

Immunisation Registries at regional level in Italy and the roadmap for a future Italian National Registry

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Parole chiave: Informatizzazione dei registri vaccinali, Italia, studio cross-sectional, vaccini

Abstract

Background. Immunization Information Systems, or Immunisation registries (IRs), are essential to monitor and evaluate the accessibility, quality and outcomes of immunisation programmes both at local and national level.

Study design. We conducted a cross-sectional survey in order to investigate and map the level of IRs implementation obtained by the 21 Italian Regional Health Authorities. On this basis we defined a roadmap towards implementing an Italian National IR.

Methods. We designed an online questionnaire. Data were collected from July to September 2016 from all the 21 Regional Health Authorities in charge of infectious diseases control and immunization management.

Results. 18/21 Italian Regions have fully implemented an IR, out of them, 11 use the same software for all Local Health Units. Two Regions have partially implemented their IRs and one Region is not yet computerised.

Conclusions. The decentralization of the Italian Health System is reflected also on the IRs characteristics and functionalities in terms of fragmented implementation of IRs and diversity in the software systems and data flows in place. Future efforts should not only aim not only to clarify the functionalities of Regional IRs, but should also aim to define how aggregation of data at national level can be optimised.

Introduction

Infectious diseases still are among the top ten causes of death, both in low and high income countries (1). Vaccination is an essential tool to prevent the diseases and their sequelae. For this reason, in the majority of the European countries, vaccinations are

mandatory or actively recommended by the Public Health Authorities (2).

In order to reduce the burden of vaccine-preventable diseases, monitoring of vaccination programmes is essential and, to achieve this, high quality data are needed. The impact of vaccination policy should be regularly assessed through

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measures of coverage, safety, effectiveness and equitable access (3). This is the reason why, since the early 2000s, Immunisation Registries (IRs) have been recognized as an essential component of vaccination programmes (4). The US Centers for Disease Control and Prevention (CDC) define IRs as: “confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area” (4). IRs are an important instrument to assess and monitor accessibility, quality and outcomes of immunisation programmes both locally and nationally. Electronic records can reduce public cost and increase quality, timelines and precision of coverage data. In other words, IRs can support both the clinical management of individuals and public health issues related to immunization. Firstly, IRs can be a clinical decision support system for physicians administering vaccinations. IRs can highlight possible risk factors, reduce missed opportunities (5) and increase the timeliness of vaccine administration. Secondly, from a public health perspective, IRs can provide updated data on vaccine safety, vaccine coverage, and can contribute data for the estimation of vaccination failures. IRs data can also specifically support public health authorities responding to outbreaks of vaccine-preventable diseases and promoting vaccine accountability (6-9).

In Italy, several vaccines are actively offered to the population and administered free of charge by public vaccination services. The Italian Health System is decentralized, therefore a National Immunisation Plan (NIP) providing a national strategy is issued by the Ministry of Health (10) but implemented at regional level. On this basis, 21 Regional Immunisation Plans (RIPs) are then produced, one each, by 21 Regions/Autonomous Provinces (hereby all called “Regions”). These Regional plans define the regional immunisation offers leading

unavoidably to heterogeneity in vaccine schedules and vaccination management across the country. In addition, the IRs, used for the local management of the vaccination programmes, can be dissimilar from one Local Health Unit (LHU) to the other, even within the same Region.

The Italian National Public Health Institute (Istituto Superiore di Sanità, ISS) conducted two surveys to map the distribution of IRs within Italy. In 2008, only nine Regions used IRs and, among those, only five used the same software in all LHUs (11). In the following years, IR use became more common in Italy. A second survey, conducted in 2011 (12), showed that 15 Regions used an IR covering all the territory, however only eight out of them used the same software in all LHUs. Among the remaining 6 Regions, 5 were partially computerized (with a range of LHUs using an IR from 25% to 92%) and one Region did not use IR at all.

Policymakers have been encouraging the implementation and the use of the electronic health records, including IRs, at local and regional level. In 2007, the Italian Ministry of Health, within the “MATTONI” (“Bricks”) Project, promoted and funded an inter-regional workgroup (13), whose primary aim was to define the minimum set of variables needed to compare data between Regions and to build up a national registry on immunizations; however, these variables have never been used for exchange or aggregation of data. Recommendation to implement IRs were also included in several national strategic documents, such as the National Plan for Measles and Congenital Rubella Elimination (14, 15), the National Prevention Plan (NPP) 2014-2018 (16) and the NIP 2017-2019 (10). The objective is “to complete the transition from paper to electronic immunisation registries, to increase data sharing between and within regional and national levels and to guarantee interoperability among electronic vaccination registries and other

population registries (such as infectious diseases surveillance databases, databases of adverse events following immunizations, civil registries, etc.)” (16).

Notwithstanding, a computerized tool to monitor vaccination coverage at national level is still missing. For this reason, the Ministry of Health is currently designing a national IR that could aggregate data from different regional and local IR systems.

In order to obtain an updated picture of IRs implementation in Italy and the degree of heterogeneity among systems in use, we conducted the present cross-sectional survey.

The purpose of this study was to map and characterize IR implementation across the 21 Italian Regions in order to inform the scientific and the National Health Service communities about the development of a national roadmap towards the implementation of an Italian national IR.

Methods

We performed an observational survey based on Regional Experts’ professional opinions. We designed an online questionnaire (SurveyMonkey®) to map the IR implementation in the 21 Italian Regions. We used a methodology borrowed from previous studies (11, 12) so that results could be compared with previous findings.

The survey contained 18 questions exploring IR implementation at regional level and/or in each LHU. Participants were asked whether the same IR was used in all the LHUs of the Region, the system’s characteristics including the frequency of data transmission and whether automatic calculation of LHU/regional vaccination coverage was possible.

The data requested were prepared and submitted online by the 21 regional coordinators for infectious diseases and vaccinations.

We classified a Region as fully implementing IR, when IR was used by all LHUs in the Region. When IR was used in a part or in no LHUs within a Region, we classified Regions as partially implementing IR or not implementing IR, respectively.

We analysed data using Excel. We performed a frequency analysis for all the categorical variables, reporting proportions. We then compared the results of this survey with those of the previous one, conducted in 2011, trying to show the advances in the implementation, if any.

Results

The survey was launched in July 2016 and data were collected until September 2016.

As shown in Table 1, all the 21 Italian Regions participated in the survey (response rate 100%). Eighteen/21 Regions (86%) were fully implementing IR. At the local level, 100/120 Italian LHUs (83%) were reported using IR. Among IR fully implementing Regions, 11 (61%) used the same software in all LHUs. Two Regions partially implemented IR (in 20% and 86% of the LHUs, respectively) and one Region did not implement IR at all.

Considering the use of IR for case-management, 11 of the 18 fully implementing Regions use IR to automatically list people who need to be called for vaccination and 8 Regions use IR to manage vaccination appointments. From a public health perspective, as reported in Table 1, twelve Regions use an IR able to make an automatic vaccination coverage estimation. Table 2 shows the main characteristics of the IR in place in the 11 fully implementing Regions using the same software in all LHU.

All LHUs are required to send data on immunization to their Regional Health Authorities. In eight Regions, all LHUs and Regional Health Authorities work on a single

Table 1 - Computerisation level of RIRs in Italy and data management at regional level, 2016

Level of computerization	Number of Regions	Number of LHUs with IIS	Regions able to calculate automatically the immunization coverage	Regions that have access to immunization data	Frequency of submission from LHUs to Regions
Full computerized and same software among LHUs	11	47/47	9/11	Individual data in real time = 7	Real time = 7
				Aggregated data* = 4	Biannual = 1 Annually = 3
Full computerized but different software	7	53/53	0/7	Individual data in real time = 1	Real time = 1
				Individual data = 3	Quarterly = 2 Biannual = 1
				Aggregated data* = 3	Annually = 3
Partially computerized and same software	1	1/5	1/1	Aggregate data* = 1	Annually = 1
Partially computerized but different software	1	6/7	0/1	Aggregate data* = 1	Annually = 1
No computerized at all	1	0/8	0/1	Aggregate data* = 1	Annually = 1

* only doses and the vaccination coverages are submitted

database and have access to immunization data in real time at every level. Three Regions reported receiving case-based data from the LHUs. The remaining ten Regions (including one fully implementing but without the same software in all the LHUs) reported receiving aggregated data (i.e. doses administered and vaccination coverage data)

(Table 1); data were not available in real time but aggregated and consolidated periodically (quarterly to biannually). The complexity of the distribution of IRs in Italy is shown in Figure 1.

Figure 2a and 2b show the percentage of Regions in which vaccination coverage data are available for the time period 2012-

Table 2 - Major characteristics of RIR, in the fully computerised Regions with or without the same software among the LHUs.

Characteristics	Number of Regions (%)
Capacity to list the persons to be invited for vaccination	11/11 (100)
Managing vaccination appointments	8/11 (72.7)
Printing of invitation letters	10/11 (90.96)
Producing a list of vaccination delays	9/11 (81.8)
Recording high-risk factors	9/11 (81.8)
Collecting information on reason for no vaccination	8/11 (72.7)
Managing vaccine storage	9/11 (81.8)



Fig. 1 - Existence and characteristics of the Regional RIRs in Italy, by Region, 2017

2014 - for all children and children at risk respectively - by antigen. Data availability is presented both for vaccine-preventable diseases targeted in the 2012-2014 NIP (Measles, Mumps, Rubella, Meningococcal C, Varicella, Pneumococcal) and for those not yet targeted (Rotavirus, Meningococcal B, Meningococcal ACWY).

Eighteen of the 21 Regions are planning to modify or implement the Regional Immunisation Register (RIR). Out of those, two are planning to increase interoperability among different data sources across the LHUs, five are involved in the implementation of additional IR software functionalities, nine are planning to implement a RIR and two to change software.

Discussion and conclusion

The decentralization of the Italian Health System has deeply affected the development of RIRs, their characteristics and functionalities. Data on immunization are sent to Regional Health Authorities in different ways and times, thus making it more difficult to estimate the vaccination coverage nationwide.

Investments need to be targeted not only to the purchase of the IR software but also to identify its optimal use, in order to achieve the objectives of the vaccination strategies (17), including the monitoring of the impact.

At the present, only eight Regions have

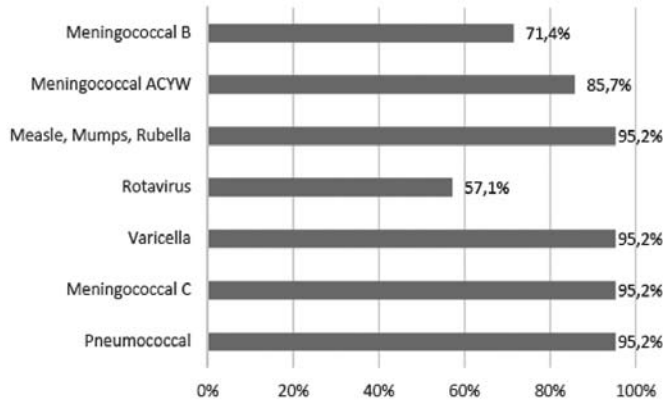


Fig. 2a - Percentage of Regions with coverage data available for paediatric vaccination included and not included in the Vaccination Plan 2012-2014, for children at risk

an optimal IR due to full implementation with access to individual data. In these Regions, regional authorities can therefore access immunization data from all LHUs in real time and LHUs can also have access to data of residents in other LHUs of the same Region.

The use of IR to improve the vaccination process management and to reduce workload (7) is still limited in Italy. Similarly, the use of IRs to automatically monitor vaccination coverage is not widespread.

Comparing these results with those obtained in the previous survey, it is evident that important improvements took place (12): the fully computerised Regions increased from 15 to 18 and the Regions that have access to computerised individual data from 6 to 11.

Unfortunately, due to the surviving high heterogeneity, it is not possible to set up a national immunisation registry in Italy simply using the same software. For this reason, all the future efforts have to improve

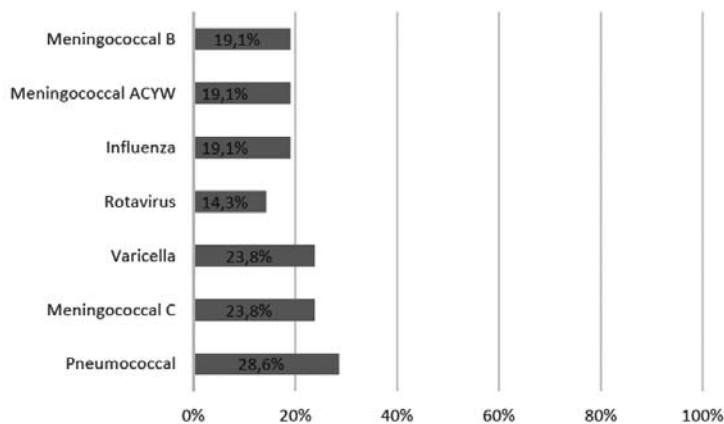


Fig. 2b - Percentage of Regions with coverage data available for paediatric vaccination included and not included in the Vaccination Plan 2012-2014, for children at risk

data management at regional level and data transmission to the national level in order to guarantee timeliness and quality in the transfer of data.

The patchy picture of the IRs at regional level, with different software, status of implementation and functionalities, has persuaded the Ministry of Health to define a national strategy starting from existing systems.

Based on the experience of another data flow established on individual data (i.e. oncologic screenings), the Italian Ministry of Health decided to use a model based on data transmission, from the 21 Regions, of individual anonymised records for each vaccination. Every record should include information on the person, on the vaccine, on the administration and the number of the doses and on the outcome of vaccination.

The Italian legislation does not allow to include information able to identify individuals if this does not contribute to the final purpose of the database. For this reason, this type of information will be ciphered. However the same code will be consistently assigned to the same individual for all vaccines and doses received in any Italian LHM. This coding system, based on non-identifying unique keys, could be used in the future to link this national IR (NIR) with the national adverse events database. For this reason the implementation of regional IRs (RIRs), covering in real time the entire territory, is strongly promoted. This objective is already present in the NIP 2017-2019 (10) and in the NPP 2014-2018 (16).

The implementation of a NIR will enable authorities to estimate vaccination coverage and to monitor the vaccination programmes in real time at regional level and - periodically - at national level. Conversely, the national IR will not include functions for managing vaccination offer and vaccine administration, that are needed only at local level.

The Ministry of Health will start in 2017 a pilot project, already funded for the first year,

with the main objective to define in detail the characteristics of the national IR, including the data format to be used to collect records from the Regions.

Individual high quality data on vaccination status is vital to assess vaccination strategies and to measure vaccination compliance from the population. Vaccination coverage is one of the pillars of this monitoring system. Electronic systems can support the collection and analysis of these data. This analysis highlights which Regions are more successful in the adoption and implementation of RIR. As long as RIRs are not fully implemented in all Italian Regions, it is not yet possible to have a “near real-time” national overview of the performance of vaccination programmes.

Future efforts should be centered on mapping progress towards implementation of RIRs and on how to optimise vaccination record aggregation at national level (avoiding duplication and compensating for missing records).

Finally, it is also important to research how the RIRs can exchange vaccination records to guarantee to every citizen the access to an updated vaccination certificate also when people move from one Region to another within Italy.

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Riassunto

Le anagrafi vaccinali regionali ed il percorso verso un sistema unico nazionale

Introduzione. A partire dagli anni 2000, le anagrafi vaccinali informatizzate (AVI o registri vaccinali informatizzati), sono considerate essenziali nei programmi di vaccinazione. Esse rappresentano uno strumento importante di valutazione e monitoraggio dell'accessibilità, della qualità e dei risultati ottenuti dai programmi di immunizzazione, sia a livello locale che nazionale.

Disegno dello studio. È stato condotto uno studio *cross-sectional* mirato a valutare le diverse fasi di implementazione delle AVI nelle 21 Regioni/PP.AA al fine di descrivere la tabella di marcia necessaria allo sviluppo, in Italia, di un Registro Vaccinale Nazionale.

Metodi. I dati sono stati raccolti mediante un questionario elettronico (SurveyMonkey®), inviato ai referenti per le attività vaccinali delle 21 Regioni/PP.AA. L'indagine è stata avviata nel mese di luglio 2016. Al sondaggio hanno partecipato tutte le Regioni/PP.AA, con un tasso di risposta del 100%.

Risultati. Le 21 regioni/PP.AA. comprendono 120 Aziende Sanitarie Locali (ASL); di queste, l'85,7% dispone di una AVI completamente informatizzata. 11 Regioni/PP.AA usano lo stesso software tra le proprie ASL, mentre 7 Regioni usano software differenti; due regioni sono parzialmente informatizzate e una regione non lo è affatto.

Conclusioni. Il decentramento del Sistema Sanitario Nazionale si riflette nella diffusione frammentata delle AVI con diverso livello di implementazione, caratteristiche ed operatività. Ulteriori futuri sforzi dovrebbero mirare a rendere omogenee le funzionalità delle AVI, e a comprendere come ottimizzare il sistema, permettendo di verificare in qualsiasi momento lo stato di vaccinazione di ogni cittadino.

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