed to improvements in vaccination coverage both in England and elsewhere [12,18]. While this has been achieved in England through multiple CHISs which are not all interoperable, the development of a single national register would reduce the complexities of maintaining accurate and complete immunisation records for the entire population.

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# The Norwegian immunisation register – SYSVAK

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The Norwegian immunisation register, SYSVAK, is a national electronic immunisation register. It became nationwide in 1995. The major aim was to register all vaccinations in the Childhood Immunisation Programme to ensure that all children are offered adequate vaccination according to schedule in the programme, and to secure high vaccination coverage. Notification to SYSVAK is mandatory, based on personal identification numbers. This allows follow up of individual vaccination schedules and linkage of SYSVAK data to other national health registers for information on outcome diagnoses, such as the surveillance system for communicable diseases. Information from SYSVAK is used to determine vaccine coverage in a timely manner. Coverage can be broken down to regional / local levels and used for active surveillance of vaccination coverage and decisions about interventions. During the 2009 influenza A(H1N1) pdm09 pandemic, an adaptation of SYSVAK enabled daily surveillance of vaccination coverage on national and regional levels. Currently, data from SYSVAK are used, among others, in studies on adverse events related to pandemic vaccination. Future challenges include maximising usage of collected data in surveillance and research, and continued improvement of data quality. Immunisation registers are rich sources for high quality surveillance of vaccination coverage, effectiveness, vaccine failure and adverse events, and gold mines for research.

## Background

Norway has 15 national health registers, including the Norwegian immunisation register, SYSVAK. The national health registers have been established by national health authorities to safeguard nationwide commitments and are legally anchored in §8 of the Norwegian Law of Health Registers [1]. The registers are nationwide with mandatory notification requirements, and contain exposure and / or outcome data on selected health measures. All registration is based on unique personal identification numbers issued to Norwegian citizens at birth or immigration, which allow linking of different health registers at individual level. The general aim of the Norwegian national health registers is to support health surveillance, research, quality control and improvement of the health system performance.

The Norwegian immunisation register, SYSVAK, is a national electronic immunisation register. Prior to SYSVAK becoming nationwide in 1995, some counties had already recorded information in its precursor, SYSBARN. SYSBARN was established as a pilot project in 1976 in five of 19 Norwegian counties (Hordaland, Akershus, Hedmark, Oslo and Østfold) [2]. The aims and provisions of SYSVAK are anchored in regulations to the Norwegian health registers act, the SYSVAK regulations [3]. The scope of this paper is to describe the organisation and objectives of SYSVAK and briefly describe the Norwegian immunisation programmes. Data collection, data security measures and confidentiality issues are described, as are routines for access to SYSVAK data for surveillance or research purposes. The use of SYSVAK data for estimating vaccine coverage, surveillance and research are briefly exemplified and future challenges outlined.

## Organisation of SYSVAK

SYSVAK is run and administered by the Department of Vaccines at the Norwegian Institute of Public Health (NIPH) in Oslo. The Department of information technology (IT) and e-medicine is responsible for maintenance and technical adaptations in the register. Healthcare providers in the local municipalities are responsible for administrating the vaccines and for notifying the vaccination to SYSVAK.

## SYSVAK objectives

The original aim of SYSVAK was to register all vaccinations in the Childhood Immunisation Programme for the following purposes:

- to maintain an overview of the individual vaccination status of all vaccinees, ensuring that all children are offered adequate vaccination according to the schedule in the Childhood Immunisation Programme and to ensure a high vaccination coverage;
- to monitor vaccination coverage for vaccine preventable diseases in the Norwegian population at national, county and municipality levels; and to form a reliable basis for research into the effectiveness and safety of the vaccines in the programme.

Since 2009, SYSVAK has expanded and currently the register includes besides information on all vaccinations in the Childhood Immunisation Programme, all

human papillomavirus (HPV) vaccinations (including vaccinations given outside the Childhood Immunisation Programme to older girls, boys and adults), and vaccination against all other vaccine preventable diseases (influenza A(H1N1)pdm09, seasonal influenza, travel vaccines, etc.). Health professionals are obliged to notify all vaccinations in children and adults to SYSVAK. However, a set of different rules applies regarding the need for consent from the vaccinee or their parent / guardian (Table).

## The Norwegian Childhood Immunisation Programme

The Childhood Immunisation Programme is organised within the public health service. The programme is set at national level and applies to the whole country. The local municipality health services are responsible for delivering the vaccines included in the immunisation programme. The immunisations are provided by public health nurses. General practitioners (GPs) usually play no role in delivering vaccines within the Childhood Immunisation Programme. Infants and toddlers are vaccinated at public health clinics, while school children are vaccinated within the local school health services. Practically all infants and pre-school children in Norway are followed up at the public health clinic, and the majority of Norwegian children are enrolled in public schools, with only 1.7% attending private schools [4].

Public health clinics and school health services are statutory services that provide health promotion and prevention services for pregnant women, parents, children from birth and adolescents up to 20 years of age. Nurses, doctors and midwives are usually the core staff at a health clinic. The service is a comprehensive offering that includes health checks, vaccinations, health education and counselling free of charge. Given the preventive nature of the service, children with acute or chronic medical conditions are referred to their GP for treatment and follow-up. Special at-risk children, for instance preterm newborns, children of hepatitis B surface antigen (HBsAg)-seropositive (infectious) mothers or those with complicated medical conditions, may receive their first vaccines in the hospital. However,

after that, most vaccinations in these children take place at the public health clinic.

All vaccinations within the Childhood Immunisation Programme are free of charge. The uptake of the vaccines in the Childhood Immunisation Programme is monitored by NIPH through the Norwegian immunisation register, and is generally high, between 92-95% [5]. All vaccinations are offered on a voluntary basis. The vaccines for the programme are distributed free of charge from NIPH to the local vaccine providers, independent of notification to SYSVAK.

## The influenza immunisation programme

In Norway, influenza vaccine is recommended to defined risk groups including elderly aged 65 years or older, through the influenza immunisation programme. The influenza vaccine, as well as other recommended vaccines, is provided both by GPs and through public and private health services [6]. Some vaccinations are also provided by hospitals. Influenza vaccines are not publicly reimbursed.

## Data collection

In general, notifications of vaccinations within the Childhood Immunisation Programme are electronically transferred from the patient record systems to SYSVAK. The vaccinations are entered only once in the electronic patient records (EPR) system, and transferred automatically to SYSVAK. The files are transferred in a standardised xml-format and the integration module with the EPR systems makes data entry fast and easy for the users.

SYSVAK supports reporting of the following variables:

- personal identification number and name of vaccinee;
- specific code and name of each vaccine;
- batch number of the vaccine;
- date of vaccination for each dose;
- date of notification to SYSVAK for each dose; and
- name and location of vaccinating unit (health clinic, GP, etc).

**TABLE**

Notification to the Norwegian immunisation register SYSVAK and need for respective consent from vaccinee

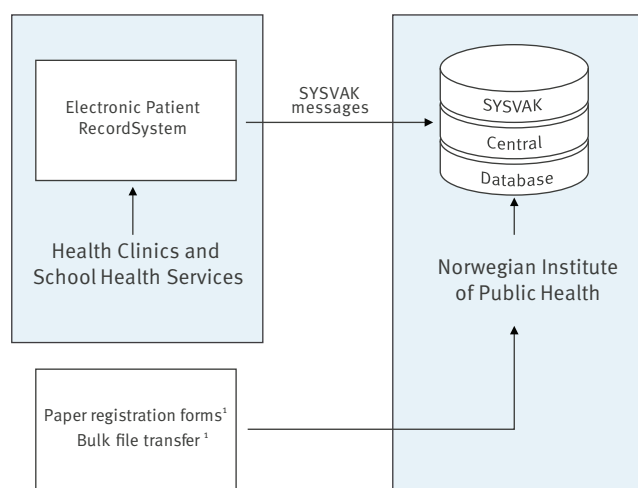
Vaccination Programme	Consent	Notification
Childhood Immunisation Programme, including human papillomavirus	Not needed	Mandatory
Pandemic influenza	Not needed	Mandatory
Human papillomavirus vaccination of girls outside the Norwegian Childhood Immunisation Programme, boys, adults	Required	Vaccinee, parent/guardian can object to notification
All other vaccinations	Required	Oral consent from vaccinee, parent / guardian sufficient



All EPR systems are based on the national personal identification number as the unique identifier of the vaccinee. This is also the identifier in SYSVAK. The national personal identification number is verified against the Norwegian population register when the message is transferred to SYSVAK.

Data from public health clinics and school health services are almost entirely (>99%) electronically transferred to SYSVAK (Figure 1). At present, some other public and private health services have also adapted their EPR systems to the integration module. Those who have not installed the integration module supply data to SYSVAK via paper forms or via bulk file transfer. Electronic notification is not yet implemented in most hospitals, and hospital vaccinations of neonates are notified to SYSVAK in collaboration with the child's local health clinic that submits the notification electronically to SYSVAK, or via paper forms. There may be some potential for underreporting but to an extent that is negligible.

**FIGURE 1**  
Data entry into the Norwegian immunisation register SYSVAK



<sup>1</sup> From health clinics, school health services and general practitioners lacking the integration module necessary for electronic transfer of data to SYSVAK.

### Access to data and security

The EPR integration module described above allows healthcare personnel access to search SYSVAK for all vaccines pertaining to one specific vaccinee. This enables active follow-up of the individual immunisation, facilitates timely and correct immunisation, accurate vaccination history, compliance to the programme and completeness of vaccination schedules.

All health information in Norway is regarded as sensitive information, and access to SYSVAK is strictly

regulated. Access to SYSVAK is granted on an individual basis via the national health network and all activities are logged. All GPs, hospitals, public health clinics, and other public or private health services are connected via the national health network. This network provides a secure channel for communicating health information in Norway. All health information is encrypted prior to transfer via the network.

Access to data from SYSVAK for research purposes may be granted after application to the NIPH at data-tilgang@fhi.no. To ensure adequate data protection and safeguard privacy, permissions from other regulatory bodies like the Regional Committee for Medical Research Ethics or the Norwegian data inspectorate may also be required.

### Vaccination coverage

Vaccination coverage for all vaccines in the Childhood Immunisation Programme is published regularly on the NIPH website [5] and reported annually to the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF). The information from SYSVAK can be broken down to regional or municipality levels, allowing active surveillance of vaccination coverage locally and making national or local interventions possible in order to optimise coverage.

Vaccination coverage is defined as the proportion of children within a birth cohort (all children residing in the municipality/county/country as of 31 December) who have been fully vaccinated i.e. who have received all vaccine doses recommended according to the schedule.

As a part of the SYSVAK quality assurance programme, annual reports are sent to the municipality health services. The reports include information on children who are incompletely vaccinated according to age, or have discrepancies in the vaccination schedule. This routine facilitates close follow-up of all children and favours the completeness of the immunisation schedule for each individual, as well as the data quality in SYSVAK.

Vaccination coverage data are based on notification of individual immunisations, and should reflect the true vaccination coverage. When comparing vaccination coverage from Norway with data from other countries using other methods for calculating the coverage, Norway seems to have slightly lower vaccination coverage than for instance Finland and Sweden [7]. This may be due to incomplete notification or delay in the registration, or may reflect that the true vaccination coverage in Norway is lower than in neighbouring countries. However, the rigid criteria in the immunisation register of being vaccinated according to the schedule (i.e. all recommended doses at timely intervals for each specific vaccine) may also be stricter than the criteria used by others in surveys or other methods of estimating and / or reporting vaccination coverage. This may



again be reflected in slightly lower vaccination coverage estimates in Norway as compared to some other countries.

### Examples of vaccination coverage in two year-olds

In 2011, 94% of two year-olds had received three doses of diphtheria-tetanus-acellular pertussis (DTaP) vaccine according to schedule, 95% had received the *Haemophilus influenzae b* (Hib) vaccine and 94% were immunised against poliomyelitis. In total, 93% of the two year-olds had received the first dose of measles-mumps-rubella (MMR) vaccine. The seven-valent pneumococcal conjugate vaccine (PCV-7) was introduced in Norway in July 2006 and the vaccine was offered to all children born after 1 January 2006. In 2011, 92% of all two year-olds had received the vaccine according to the schedule (Figure 2).

Improving data quality has been a main focus in SYSVAK during the recent years. Quality assurance of data and close contact with reporting units, public health clinics and school health services have proven crucial for obtaining good quality and completeness of data in the register. A slight increase in overall coverage has been observed during the last ten years and may either reflect this activity, or represent an actual increase in the true vaccination coverage.

The reduction in the uptake of MMR vaccine in two year-olds, especially in 2002 and 2003 (Figure 2), however, reflects a true decrease in coverage. This drop coincided with the debate following the false claims about the link between MMR vaccine and autism put forward by Wakefield et al. in a later retracted paper in the *Lancet* in 1998 [8]. In Norway, this debate was brought to the public attention in a television programme in the autumn of 2001, and many parents chose not to have their children vaccinated with the MMR vaccine hereafter.

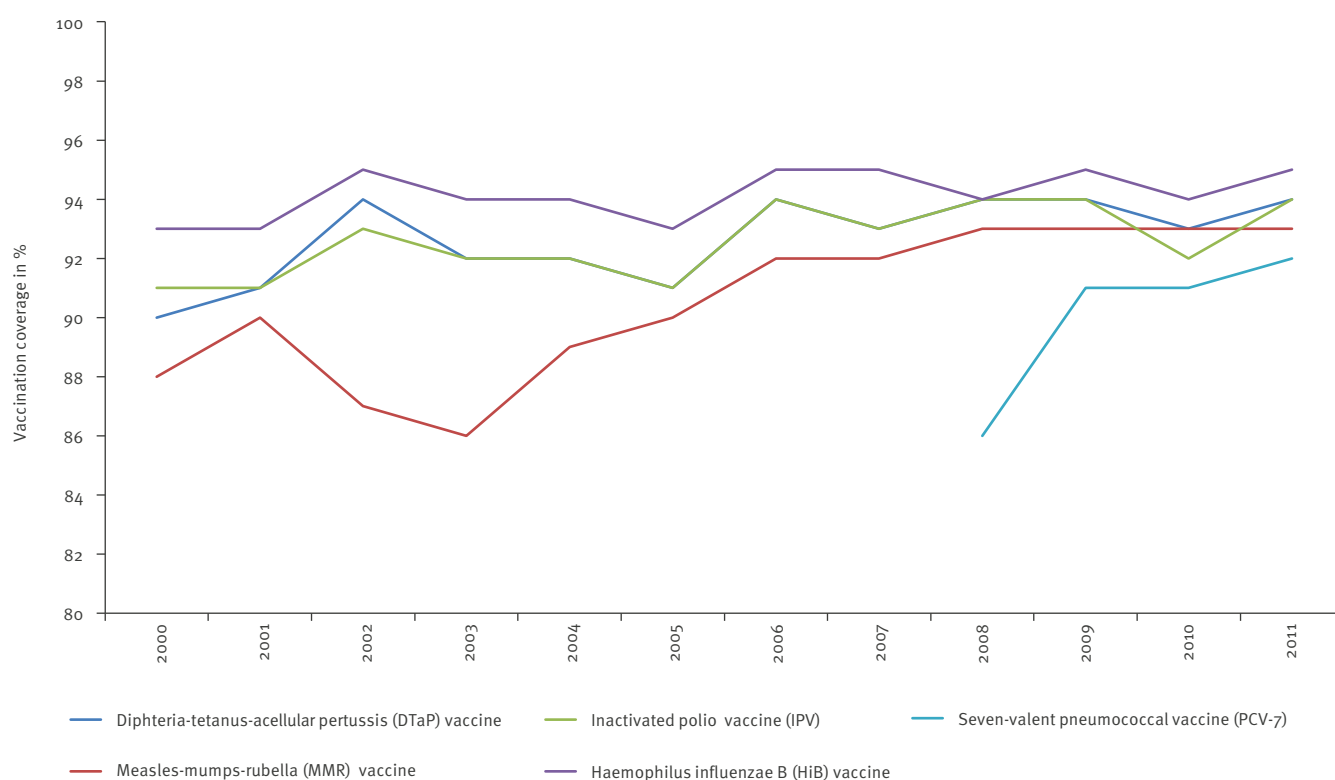
### Epidemiological surveillance and research

The national immunisation register is a valuable tool in epidemiological surveillance, research and quality control. Reliable vaccination data are instantly available and can be accessed for individual ascertainment in outbreak situations, or in cases of suspected vaccine failure or adverse events following immunisation (AEFI). Additional information on outcomes and exposures on individual as well as population levels can be obtained through linkage to other national health registers for vaccine safety and effectiveness studies, as well as studies of attitudes towards vaccination and a number of other research areas.

The use of data from SYSVAK for research purposes has so far been limited, and few scientific papers published [9,10]. However, since the influenza A(H1N1)

**FIGURE 2**

Vaccination coverage in two year-olds who received all recommended vaccines, Norway, 2000-2011



Source: Norwegian immunisation register SYSVAK, Norhealth, 2012.

pdm09 pandemic, there has been a significant increase in applications for access to data from SYSVAK, as described in more detail below. During the years 2006 through 2009 there were five projects using SYSVAK data, whereas in 2010 and 2011 altogether 16 applications for data access from SYSVAK were received.

### Measuring the effectiveness of a vaccine programme using SYSVAK data and data linkage

The fact that all registrations into SYSVAK are based on national personal identification numbers allows extensive linkage of information from different sources, both exposure data and outcome data. As an example, PCV-7 was licensed in Norway in 2001, and introduced into the Childhood Immunisation Programme in 2006. The vaccination coverage was monitored using data from SYSVAK, and quickly reached high levels. The effectiveness of the PCV-7 vaccination programme was assessed using (i) data on invasive pneumococcal disease (IPD) incidence obtained from the Norwegian Surveillance System for Communicable Diseases, (ii) pneumococcal serotype distribution obtained from the National Reference Laboratory for Pneumococci, NIPH, Oslo and (iii) vaccination coverage and individual vaccination status from SYSVAK. The incidence rate of IPD among children under two years of age declined rapidly after introduction of the vaccine. The decline was due to a significant fall in incidence rates of vaccine serotype IPD, while no decline in non-vaccine serotype IPD was seen. No cases of vaccine failures were detected [9, 10].

### SYSVAK and the 2009 influenza A(H1N1)pdm09 pandemic

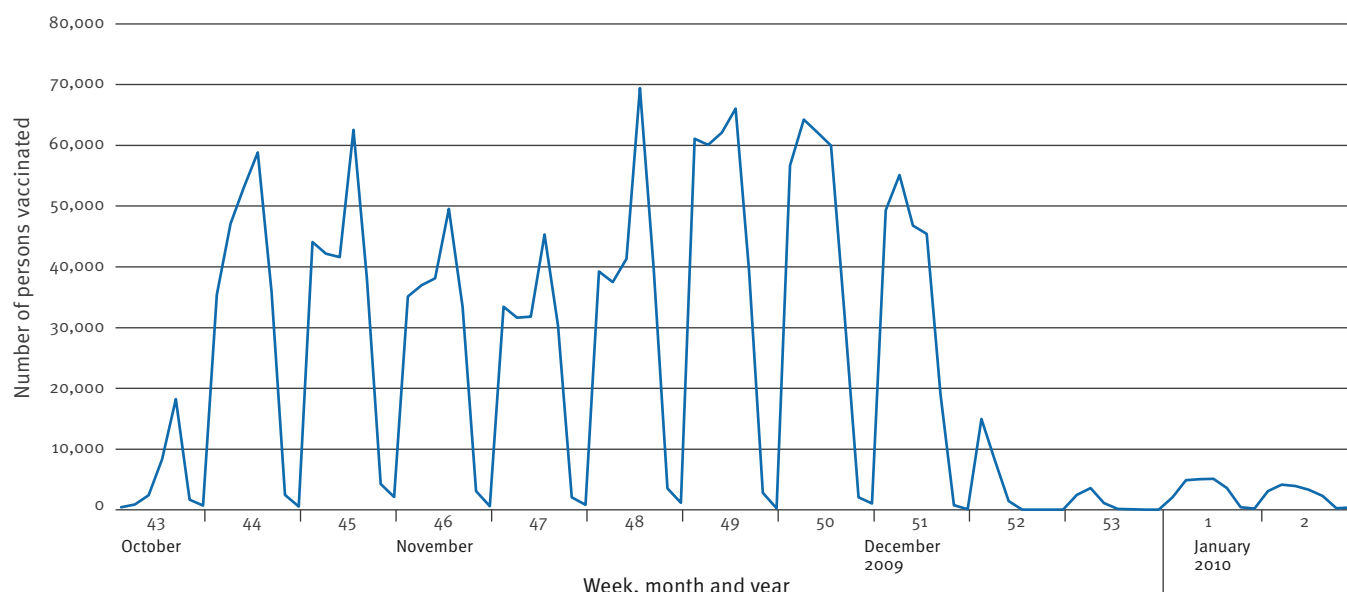
Notification and access to SYSVAK is usually not permitted via the internet. However, during the influenza A(H1N1)pdm09 pandemic, the NIPH recognised the need to register all vaccinations against pandemic influenza for surveillance purposes and a specific permit was issued to allow easy access to SYSVAK. A specific internet-based application was developed, enabling local healthcare providers to register all vaccinations through a readily accessible web-based interface. Through this system, the notification of pandemic vaccinations was transferred directly to SYSVAK at the time of the vaccination, enabling a day-to-day surveillance of vaccination coverage on national as well as regional levels (Figure 3).

According to data from SYSVAK, 1,963,895 individuals received at least one dose of vaccine against 2009 pandemic influenza. The notification to SYSVAK was, however, not entirely complete. Based mainly on the reports on remaining stockpiles in the municipalities, it is estimated that about 90% of vaccinees were registered in SYSVAK during the pandemic. A provisional estimate by the Norwegian health authorities indicates that 2.2 million people (45% of the population) were vaccinated [unpublished data].

Since the 2009 influenza A(H1N1)pdm09 pandemic, a number of studies have been set up to explore the effects of vaccination or influenza on selected health outcomes, among them pregnancy outcomes and neurological disease. Extensive linkage of register data

**FIGURE 3**

Daily administration of vaccine against pandemic influenza A(H1N1)pdm09, Norway, October 2009-January 2010



including SYSVAK has been performed for this purpose, and results are still pending.

SYSVAK data are currently also being linked to cohort data from the Norwegian Influenza Cohort, NorFlu. NorFlu is a cohort of 3,500 women recruited while pregnant during the 2009 pandemic [11]. The purpose is to study a number of pregnancy outcomes including fetal death, gestational length and birth weight following exposure to pandemic influenza, pandemic vaccination and antiviral medication in pregnancy. Data from SYSVAK is also being linked to the Norwegian Mother and Child Cohort Study, MoBa [12].

Reliable data on vaccination status is crucial in the assessment of AEFIs. Currently, data from SYSVAK are used in studies on adverse events related to pandemic vaccination such as a large national linkage study as well as the European Vaccine Adverse Events Monitoring and Communication (VAESCO) study on narcolepsy following immunisation against pandemic influenza A(H1N1)pdm09. A vaccine effectiveness study following immunisation against influenza A(H1N1)pdm09 using SYSVAK data was recently published [13].

### Future plans and challenges

In order to make relevant information available to the public, the Norwegian Ministry of Health and Care Services launched a new web-based initiative in June 2011, allowing the public to access information on their personal health from the national health registers, via [www.helsenorge.no](http://www.helsenorge.no) and the NIPH website. SYSVAK is one of the first national health registers to enter this service which sets off a new application for the established national health registers. As part of this effort, the service called 'My Vaccines' was recently launched by NIPH.

'My Vaccines' holds records of an individual's vaccinations in Norway, provided that they have been notified to SYSVAK. Access requires a personal log-in procedure after which individuals can download vaccination certificates in Norwegian and English with information on their vaccinations recorded in SYSVAK. Parents can also download vaccination certificates for their children. So far, our experience with the new service is limited.

SYSVAK holds valuable data on vaccinations in Norway. With the aim to maximise the use of collected data in surveillance and research, efforts are needed to use it more actively in monitoring vaccination coverage on individual and group levels. Added value in surveillance of replacement of viral or bacterial strains or in estimating vaccine effectiveness is obtained by linkage of immunisation data to data retrieved from the Surveillance System for Communicable Diseases, which is also run and administered by the NIPH.

Linkage may also be performed to other national health registers, for instance the Cancer Register of Norway, or the Norwegian Patient Register, which holds

outcome diagnoses on all in- and out-patient contacts to Norwegian hospitals and specialist healthcare centres. Through such linkages extensive surveillance for a number of vaccine-preventable diseases may be upheld. For instance, we aim to establish a system for systematic surveillance of suspected adverse events following immunisation through linkage between SYSVAK (which holds exposure data on vaccinations) and the Norwegian Patient Register.

A national surveillance programme was set up in Norway following implementation of the HPV vaccine in the Childhood Immunisation Programme [14]. This surveillance programme includes continuous monitoring of vaccination coverage at all levels and effectiveness of vaccination against HPV infection, pre-cancerous cervical lesions and cancer in the female population. Information on vaccination status is retrieved from SYSVAK and will subsequently be linked to outcome data on HPV infection collected in ongoing population-based prevalence studies, and, at a later stage, to the Cancer Register of Norway for information on pre-cancers and cancers.

We undertake continuous efforts to improve data quality in SYSVAK. Specifically, we aim to complete registration coverage by notification requirements for all vaccinations in children and adults. A further goal is that all notifications should be delivered electronically by EPR integration modules from all public and private health services in Norway for the full set of variables. This would eliminate notification by paper forms and bulk file transfer. To help eliminate paper forms, a web-based interface to SYSVAK for registration via internet is also under development.

To our knowledge, Norway, along with Denmark which will implement a national immunisation register during 2012–13, is one of very few European countries, with mandatory, nationwide immunisation registers based on personal identification numbers [15]. We believe such registers are crucial to provide reliable information on vaccination coverage and adherence to recommended vaccination schedules. Furthermore, immunisation registers are rich sources for high quality surveillance of vaccine effectiveness, vaccine failure and adverse events, and gold mines for future research. We encourage the establishment of immunisation registers in other countries, and continue the efforts to maximise the quality and use of SYSVAK.

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# Computerised vaccination register for the Murcia region, Spain, 1991 to 2011

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We describe the Murcia regional vaccination register in Spain, which was set up in 1991, detailing its main features, advantages and limitations. We also report on some recent special actions carried out that led to an improvement in vaccination coverage against measles, rubella and mumps (MMR): by using the vaccination register, we were able to identify and vaccinate persons aged under 20 years in a measles outbreak in 2010 in the town of Jumilla who were not adequately vaccinated for their age with MMR vaccine. From spring 2012, use of our register will enable us to identify susceptible individuals in our region under 40 years of age who have received fewer than two doses of MMR vaccine and call them for the appropriate vaccination. We also set out our experience in the use of barcodes to identify individuals and collect vaccine data: our data show that the barcodes help to improve data quality and completeness. Finally, we identify certain challenges in search of greater standardisation for systems and encoding that is necessary to enable an easy exchange of data between different registers.

## Introduction

Vaccine information systems or registers are a major tool that allows public health personnel to measure, maintain and increase vaccine coverage levels and also to gather information automatically about an individual's vaccine needs. Among other things, such registers allow relatives or the person concerned to be given reminders about the doses still to be received in order to complete a primary or booster series – helping healthcare personnel to vaccinate a person at the most appropriate time – or for them to be asked to provide missing vaccine-related data. The registers can also provide official certificates of a person's vaccination status and detect unvaccinated groups and areas or local population groups with low coverage in which outbreaks of vaccine-preventable diseases are likely to occur [1,2]. They can also help to improve data quality and monitor the implementation of new vaccination recommendations [3]. In addition, they also enable the registration of side effects and the monitoring of vaccine effectiveness. All these advantages have been demonstrated in countries with extensive experience

of computerised vaccination registers such as Australia [4] and the United Kingdom [5].

In this article, we describe the centralised, computerised vaccination register of the region of Murcia in Spain, showing how it has been used, as well as its limitations and the resources needed. Murcia region – one of the 17 in the country – has a population of 1,471,406 inhabitants, of whom almost 18% are under the age of 14 years [6]. Over the last 10 years, the mean number of births per year was about 17,000, having risen from 13,000 in 1999 to about 18,300 in 2010 [6]. The region has received devolved powers from central government covering public health and healthcare provision, although in some matters, such as the vaccination calendar, it coordinates its activities with those of the other regions and with the national health ministry.

There are similar centralised regional registers in the Spanish regions of Galicia, Valencia, La Rioja and Andalusia, as well as in some cities such as Barcelona and Salamanca: these registers are not connected to each other. Elsewhere in Spain, vaccines administered are recorded on an individual's case report in primary healthcare: there is no centralisation of data at the country level. Work is currently under way to develop a single format for recording a person's case history at the national level that would also incorporate the person's vaccine data.

Most of the regions use official population figures for calculating coverage, except for La Rioja and Murcia which have their own population databases.

Public and private health providers, mostly in primary healthcare, carry out the vaccinations. In the primary healthcare centres, data are entered by the health professional who administers the vaccine. In the management centres of the vaccination register, clerical staff enter the data.

The vaccines included in the vaccination calendar are paid for by the regional government: those not included in the calendar are paid for by parents or guardians.



## Description of the vaccination register of Murcia region

The computerised vaccinations register was set up in the Murcia region in 1991. It was founded on an earlier register for infants that recorded only the primary vaccination series (i.e. vaccines received in the first two years of life). The computerised register has evolved over time, so that it currently records all vaccines administered in the region, whether in the private or the public sector, during childhood or adulthood, and also includes vaccines that are not part of the official vaccination calendar. All primary healthcare centres in the region participate in the register.

### Inclusion of individuals in the register

Murcia's vaccination register is part of the regional public health information system. The register uses a single population database (PER\_SAN), which is fed with real-time updates from the regional population database of the healthcare system. These are classified as new entries, deletions, deaths, change of address, change of paediatrician or family physician, etc.

Various processes are used to include individuals in the register's population database, PER\_SAN (Figure 1).

- When a child is born in hospital, the public health information system assigns them a personal regional identification code (a barcode), which is given to the parents on labels. This is part of the documentation parents receive after childbirth, which also includes notification cards that they take with them to accredited vaccination centres, be they public or private. The barcode is recorded in the PER\_SAN database through the results of screening for neonatal hearing loss.
- The same barcode is also used in a programme to detect congenital errors of metabolism. Blood and urine samples are taken on the third day of life and sent to a laboratory together with a card containing the newborn's personal details. Attached to this card is one of the barcoded labels given to the parents at the hospital. This barcode is recorded in the PER\_SAN database when the laboratory results have been obtained.
- When parents or guardians apply for a health insurance card for their child, the child's details are manually included in the PER\_SAN database. This applies too if the child was not born in hospital.
- If a person (child or adult) comes to live in the region, when they visit a primary healthcare centre, a form containing their details (identification card) is sent to the vaccination register. These details are added to the PER\_SAN database manually.

Data duplication is prevented by a double check, one automatic and the other manual.

i. Automatic check: an identification code assigned by PER\_SAN to each person included in the database and the regional personal identification code (the code

issued by the public health information system) enable the duplication of individuals to be avoided, through searches that are automatically carried out when the codes are entered. In addition, whenever a person is entered into PER\_SAN manually, internal search processes are run automatically to identify whether that person is already present on the database and thus prevent a duplicate entry.

ii. Manual check: two technicians work on the PER\_SAN database to identify duplicates and correct any database errors.

### Inclusion of vaccination data in the register

Our register can import vaccine-related information from primary healthcare case reports, but the primary healthcare information system is not currently ready to import data from our register. However, our register is available through the Internet, so any authorised healthcare professional can consult a patient's immunisation status regardless of where the person was vaccinated.

At primary healthcare centres that participate in the register, a person's vaccination details are entered into a computerised case report, using the same codes as in our register. Thus whenever we incorporate data from these computerised case reports, the system detects whether the vaccination has already been recorded for that person and, if so, does not include it in the register.

### Data input

The register records the date the vaccine was administered, the vaccination post at which it was administered, the product administered, dose order number (whether this was the first or second dose, for example) and the manufacturer and batch of the vaccine. The indications for the vaccine are also recorded, either using the official vaccination calendar or any special indication due to the individual's medical circumstances, such as being in a risk group for a particular disease, having a chronic illness, etc. Whenever a vaccine-related adverse effect occurs, this can also be recorded. In addition, the reasons for not administering a vaccine, such as contraindication or refusal to receive it, are also included.

At all the primary healthcare centres in the region, around 25,000 vaccine doses administered are recorded every month, except in the influenza vaccination season, when as many as 140,000 monthly doses can be recorded. Our register imports these data, but approximately 10% of the doses recorded on the primary healthcare computerised case reports each month cannot be imported into our system due to encoding errors that arise due to the manual input of all the data (vaccine code, manufacturer and batch). In order to ensure that this information is not lost, we still use the same dose notification system we started with in 1991: the notification cards given to parents after childbirth. These cards include adhesive labels with the barcode

identifying each child. The product administered, the dose order number, batch number, date of administration and name of the vaccination centre are recorded on the card. These cards are then sent by post to one of the register's four management centres, where a check is made to see whether that dose is already recorded in the register.

One aspect of importing dosage information is the use of a barcode scanner that reads the details of the vaccine (commercial name, manufacturer, production site and batch number). The scanner software breaks down the information from the barcode (Figure 2). Currently, four of the six manufacturers supplying the region with vaccines (GlaxoSmithKline, Baxter, Pfizer and Sanofi Pasteur MSD) include two barcode labels with each dose of vaccine: one of these is placed on

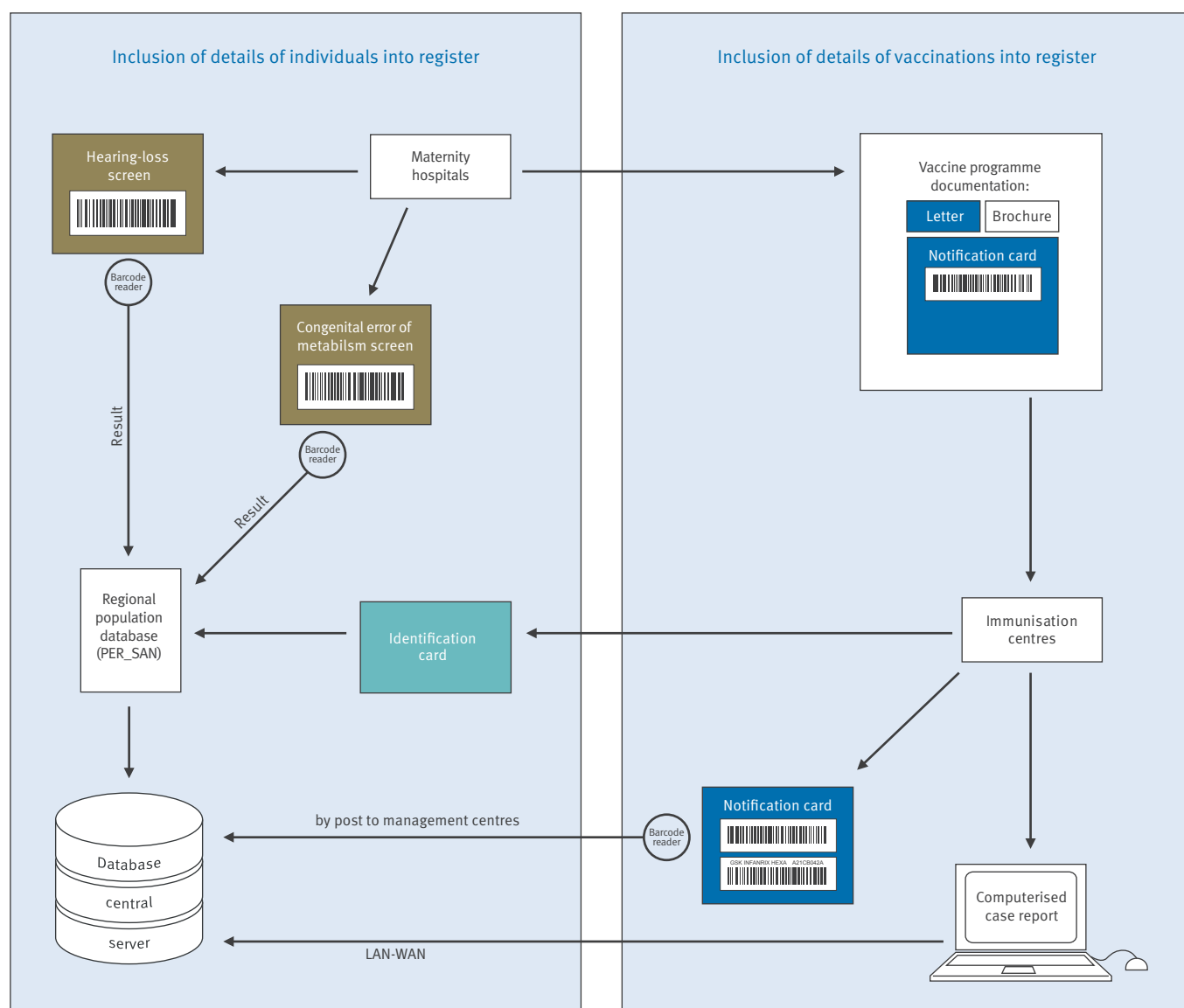
the notification card and the other on the child's own vaccine administration record.

In the Spanish regions, the use of these labels is voluntary, but the Ministry of Health has established a standard label format for manufacturers who decide to use barcodes. In order to promote the supply of such barcoded labels by manufacturers, a technical criterion for their design is included in the competitive tender procedure used for the acquisition of vaccines. Reading such labels with a barcode scanner means that only the administration date, the dose order number and the vaccination centre need to be recorded manually.

Primary healthcare centres are not equipped to scan the barcode labels. In order to assess the advantage afforded by recording doses using a barcode scanner, we analysed the details of doses recorded in the primary healthcare system for vaccines supplied with

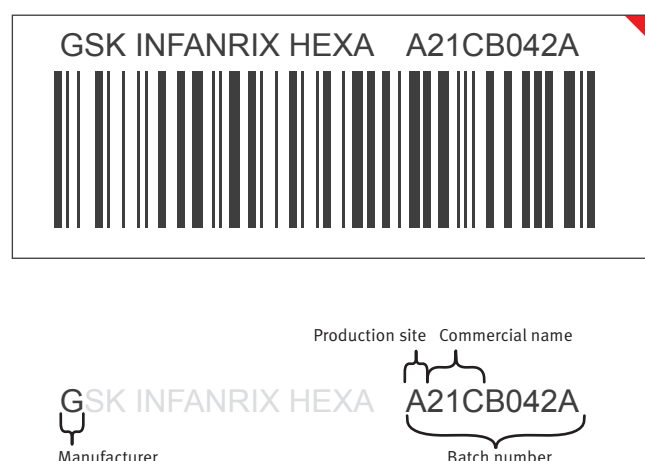
**FIGURE 1**

Data flow in the computerised vaccination register for Murcia region, Spain



LAN: local area network; WAN: wide area network.

**FIGURE 2**  
Composition of a vaccine barcode, Murcia region, Spain



barcode labels. During 2010, the region's primary healthcare teams recorded the administration of a total of 200,352 doses of six different vaccines that have these labels. Of the total number of doses, 17,511 (8.74%) did not have their batch number correctly recorded, 1,162 (0.58%) had no batch number recorded and 16,349 (8.16%) had an incorrect batch number. Regarding the name of the manufacturer, 38,247 (19.09%) of the doses did not have this information correctly recorded: 11,059 (5.52%) had no manufacturer recorded and 27,188 (13.57%) showed the wrong manufacturer. In contrast, 100% of the doses obtained through the barcode scanner had all their details correctly recorded.

### Access to an individual's vaccination data

As mentioned earlier, one important advantage of a vaccination register is that by incorporating in a centralised system all the doses administered, any authorised healthcare professional can access an individual's vaccination history from their work station (data security is regulated by national legislation).

There are several levels of data access, depending on the healthcare professional's role. The access level ranges from full, for example, for coordinators of the vaccination register, to minimal, for those who can access only minimal personal and vaccination details (Table). The coordinator authorises the access and the person requesting access is given an appropriate password that safeguards the confidentiality of the data.

The case report information system used for public healthcare services in the region does not allow professionals at one health centre to consult the vaccine information recorded in the case reports at another. In order to facilitate access to this information for healthcare professionals, a web-based system has been created for the regional vaccination register so that, if granted the appropriate access, it is possible to view

vaccination details and the outcome of the neonatal hearing-loss screen.

### Features of the regional register

The large amount of data collected allows us to define a number of special features of the register.

#### Routine interventions

- Reminders sent out for vaccine doses at the age of six years (diphtheria-tetanus-acellular pertussis vaccine, mumps-measles-rubella (MMR) vaccine), at age 11 years (varicella vaccine, only for susceptible children) and at 14 years (diphtheria and tetanus for boys and girls, human papillomavirus for girls).
- Reminders sent out for influenza vaccination for adults aged 60 years.
- Regular reminders sent out to those insufficiently immunised.

#### Special interventions

The register allows us to carry out special actions from time to time to help increase coverage levels and identify poorly immunised population groups – a very useful option when facing an outbreak of diseases that can be prevented through vaccination. For example, during 2010, there was an outbreak of measles in the town of Jumilla, with a total of 90 confirmed cases. By using the vaccination register, we were able to identify those persons under 20 years of age who were not adequately vaccinated for their age with MMR vaccine. A total of 3,195 letters were sent out to individuals between 6 months and 20 years of age (or their parents or guardians) and 1,667 doses were administered during the month after the letters were sent out (the mean monthly number of vaccine doses in that town is 68). Simultaneously, we were able to update the

**TABLE**

Levels of data access, regional vaccination register, Murcia region, Spain

Healthcare professional's role in the vaccination register	Level of access
Consulting vaccination records	Can view data on vaccines administered to an individual. Has access to minimal personal information.
Operational	Can consult and input information on vaccine doses. Has full access to personal information.
Management	Can consult, input and evaluate information on vaccine doses. Has full access to personal information.
Coordination	Has access to all the register's functions, including the management of software, and the allocation and authorisation of access levels.

information about the doses administered that we did not have on record in our vaccination register.

From spring 2012, use of our register will enable us to identify susceptible individuals in our region under 40 years of age who have received fewer than two doses of MMR vaccine and call them for the appropriate vaccination.

Having people's mobile telephone numbers (part of the information recorded in the vaccination register) allowed short message service (SMS) text messages to be sent to teenage girls who had not completed the vaccination regime against human papilloma virus, thus increasing coverage by 5.1% in the cohort of girls born in 1994 [7].

Regarding data management, our system allows vaccination coverage to be calculated at different levels of data disaggregation, making it easier for healthcare professionals to carry out actions at the level of the individual.

### **Resources needed for the maintenance of the register**

The features of the register allow actions to be taken that would be impossible or very complicated without them. Some of these actions would probably require additional human resources and so such actions would be hard for a region such as ours to undertake. Even so, maintenance of the register requires a considerable involvement in terms of human resources. A total of 19 people – at various professional levels (medical doctors, nurses and clerical staff) – at the four management centres work on maintaining the register. In addition, two people are devoted exclusively to maintaining the PER\_SAN database, which is shared by almost all public health programmes in Murcia.

To ensure that everything works correctly, we have the support of highly qualified informatics staff who, in addition to having developed the software application, enable us to incorporate improvements as and when required without having to resort to external resources.

### **Limitations of computerised vaccination registers**

Although there are a large number of advantages associated with computerised vaccination registers, there are also some drawbacks. Vaccination coverage levels determined from such a register are always underestimated and the number of doses administered (used as the numerator) is always lower than the actual number of doses administered as there are always notification failures [8]. On the other hand, despite the maintenance efforts and the quality assurance checks, the denominator may be overestimated as insufficient information may be received about deaths or changes of address: the latter may have an impact given the extent of migration flow in and out of the region associated with seasonal agricultural activities in the Murcia region.

### **Challenges of vaccination registers**

The first challenge is the systematic use in all countries of vaccination registers with certain minimum functional standards in order to make them compatible [9]. Standardisation in the methods for calculating coverage would make it easier to obtain and compare the levels between countries or even between areas within a single country [10–15].

Another equally important challenge is the standardisation of vaccine- and batch-encoding methods. The batch-encoding system we use – based on what was supplied by a manufacturer we were developing the project with – would help to ensure that the information provided about a batch is homogeneous in all countries using the system. It would be desirable for this or another encoding method to be agreed upon by consensus among the European regulatory agencies, as this would enable the automated inclusion of a larger number of data elements into the vaccination registers, which would be a great improvement in the quality of the information system [16,17].

### **Conclusions**

Vaccination registers are a valuable tool for the management of vaccination programmes. Our regional register has enabled us, among other things, to improve vaccination coverage against measles, rubella and mumps, and against the human papillomavirus in adolescent girls. We believe that at global level we are still at an early stage in terms of developing and using such registers and we therefore still have the chance to take decisions that will enable improvements to be made that will facilitate widespread use of registers in those areas or countries where they are not yet present. Additionally, it is desirable that there should be a high degree of compatibility between the registers used. These are challenges facing those involved in running vaccination programmes, regulatory agencies and health authorities.

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# Australian immunisation registers: established foundations and opportunities for improvement

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The National Immunisation Program Schedule in Australia is formulated and funded nationally under the population-wide Medicare system. The policy is implemented by the eight state and territory jurisdictions. The national immunisation registers consist of the Australian Childhood Immunisation Register (ACIR), and, more recently, the National Human Papillomavirus (HPV) Vaccination Program Register. Moreover, a variety of jurisdiction-based registers and primary care practice software systems exist, which interact with the national registers. General practitioners can obtain reports listing patients under seven years attending their practice and recorded as 'not fully immunised', and immunisation coverage rates for their practice linked to government incentives through Medicare. A 2011 report documents national coverage of 91.8% fully immunised at 12 months, and 92.6% at 24 months. The HPV register provides information on vaccination coverage with the potential to link with a register of cervical cancer screening results. Limitations of current national register include inability to easily access immunisation histories beyond seven years of age, and issues of underreporting and timeliness, which impact significantly the immunisation coverage estimates. The linkage of these registers with healthcare outcome data will further enhance public health outcomes by enabling rapid, population-level vaccine safety and effectiveness investigations in a nation with a track record as an 'early adopter' of new childhood vaccines.

## Introduction

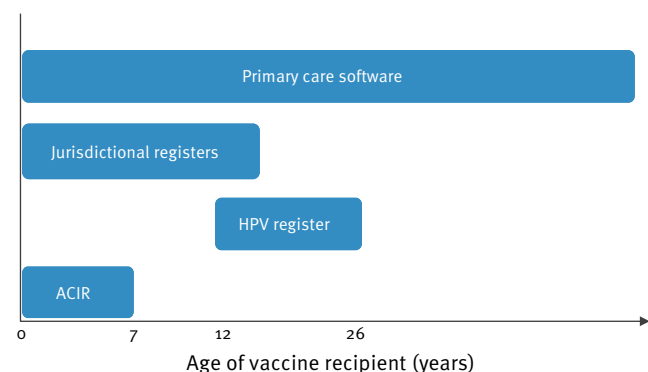
Defined as population-based, confidential systems containing vaccination histories [1], immunisation registers have been pivotal in ascertaining and improving individual and population-level compliance with

vaccination schedules [2]. Used to identify at-risk populations for vaccine-preventable diseases (VPD), registers document and increase vaccination coverage via 'planned' immunisations with recalls and reminders or opportunistic immunisations [1,3]. In certain countries, immunisation registers have also been used to assist in the establishment of health policies, as well as to provide a link for parent and provider incentives to improve immunisation rates [4]. More recently, direct linkage of immunisation registers with health outcome data has provided opportunities to examine vaccine safety and effectiveness [5, 6].

Currently, the Australian immunisation policy is formulated and funded nationally under the population-wide Medicare system, but implemented by the eight state and territory jurisdictions. The National Immunisation Program (NIP) Schedule covers all Australian population as an approved antigen-based schedule, with potentially multiple manufacturers with nationally approved vaccines purchased centrally. These include diphtheria, tetanus, acellular pertussis, inactivated polio, hepatitis B, *Haemophilus influenzae* type b (Hib), pneumococcal conjugate (from July 2011, the 13-valent conjugate vaccine replaced the seven-valent conjugate vaccine), rotavirus, measles, mumps, rubella, varicella, group C meningococcal conjugate and human papillomavirus (HPV) vaccines.

As a result, there is a combination of national- and jurisdiction-based registers, with overlapping and sometimes synergistic functions (Figure 1).

The national immunisation registers consist of the Australian Childhood Immunisation Register (ACIR), and more recently the National Human Papillomavirus

**FIGURE 1****The Australian immunisation registers**

ACIR: Australian Childhood Immunisation Register; HPV: human papillomavirus.

Vaccination Program Register (HPV Register) [7,8]. There are a variety of jurisdiction-based registers, largely aimed at delivering local government-based immunisations, as well as primary care practice software systems that interact with the national registers. As an early adopter of such registries, the experience of this federation of eight states and territories may help illustrate issues facing similar initiatives within Europe. This review will describe the range of immunisation registers in Australia and discuss the benefits, limitations of and challenges for these current systems.

### The Australian Childhood Immunisation Register

The ACIR was introduced in 1996 as part of the Immunise Australia Program, a joint Commonwealth and state/territory government programme, as part of a series of measures to help reduce incidence of VPD in Australia. The ACIR is administered and operated by Medicare Australia, the universal health insurance scheme in Australia [8]. It records details of vaccinations given to children under seven years of age who live in Australia, including vaccine batch details. Since 2001, immunisations administered overseas may be retrospectively recorded if an immunisation provider endorses their validity based on written documentation or confirmation from the previous provider. The ACIR is accessible until a child is 14 years of age and was predominantly established to capture routine NIP vaccines. It is described as the world's first attempt in developing a near-complete population-based immunisation register [1]. It is estimated that 99% of children in Australia are registered with Medicare (under a unique number for each child) by 12 months of age and those not registered with Medicare by then can be added on via supplementary numbers to the ACIR [1]. Participation of children in the ACIR is opt-out [1]. Based on a survey in 2004, approximately 3% of children have incomplete immunisation due to medical contraindications or parents' with conscientious objections to immunisation [9]. These children are still registered with the ACIR after parents have discussed the

risks and benefits with a recognised immunisation provider [1,9,10].

### Data collection and coverage measurement

The ACIR receives daily information from direct online notifications, provider software applications (jurisdictional agencies and General Practice management software applications) or paper forms mailed from immunisation providers (Figure 2).

Marked proportional increase of online notifications has been observed, from an initial 6% in 1998 to 65% in 2007 [1]. Individuals registered with Medicare Australia will have a unique number that can be used across databases in Australia, although with limitations set by federal privacy legislation. Medicare Australia provides immunisation history statements at milestone ages and for requests at an individual level, information about a child's immunisation status to help determine eligibility for the Australian Government's family assistance payments, and quarterly coverage reports at the immunisation provider, local, national and state level [3]. General practitioners (GPs) are also able to obtain reports listing patients under seven years of age who attend their general practice and who are recorded as 'not fully immunised', and immunisation coverage rates for their practice which is linked to government incentive payments through Medicare.

Immunisation coverage is measured cross-sectionally at the individual or general practice level, and by cohort method at the population level. With the latter, a cohort of children is defined by their date of births in three-month groups. The immunisation status of this cohort is then assessed at the three key milestones of 12 months (for vaccines due at six months), at 24 months of age (for vaccines due at 12 months), and at five years of age (for vaccines due at four years) [8]. Children registered with Medicare who have completed the primary schedule represent the numerator and the total number of children registered in Medicare in the same age cohort represents the denominator [1,11].

To be fully immunised at the milestone ages, the following vaccines need to have been received [1,12]:

- 12 months: three doses of diphtheria (D), tetanus (T), and acellular pertussis (Pa)-containing vaccine, three doses of inactivated polio vaccine (IPV), two or three doses of *Haemophilus influenzae* type b (Hib) vaccine (depending on vaccine type), and two or three doses of hepatitis B vaccine (depending on vaccine type).
- 24 months: three doses of DTPa-containing vaccine, three doses of IPV, three or four doses of Hib vaccine, three or four doses of hepatitis B vaccine (depending on vaccine type) and one dose of measles-mumps-rubella (MMR)-containing vaccine.
- 48 months: four doses of DTPa-containing vaccine, four doses of IPV, and two doses of an MMR-containing vaccine.

As per the ACIR overdue rules, an individual is considered overdue one month post the due date for all immunisation time points detailed above [13].

Prior to the introduction of the ACIR, coverage was estimated in 1997 for all age cohorts to be 75% or less [1,10]. The 2011 coverage reports document 91.8% fully immunised at 12 months, and 92.6% at 24 months (Figure 3) [14].

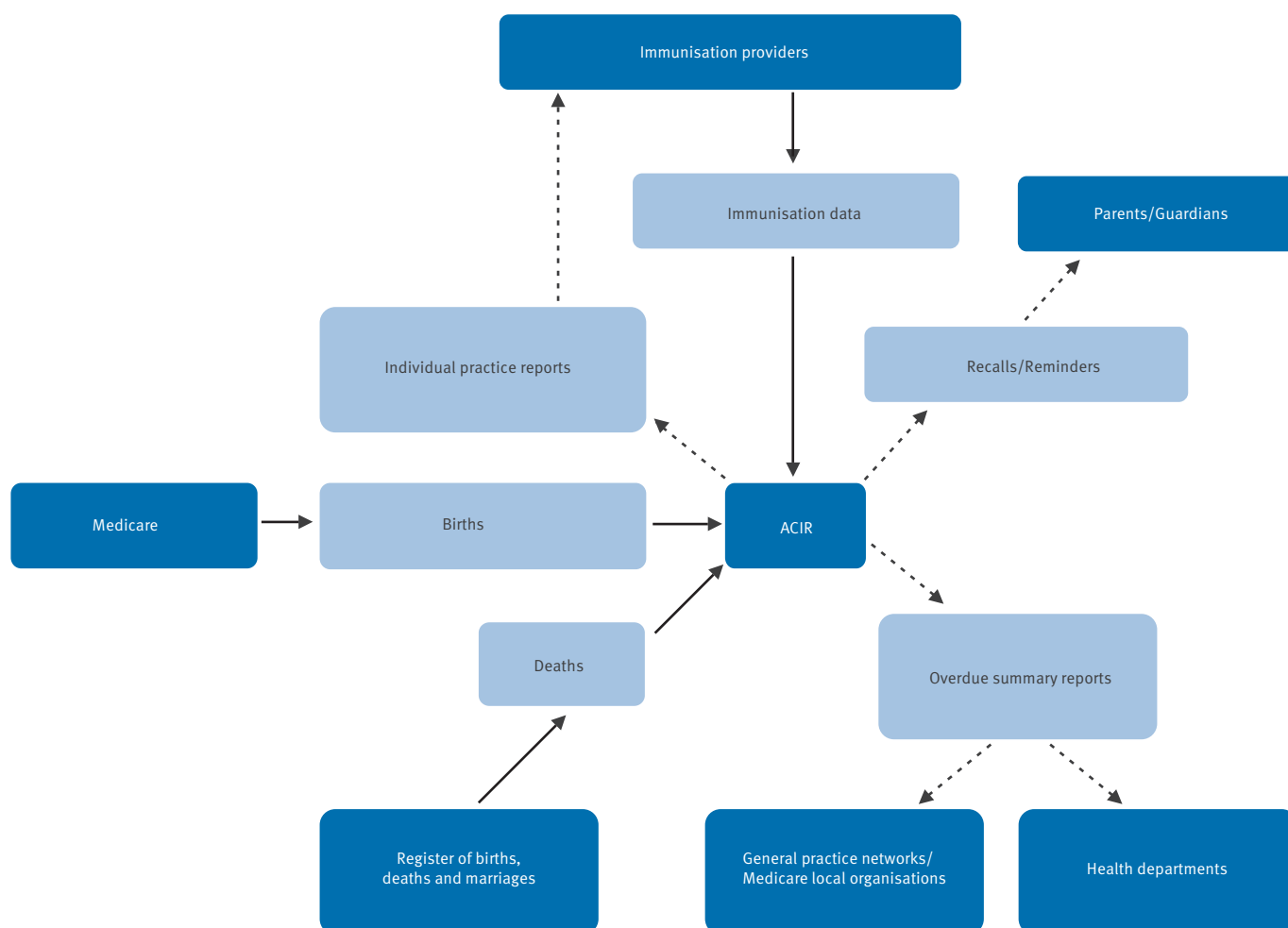
For vaccines that require more than one dose, for instance with DTPa vaccine, the child is assumed to have had earlier doses of the vaccine as long as the last dose has been given [3]. This assumption has been validated by a national population-based telephone survey demonstrating this method still underestimates coverage by up to 5% due to under-reporting [15]. All children should ideally be registered with Medicare by the age of six to eight weeks when the first doses of DTPa, IPV, Hib, rotavirus and PCV7 vaccines are due.

Children not registered with Medicare by this age are provided a supplementary number with ACIR, which may not be linked to their unique Medicare identifier number when finally registered thus reflecting incorrect vaccination histories. The lag time between date of birth and Medicare registration remains significant with lag time beyond two months doubled among those children with missing doses versus those registered promptly after birth [1,3].

The ACIR also plays a role in evaluating immunisation coverage among the indigenous population, representing 2.5% of the Australian population [16]. The status is recorded as 'indigenous', 'non-indigenous' or 'unknown' as self-reported to Medicare or by the provider to ACIR. Status reporting has improved remarkably with 99% recorded in 2007 as opposed to 42% in 2002 for infants aged 12-14 months [17]. Coverage estimates for 12 months and five years are lower for children registered as indigenous by their parent/s and

**FIGURE 2**

Flow of information to the Australian Childhood Immunisation Register (ACIR)



ACIR: Australian Childhood Immunisation Register.

Adapted from: Hull BP, McIntyre PB, Heath TC, Sayer GP. Measuring immunisation coverage in Australia. A review of the Australian Childhood Immunisation Register. *Aust Fam Physician*. 1999;28(1):55-60 [3].

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have remained stagnant for the last six years, although estimates at 24 months are similar, suggesting timeliness is a major factor [17]. Hepatitis A and 23-valent pneumococcal polysaccharide vaccines recommended and funded only for indigenous children are also documented in ACIR and also show suboptimal coverage estimates [1,10, 18].

### Factors for improvement in recorded coverage

Immunisation coverage rates have improved with time and better understanding of the function of the ACIR. This could reflect the improvement in provider notification, less delay with increased use of electronic notifications, and the ongoing introduction of combination vaccines contributing to an increase in vaccination coverage [1].

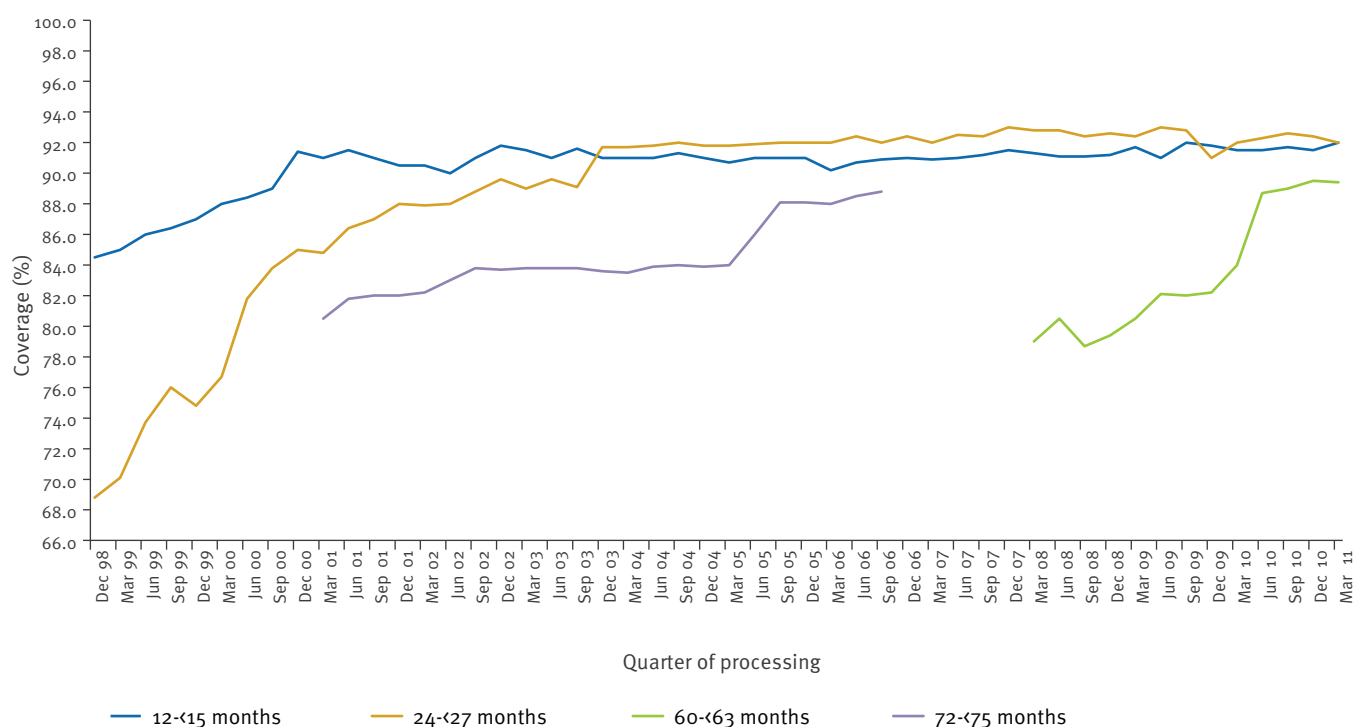
The introduction of immunisation incentives for parents and providers in 1997 and 1998 respectively have also contributed significantly to improved coverage. Parental incentives were introduced to provide a prompt for parents and providers to complete immunisation, or to confirm their conscientious objection or medical contraindication to vaccination. The income-linked parental incentives include the Maternity Immunisation Allowance (MIA) and Child Care Benefit (CCB) [1]. Paid at two separate time points, the MIA, a non-taxable amount of AUD 258 (approximately EUR 203) can be claimed on or before the child's fifth

birthday if the child is shown to have completed immunisation (or has a registered conscientious objection or medical contraindication to vaccination) [19]. However, from July 2012, MIA will be replaced by the existing Family Tax Benefit Part A supplement where children must be fully immunised for parents to receive AUD 726 (approximately EUR 571) for each child at each immunisation checkpoint at ages one, two and five years [20]. The CCB incentive partially reimburses parents who use approved or registered childcare and the amount depends on the family's yearly income, but can potentially be a much larger financial benefit than the MIA [21]. It was suggested parental incentives played an independent role in the increase of completed immunisation coverage at 24 months [1].

For the immunisation providers in primary healthcare settings, the General Practice Immunisation Incentive (GPII) Scheme was introduced in 1998 to encourage immunisation notifications and to achieve at least 90% of practices to fully immunise 90% of children aged below seven years attending their practices [22]. In 2008, the federal budget ceased the GPII Service Incentive Payment (SIP). The SIP was a payment (AUD 18.50) made for notification by the provider of completion of vaccination at a certain milestone age. To date, discontinuation of SIP has not affected immunisation coverage, however longer term analysis may be warranted [23]. The other two components of the GPII scheme remain, namely the Information Payments (up

**FIGURE 3**

Australian Childhood Immunisation Register (ACIR) standard coverage by age cohort, December 1998–May 2011



The coverage at five years of age is for vaccines due at the age of four–five years; this was changed in December 2007 from the age of six years. Source: Australian Childhood Immunisation Register (ACIR). Standard Coverage for Australia [14].

to AUD 6 (approximately EUR 5), paid to all immunisation providers after notification of administration of all the milestone age NIP vaccines) and the GPII outcome payments (for practices with  $\geq 90\%$  of fully immunised children) [10,22].

## The National Human Papillomavirus Vaccination Register

The HPV register was legislatively enabled in 2007 and became operational in 2008 [24,25]. The Australian Government funded the quadrivalent vaccine 4vHPV, (Gardasil, Merck, New Jersey, USA) as part of the programme in 2007. The bivalent 2vHPV vaccine (Cervarix, GSK, Uxbridge, UK) was licensed in late 2008, but the national programme in Australia is using the 4vHPV vaccine. This programme is targeted at pre-adolescent and adolescent females, with a funded ongoing school-based vaccination for 12- and 13-year-old girls. A two-year catch-up programme was also initially funded by the Australian Government for 13–18-year-old girls in schools and 18–26-year-old women through general practice and community-based programmes [25].

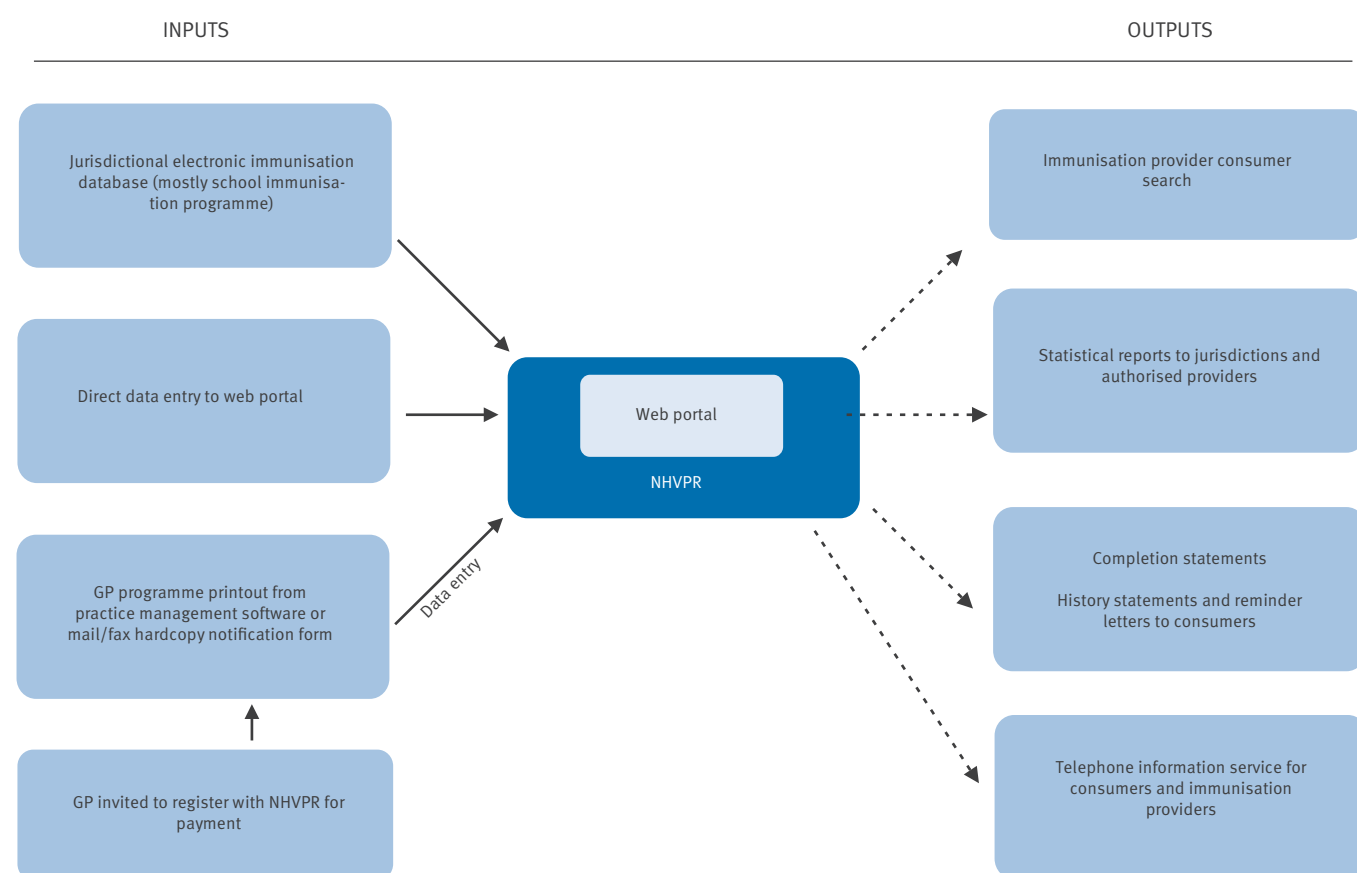
The Victorian Cytology Service currently operates the HPV register, which is also responsible for the Victorian

Cervical Cytology Register [26]. Prior to the establishment of the register in 2008, data from schools were held at local or State Health Department levels while GP-held data were recorded and held as instructed by the Australian General Practice Network [25]. HPV vaccine data can be submitted via different jurisdictional electronic immunisation databases (mostly via school immunisation programme), direct data entry to the HPV register web portal and GP notification via mail or fax from practice management software (Figure 4) [25]. To encourage registration, GPs were invited to register with the HPV register and on notification of a valid HPV vaccine dose, GPs were remunerated AUD 6 (approximately EUR 5) per vaccination encounter. This incentive attracted over 96% of GPs invited to register by March 2010, and was discontinued in June 2010, following the completion of the HPV vaccination catch-up programme [25].

The register provides information on vaccination coverage with the potential to link with a disease register of cervical cancer screening results. Coverage in Australia is currently calculated by age of all eligible females in the programme i.e. 12–26-year-olds in 2007 and 12–13-year-olds each year [25]. The numerator for

**FIGURE 4**

National Human Papillomavirus Vaccination Program Register (NHVPR) operations: data inputs and outputs, Australia



GP: General practitioner; NHVPR: National Human Papillomavirus Vaccination Program Register.

Source: Gertig DM, Brotherton JM, Saville M. Measuring human papillomavirus (HPV) vaccination coverage and the role of the National HPV Vaccination Program Register, Australia. CSIRO PUBLISHING. Sexual Health. 2011;8(2):171-8. Available from: <http://www.publish.csiro.au/paper/SH10001.htm> [25].



coverage is the number of females in the target population who have received three 4vHPV doses. Coverage with one or two doses of the vaccine has also been calculated [25]. Recent data from the HPV register indicate promising 4vHPV coverage of the target group of 12–15-year-olds with 72–73% having completed three doses. International standardised coverage methods have yet to be agreed for 4vHPV, limiting comparisons of the effectiveness of HPV vaccines [24,25].

The HPV register also plays an important role in providing consolidated information on school and primary care vaccine doses, which would be useful to follow up on overdue vaccinations. In the future, this information will also provide the opportunity to notify young women if a booster dose is required [25]. A limitation of this HPV register was that it was not established before the National HPV immunisation programme commenced in 2007 and does not capture co-administered vaccines. It has also been proposed that Australia will soon begin immunising 12–13-year old boys under the NIP [27].

There have been calls internationally for HPV vaccination registers to be combined with a cervical cancer screening register, to incorporate vaccination status, cytology, histology and HPV DNA test results [25, 26]. A recent ecological study analysing the early effects of the HPV vaccination programme on cervical abnormalities in Victoria showed a decrease of 0.38% (95% confidence interval: 0.61–0.16;  $p=0.003$ ) in high-grade cervical abnormalities in the three years after vaccine introduction, compared with four years before [26]. Linking of cervical cytology to vaccination status would allow testing of a causal link between HPV vaccines reducing cervical abnormality rates [26].

### Jurisdictional vaccination registers

All jurisdictions with the exception of Tasmania and the Australian Capital Territory have separate registers: to record adolescent vaccines administered in the school-based programmes (New South Wales, Western Australia); school and local government-administered child and adolescent vaccines (South Australia, Victoria); or all childhood and NIP vaccinations administered (Queensland, Northern Territory). All are managed at the jurisdictional level, with the exception of the Immunisation Provider System (ImPS) in Victoria and South Australia, where electronic records are held at local government level, and all upload directly to ACIR or the HPV Register. Local reports of vaccine coverage are generated from ImPS and forwarded to the state Departments of Health for completion of vaccination records [28].

### Primary care software

In 2007, it was estimated that Australian GPs were providing 71% of recorded vaccinations on the ACIR, with substantial jurisdictional variation [3]. Prior to the introduction of ACIR, many GPs had implemented various non-compatible decentralised immunisation record systems [29]. The introduction of the ACIR was

seen as addressing this issue and to improve population vaccination recording.

There are a number of commercial providers of GP practice software systems, with the ability to interact directly with ACIR and indirectly with the HPV Register. Varying in their immunisation recording capabilities, they represent the major data records for NIP vaccines for adults (e.g. pneumococcal and influenza vaccinations for the indigenous, elderly and ‘medical at risk’) and non-NIP vaccines (e.g. travel vaccinations), jurisdiction-funded vaccines e.g. adult pertussis (dTpa) and adult MMR vaccines, funded non-NIP vaccines requiring co-payments e.g. ‘medical at risk’ adult pneumococcal and privately prescribed vaccines). Records are held at practice level, but it is possible for anonymised data directly linking immunisations with subsequent attendances for healthcare at the practice to be extracted across multiple practices. The recently announced National Prescribing Service ‘MedicineWatch’ programme linking medicine use with potential adverse outcomes in primary care is a potential example of these systems. A limitation is that the GP software is provided by commercial companies, not the Australian Government, hence changes in the NIP are often not reflected in the software until the company decides to run an upgrade.

### Other registers: Q fever vaccination register

The Q fever vaccination register is an industry-based register run by the Meat and Livestock Australia (MLA) corporation for recording vaccination and immunity status for the federally-funded Q fever vaccine in humans. It is accessible via the internet to medical practitioners and meat processors [30].

### Limitations of the current immunisation registers

The absence of immunisation histories beyond seven years of age is a critical limitation of the ACIR. Whilst records are now available up to 14 years of age, late childhood and adolescent vaccines are not captured in ACIR. There has been a call for a ‘whole-of-life’ immunisation register that will record child, adolescent and adult immunisations including tetanus, influenza and pneumococcal immunisations [31,32]. Currently self-reporting of these vaccinations have been described as problematic with limited validity and poor coverage estimates of 71–79% of influenza vaccine and 51–53% of PPV23 [31]. It is anticipated that with a ‘whole-of-life’ immunisation register, health outcomes can be improved further by identifying missed vaccinations and prevent over-vaccination [32]. The HPV register for instance would seem an appropriate extension of the ACIR. Other registers such as the Australian Donor Organ register and the bowel cancer screening register have been suggested to be included in this ‘whole-of-life’ register [32]. In 2006, the Australian Government Department of Health and Ageing funded a scoping study for the redevelopment of ACIR, the results of which are still pending [32]. A National Immunisation

Strategy commissioned in 2010 and yet to be released, is anticipated to consider this issue and will hopefully provide stimulus for action on a 'whole of life' register.

A well-documented cause of lower immunisation coverage particularly with ACIR is inadequate reporting of immunisation encounters by immunisation providers [1,33]. ACIR has been reported to underestimate immunisation coverage by up to 5% in most states [15]. Moreover, electronic exchange of information is unilateral between primary care software systems and ACIR resulting in the tedious task of manually updating vaccines already on ACIR through individual requests or manual practice reports. A study evaluating home immunisation in a socially disadvantaged area also highlighted under-reporting with discrepancies of 11-14% between ACIR vaccination status versus actual vaccination status when checked prior to the commencement of the study [34].

Other limitations in Australia include the unreliable reporting of 'additional' NIP vaccines recommended for special at-risk patient groups in ACIR and the potential impact upon GP reporting to the HPV Register after the removal of the financial incentive for notification of vaccination. In addition, ACIR coverage calculations and GPII outcome exclude established vaccines introduced after 1996 (thus excluding rotavirus, pneumococcal conjugate, group C meningococcal, and varicella vaccines). However, this issue will be addressed with the latter three vaccines being included in the list of immunisations to be assessed as fully immunised from July 2013 [20]. There is also the possibility of linking ACIR to electronic health records as a way to progress vaccine effectiveness evaluations as well as rapidly investigate vaccine safety signals at jurisdiction, national or international level [35]. However, federal and jurisdictional privacy regulations and the extreme difficulty of linking immunisation databases with healthcare outcomes for those patients, limits the Australian ability to investigate potential vaccine safety signals [36]. ACIR data have been used to determine the expected number of intussusceptions following rotavirus vaccination in a post-marketing safety study identifying a potential association of new rotavirus vaccines with intussusceptions in Australia [5]. It has also been linked with hospital data to illustrate a link between MMR vaccine and idiopathic thrombocytopenic purpura [6].

## Conclusion

Currently, Australia boasts a near-complete population-based childhood immunisation register with the ACIR. However, the obvious void of immunisation histories beyond seven years of age means that calls for a 'whole-of-life' register are ongoing. In addition, it only covers NIP routine vaccines introduced before 1996, and the HPV register sits separate to ACIR. These registers could provide a framework to expand immunisation registers linked to electronic health records. Limitations of current registers are still widespread, particularly with issues of under-reporting and

timeliness, which impact significantly to immunisation coverage estimates. Nevertheless, these available immunisation registers form a fundamental platform for further improvement in immunisation coverage. The linkage of these registers with healthcare outcome data will further enhance public health outcomes by enabling rapid, population-level vaccine safety and effectiveness investigations in a nation with a track record as an 'early adopter' of new childhood vaccines.

## Conflicts of interest

NWC and JPB have acted as chief investigators for epidemiological studies sponsored by vaccine manufacturers (CSL) and serological testing (Merck). All payments, including for sitting on advisory boards (NWC), data safety monitoring boards (JPB), lecturing (NWC) and travel expenses for attendance at scientific meetings, are paid directly to an administrative fund held by Murdoch Childrens Research Institute.

GR has accepted funding from vaccine manufacturers (GSK) to attend two scientific meetings and to sit on an advisory board, and has lectured at GP education events that have been sponsored by vaccine manufacturers (CSL, GSK, Wyeth, Sanofi).

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