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National Immunization Program: Computerized System as a tool for new challenges

Programa Nacional de Imunização: Sistema Informatizado como opção a novos desafios

ABSTRACT

The scope and coverage of the Brazilian Immunization Program can be compared with those in developed countries because it provides a large number of vaccines and has a considerable coverage. The increasing complexity of the program brings challenges regarding its development, high coverage levels, access equality, and safety. The Immunization Information System, with nominal data, is an innovative tool that can more accurately monitor these indicators and allows the evaluation of the impact of new vaccination strategies. The main difficulties for such a system are in its implementation process, training of professionals, mastering its use, its constant maintenance needs and ensuring the information contained remain confidential. Therefore, encouraging the development of this tool should be part of public health policies and should also be involved in the three spheres of government as well as the public and private vaccination services.

DESCRIPTORS: Immunization Programs. Electronic Health Records. Medical Records Systems, Computerized. Immunization Coverage.

RESUMO

A abrangência e desempenho do Programa Nacional de Imunização no Brasil são comparáveis aos de países desenvolvidos, pois oferece número elevado de vacinas e cobertura considerável. A crescente complexidade do Programa acarreta desafios inerentes ao seu desenvolvimento, em relação à manutenção de coberturas vacinais elevadas, equidade de acesso e segurança. O sistema informatizado de imunização, com dados nominais, é um instrumento inovador para o monitoramento preciso desses indicadores e permite a avaliação de impacto das novas estratégias de vacinação. Suas principais dificuldades estão no processo de implantação, treinamento dos profissionais, domínio da tecnologia, e sua constante manutenção e garantia da confidencialidade das informações. O incentivo ao desenvolvimento dessa ferramenta deve fazer parte das políticas públicas em saúde e contar com o envolvimento das três esferas de governo e das redes de vacinação pública e privada.

DESCRIPTORES: Programas de Imunização. Registros Eletrônicos de Saúde. Sistemas Computadorizados de Registros Médicos. Cobertura Vacinal.

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Received: 10/16/2014

Approved: 1/11/2015

Article available from: www.scielo.br/rsp

INTRODUCTION

The scope and performance of Brazil's National Immunization Program (NIP) is comparable to those of developed countries.¹⁰ The program is growing in complexity both because a number of vaccines have already been made available in the routine schedule in a short period of time, and due to the inclusion of combined vaccines and the supply of already available vaccines to population groups who were not, until recently, covered by the program.⁶

This advance brings undoubted benefits, but it also highlights the challenges that are inherent for the development and success of the NPI, such as: logistical issues (cold chain and production of immunobiologicals); maintaining a homogeneously high coverage for all vaccines; verifying and monitoring the perceived risk of the disease and of adverse events following vaccination (AEFV); identifying factors that are associated with noncompliance; and preventing already controlled diseases from reemerging.^{6,13,23}

Incorporating new technologies, such as computerized systems for recording vaccination with nominal data, is critical to maintain the good quality of this program.^{3,12,13,16,23} These systems are useful tools for scheduling vaccinations, identifying and searching for missing patients and monitoring vaccination coverage and AEFV.¹² In addition, together with other information systems in health and the sociodemographic, it shows itself to be an important tool for planning and evaluating public health activities.¹²

The NPI Information System (NPI-IS), which stores nominal data, is in the process of being implemented and can be seen as a tool to address the aforementioned challenges.

The aim of this article is to discuss the computerized system's potential regarding vaccination and important aspects such as vaccine coverage evaluation, adverse events monitoring and academic research, as well as its challenges and limitations.

IMMUNIZATION INFORMATION SYSTEM

Since the 1970s, some countries such as Great Britain, the United States (USA) and Canada began using Immunization Information Systems (IIS) to make the vaccination programs more integrated.¹²

The IIS is an electronic, confidential and population-based database designed to collect and consolidate vaccination data to be used for conceiving and maintaining effective immunization strategies.³

In operational terms, the IIS can provide consistent information regarding vaccination history of

individuals throughout their life. The system automatically gives notification when a vaccination is due and when it is late. It also provides active AEFI monitoring and helps giving indications and contraindications as well as information about a vaccine's shelf life and availability.

At the populational level, an IIS is important to provide monitoring, evaluate responses to outbreaks, verify disparities in immunization coverage and offer decision-making support. With a better coverage, the rates of immunopreventable diseases are reduced, which makes the IIS an important tool for planning health services and evaluating the care that is provided.^{3,12}

IIS in Brazil

In Brazil, municipal and national initiatives that focus on developing information systems in health show a tendency to incorporate these instruments in their services and management. The *Cartão Nacional de Saúde* (National Health Card) was an important step as it integrates different sources of electronic information from patients/users and builds a health database using the citizen's identification number.⁴ This is in alignment with the *Mais Saúde* (More Health) strategic plan, in the Management Training plan, and aims to promote access to health services that is equal for all.

Specifically in the area of immunization, Brazil has relied on important instruments since the 1990s. The oldest IIS is in Serviço Especial de Saúde de Araraquara da Faculdade de Saúde Pública da Universidade de São Paulo (USP), which was developed by the Centro de Tecnologia da Informação de São Carlos (USP). In 2009, a survey was published and included information stating that IIS existed in 62 Brazilian cities.¹² It is believed that this number is currently higher, as the NPI-IS, in the process of being implemented, has been functional in some cities since 2010.⁶

Currently, the flow of information from the NPI makes it possible to perform monthly follow-ups of vaccination activities regarding the quantity of distributed and applied doses, coverage and AEFI.⁶ This system has limitations that arise from calculating immunization coverage, which makes use of population estimates in the denominator and records applied doses in the numerator. Results are influenced by incorrect data caused by migration, populational mobility and errors in the estimation of the population and applied doses.

During the quest to improve the quality of information, the NPI-IS was developed and is in the process of being implemented that will make it possible to evaluate coverage more accurately and identify vaccinated individuals. The NPI-IS will gather together, in a single database, subsystems that will provide data regarding vaccination coverage and dropout rate, in addition to AEFI

and immunobiological calculations used in the network and at Reference Centers for Special Immunobiologicals.

Among the data in the system, it is possible to identify the vaccinated and their origins, allowing the unvaccinated to be found and given a dose. The single identifying number used in the NPI-IS will be the one shown on the “National Health Card”, which will subsequently allow different national databases to be related together.⁶

IIS POTENTIAL

Vaccine coverage evaluation

Brazil has a good level of vaccinal coverage, however this is not uniform.⁶ Surveys indicate an inequality in vaccinal coverage in Brazilian cities and areas of low intramunicipal coverage.^{1,23} Generally speaking, studies show that areas with the greatest coverage are those with the worst socioeconomic indicators, which suggest equal access to vaccine.^{1,13} However, more investigation is necessary to discover if this situation happens in different contexts, namely in the Brazilian reality. In addition, it is also important to consider private medical care in the population's vaccination, as this group has a strong participation in such.

The IIS will improve this evaluation because it makes it possible to evaluate complete immunization schedules, validity of applied doses (minimum time gap between doses) and timely or late vaccine administration. However, it is worth highlighting the importance of monitoring vaccinal coverage, while considering different aspects and allowing micro-areas with lesser coverage to be identified.

Moreover, the IIS increase vaccinal coverage by scheduling vaccination (remind) and identifying and searching for missing patients (recall).¹² Studies indicate that these reminding systems improve coverage in children and adults for all vaccines. Reminding strategies range from phone calls, which are the most effective, to letters and home visits.¹¹

Studies have also evaluated automatic text messages to individuals reminding them about their vaccination. During a randomized and controlled trial, performed in the USA and aimed at children and adolescents to have a vaccination against influenza, an increase in vaccinal coverage was observed, despite still remaining low.²¹ Another evaluation of this strategy's effectiveness, which was performed in Great Britain, exemplifies the importance of this instrument.⁹

Monitoring adverse events

As vaccination programs achieve their objective of controlling diseases, vaccine safety becomes a more

obvious question due to the decrease in risk perception surrounding immunopreventable diseases and the increase in AEFI awareness.²⁴ Additionally, the increased frequency of combined vaccines being introduced has made evaluating these events even more complex.

IIS make it possible to create an active AEFI monitoring system and can assist in vaccine pharmacovigilance. Results from a study that investigated the viability of this strategy were positive and promising, especially for detecting predefined signs of these events. One major challenge is defining which AEFI should be monitored and what magnitude of change, in its frequency, should be a trigger for alert.⁵ Another example was the active AEFI monitoring with the Vaccine Safety Datalink in the USA.²⁵ This compared the observed number of AEFI with the expected number, with the base being the known rate from previous periods. Whenever the observed number was larger than what was expected, the manager was sent an alert. Only ten alerts were sent over a three-year period, one of these being genuine; however, it was this that was responsible for the change in immunization policy in the USA.²⁵

The introduction of combined vaccines enabled this Program's operationalization (immunogens being applied for various diseases in a single injection); however, AEFI evaluation was made difficult as was immunobiological safety as a result.⁷

Therefore, IIS instruments have potential for the evaluation of AEFI because they improve data quality, better define the outcomes and make comparisons between groups more effective.²⁴

Research opportunities

IIS can reduce fragmentation in vaccination records and improve service provision. This resource also makes it possible for the data to be used in vaccine efficiency studies, with methodological advantages over traditional observational ones.

The availability of individualized information means that cohort studies can be performed. These kind of studies can be conducted even in conditions where a disease has a low frequency of incidence, which is due to the vast quantity of data that is available. The comprehensive and accurate nature of information regarding the state of individual vaccination definition avoids differential bias between cases and controls. However, the IIS demands a clearly defined population-base and accuracy in recording vaccination for studies to achieve validity.^{8,14} A paired case-control study,²⁰ based on the UK General Practice Research Database, exemplifies the use of IIS in research. This research showed that the vaccination against measles, mumps and rubella was not associated with an increased risk of autism or specific developmental disorders.²⁰

IIS are useful tools as they assess the impact of immunization programs by evaluating vaccines' effectiveness on different populations, contexts and diseases. However, information quality and IIS representativeness must be carefully monitored (vaccination data), as well as data regarding the incidence of the disease in question.

Various vaccines have been introduced in the NPI during the last decade. However evaluations must be performed regarding their effectiveness, while considering the different contexts, given the continental dimensions of Brazil and the large regional disparities.

IIS CHALLENGES AND LIMITATIONS

In spite of the advantages of having electronic health records, studies have highlighted the gap between the expectations and the improvements taking place in the service.^{2,15} A lack of integration within health care and quality heterogeneity in the comprehensiveness and accuracy of data stand out among the principle problems.¹⁵ Implementing the instrument demands, in addition to acquiring and maintaining the technology, an organizational change, financial incentive, certification criteria, interoperability standards and participation in the national health policy agenda.¹⁹

IIS also face challenges concerning its operationalization, integrality and data quality (duplicity and under-recording), as well as in its technology implementation process in Brazil and ability to guarantee information confidentiality.¹²

The NPI-IS, developed by the Brazilian Unified Health System (SUS), is already being used in some cities of our Country. In addition, some sites have their own systems that have the ability to export archives to the NPI-IS. In 2012, by way of Decree 2,336/2012, the Brazilian Health Ministry built 34,000 vaccination rooms, for the public network, that were equipped with computer systems.

Training for the professionals of the services and monitoring in health also requires effort from the municipal, state and national health bodies. Moreover, the private health sector must be involved in this process.

The NPI has already performed various training schemes with view to implement the NPI-IS in a timely manner. The team that is responsible for the tool has also made video-lessons and has been constantly updating an instructive manual that contains information regarding the system's resources, and how to use them. Furthermore, some states, such as Sao Paulo, have been using the Internet to update themes related to vaccination.

The initial NPI-IS system is a desktop version and can only be used offline, with the local health departments being responsible for sending data directly to the NPI, doing so by sending encrypted file on the website. The online system is currently in development. Therefore,

other challenges inherent to NPI-IS system implementation are: having a good quality internet connection; a suitable and timely vaccination record when the system is offline; duplicate records, because vaccination rooms in the same municipality are not able to communicate with each or constantly update data, so that an individual registered in one health care facility is likely to be re-registered in another unit in the same city.

Studies have shown that IIS have good cost effectiveness attributes, with better performance in areas that have low vaccinal coverage and a larger scale operation. Costs can grow when new functions are added to the system, such as vaccine management, alerting for adverse events and connecting with other databases. However, the benefits certainly outweigh the costs, given that individual information makes it possible to better assess vaccination activities.¹² In addition, due to the fact that the vaccination schedule is complex in regarding the recommended age for each vaccine, intervals between doses and the high number of immunobiologicals, IIS may assist to operationalize vaccination activities, as they can define when the next vaccine dose will be for every child.

About the research incentive, developing innovative instruments has been among the themes of the Brazilian National Agenda for Research Priorities in Health, which was created in 2003.¹⁸ These incentives in innovation and technological development, whether in vaccine production, in the cold chain or in the information system, have reflected favorably on the development of the NIP.

FINAL CONSIDERATIONS

IIS provide more consistent data than estimates that are based on applied doses for evaluating vaccinal coverage and AEFI, which makes the tool important for planning and evaluating activities with a view to increase the number of vaccines applied.

Using this system means that areas with low coverage can be identified, thereby improving social equality for the access to immunobiologicals and health care in general. It also made active AEFI monitoring possible, which must be a priority with combined vaccine being introduced. IIS that are related to other nominal databases are useful sources of information for studies that evaluate the impact of vaccines.

The NPI-IS can be considered as a strategy to integrate nominal data from Brazilian individuals, which began from a pivotal public policy. Therefore, the system's implementation and evaluation should have a place on the national political agenda and involve both the government, as well as the population and public and private services. These conditions can make it possible to create a comprehensive computerized system and integrated health care to meet the demands of a complex immunization program.

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