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ORIGINAL ARTICLE

Result of a model of management of special vaccines

Resultado de un modelo de gestión de vacunas especiales

Sylvina Alvarado[a,b,c], Ernesto Paya[b,c], María Teresa Valenzuela[a], Rodolfo Villena[b,c]

[a]Faculty of Medicine, Master of Epidemiology, Universidad de Los Andes, Santiago, Chile
[b]Faculty of Medicine, Universidad de Chile, Santiago, Chile
[c]Dr. Exequiel González Cortés children's hospital, Santiago, Chile

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Abstract

Introduction: Special vaccines recommendation patients are a growing population. The Ministry of Health has developed a special vaccination program for these cases, through which our hospital manages vaccine forms by an established flowchart. **Objective:** To describe the special vaccines model of management results in the period between March 2015 and September 2016, and the clinical and demographics characterization of the pediatric population benefited with this program in Dr. Exequiel González Cortés Children´s Hospital. **Patients and Methods:** We performed a descriptive observational study, which covers the chronically ill patient's population who received special vaccines during the period between March 2015 to September 2016. **Results:** A total of 367 vaccine schemes were administered to 215 patients, with a total of 405 vaccines administered during the period. The medical specialties that most requested vaccines were infectology (39.1%), immune-rheumatology (24.2%) and bronchopulmonary specialists (20%). The National Immunization Program authorized 97.8% of the requested schemes (n = 359), the response time had a median of 15 days (range 0-174 days), the vaccination opportunity had a median of 41 days (range 0-287 days) and the total of schemes completed at the time of tabulating the results was 52.8%. **Conclusions:** Vaccines are one of the main public health equity policies and Chile has special vaccines request flowchart a flow chart, which requires a multidisciplinary work to provide coverage to this vulnerable child population.

Keywords:
Vaccines,
vaccine schedule,
chronic diseases

Correspondence:
Sylvina Alvarado
sylvina.alvarado.fick@gmail.com

Introduction

The pediatric patients that require specific recommendations of vaccination are the growing population within the public health system users and may present pathologies with an increased risk of immuno-preventable diseases. For this reason, staying up-to-date with their immunizations is critical to improve the protection and decrease the severity in case of acquiring one of them[1]. Various scientific articles, national and international guides recommend scheduled vaccines to use in these groups[1-6]. In general, these recommendations point to the importance of a personalized evaluation, adjusting the scheduled vaccines to the patient history and the potential risks in order to focus the work in the administration of the vaccines in a safe and effective manner[1-4]. The National Immunization Program (PNI) of Chile has given progressively protection against communicable diseases since its inception in 1978, covering currently 15 immuno-preventable diseases[7,8]. As complementary support, the PNI provides a model of management of special vaccines with an established flow (see flow diagram)[8] that allows us to provide a benefit and an opportunity of greater protection to different population at risk. This management model consists in the individual evaluation by the clinical team, who solicits the non-considered scheduled vaccines under the PNI through a medical prescription and a specific form. Then, the organization, disposal, regulation, and insurance of the medical requests to PNI are carried out by the local nurse in charge in the wait of PNI answer via email. With the answer, the patient is localized to the final administration of scheduled vaccine, considering all the time what is established in the technical norm about standard operating procedures to ensure quality in the program execution[9].

The aim of this study is to describe the results of the model of management of special vaccines implemented in our institution, for the period March 2015 to September 2016, and characterize clinically and demographically the child population beneficiated by this program in the Children's Hospital Dr. Exequiel González Cortés (HEGC).

Patients and Methods

Study design

A descriptive, observational study of the pediatric population that needed vaccines of the ministry program of special vaccines attended in the HEGC, according to the base pathology and the vaccination status for the period March 2015 to September 2016. The HEGC is a high-complexity pediatric hospital of southern area of Santiago de Chile depending on the public health system. The information is obtained from the databases of the registration of requests of HEGC and the control of special scheduled vaccines of the person in charge of local PNI. This study was authorized by Teaching, Investigation, and Innovation Unit depending on the Directory of HEGC.

Patients

The data of all the patients that were managed in the program of special vaccines of PNI. The patients were evaluated by their treating physicians, who requested scheduled vaccines or referred to infectology for that purpose. Then, the local responsible of PNI verified the vaccination status of those whose information was available in the software of the ministry of the National Immunization Register (RNI), then he derived the request to the central level, and, once approved, patients and their families were contacted to coordinate the vaccination and after the administration he registered the information in the RNI.

The patients were classified according to their clinical situation or chronicity in chronic outpatients, outpatients, and inpatients. The patients defined as chronic outpatients are those who were on regular medical monitoring in the office next to the Specialities Department (CAE) in one of the medical specialties. The acute patients that consult in the CAE and require special vaccines are known as outpatients. The patients that are hospitalized for long stay are defined as inpatients.

For the clinical characterization and demography, it was described the variants of age, sex, health insurance, medical speciality that requested the vaccine, chronicity, and vaccines administered. The health insurance was described according to those with no health insurance, the levels of the National Health Fund (FONASA) and the Programme of Compensation and Comprehensive Health Care (PRAIS) that correspond to an compensation instrument of the Ministry of Health, which respond to commitment assumed by the State with the victims of human rights violations, occurred between September 1973 and March 1990.

Evaluation of management model

For measuring the results of model of management of special vaccines of HEGC, indicators were used:

Authorization of scheduled vaccines by the PNI: a schedule is considered authorized when the PNI responds positively to the vaccination of the patient with the requested schedule and it is measured by the total percentage of requested schedules in the period.

Scheduled vaccines completed: a schedule completed is one that meets the total of the vaccines planned in the schedule by the medical indication in the evalua-

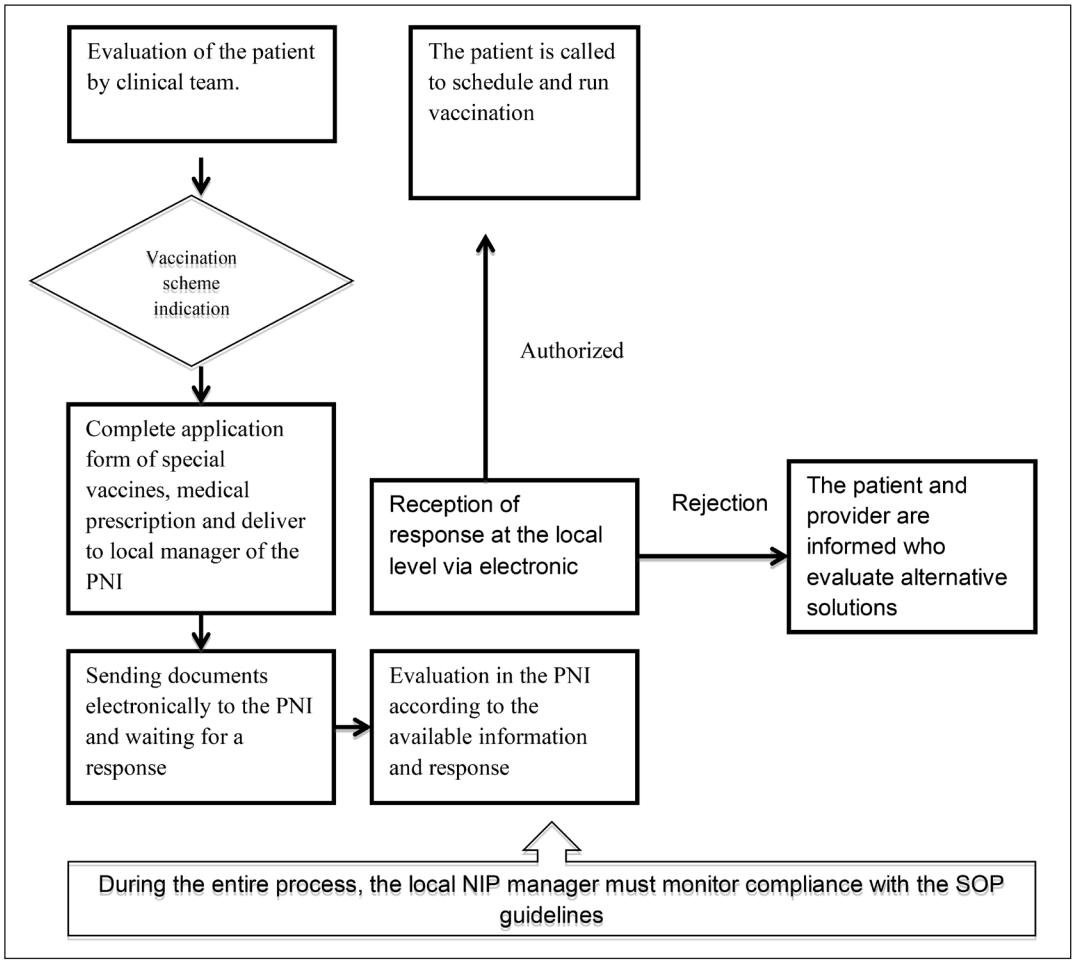

Figure 1. Flowchart of management of special vaccines for patients in HEGC during the period 2015-2016.

ted period, and it was measured in the percentage of the total of requested schedules for each vaccine in the period.

Response time of PNI: it is defined as the time that passes from the moment of the request of special schedule is sent to the PNI to the moment of the response of authorization or rejection is received, and it was measured in the number of calendar days grouped for 2015-2016.

Vaccination opportunity: it is defined as the time that pass since it is requested the special scheduled vaccine is sent to the PNI to the initiation of the vaccination of patient by the schedule. It was excluded from this measurement the patients whose mothers have HIV, since vaccines are requested to them from the first month of life and their schedule start at the two months of life. It was measured according to the number of calendar days grouped for 2015-2016.

Statistical analysis

For the data analysis, it was used central tendency statistics for continuous variables and position statistics for categorical variables. The data were collected in an Excel spreadsheet and they were analyzed with STATA 14.

Results

In the study period, it was managed 367 scheduled vaccines for 215 patients, 43.7% corresponding to men (n = 94), with a median of age of 89 months (range 0/228 months) with a total of vaccines administered until November 30, 2016. In relation to the classification of the type of patient, 88.8% (n = 191) corresponding to the chronic outpatients, acute patients were 4,7% (n = 10), and 6.5% (n = 14) were inpatients (Table 1). Since the indication of vaccines is individual and it will depend on the base disease and the immunization status of each child, there are not standardized schedule but orienting recommendations that are described by diagnosis in the Table 2.

98.9% (n = 363) of the schemes were authorized by PNI and 1.1% (n = 4) of the schemes were rejected. These rejections corresponded to varicella vaccines,

Table 1. Clinical and demographic description of the children

Demographic and clinical variables	n = 215	
Age in months (median / range)	89	0/228
Sex	n	%
Mens	94	43,7
Health forecast	n	%
FONASA A	116	54
FONASA B	36	16,7
FONASA C	21	9,8
FONASA D	27	12,5
PRAIS	6	2,8
Without foresight	9	4,2
Medical specialty that requested the vaccine	n	%
Infectology	84	39,1
Inmunoreumatology	52	24,2
Bronchopulmonary	43	20
Pediatrics	14	6,5
Oncology	11	5,12
Gastroenterology	5	2,3
Nefrourology	4	1,9
Neurology	2	0,9
Chronicity	n	%
Chronic ambulatory	191	88,8
Ambulatory	10	4,7
In-patient	14	6,5
Vaccines administered	n	%
Total	405	100
Pneumococcal conjugate 13V	77	19
Adult hepatitis B	77	19
Hexavalent	69	17
Pneumococcal polysaccharide 23V	63	15,6
Pediatric hepatitis A	49	12
ACWY conjugate meningococcal vaccine con TT/CRM_{197}	29	7,2
Tetravalent HPV	19	4,7
Pentavalent	12	2,9
SRP vaccine monodose	5	1,2
Injectable inactivated polio	2	0,5

meningococcal ACWY combined with $CRM_{197,}$ quadrivalent human papillomavirus, and 23-valent pneumococcal polysaccharide, in only one case it was due to an error in the indication. Regarding the response time of PNI to the request of vaccines, this had a median of 15 days, varying between 30 days (range 0-174) in 2015 and 4 days (range 0-119) in 2016. Lastly, the vaccination opportunity had a median of 40 days (range 0-287) in 2015 and 35 days (range 0-253) in 2016 (Table 3). The figure 1 shows the flow diagram of management of special vaccines for patients in HEGC for 2015-2016 period.

Discussion

The vaccines are one of the main equity policies in public health care, being provided for free through PNI to the whole target population for its vital cycle, primarily at a pediatric age. There are patients that require specific recommendations of vaccination since they are susceptible to immuno-preventable infections or cannot receive programmatic vaccines. Our PNI has special request procedure of vaccination for these cases, whose management to access them require of coordinated work of the health team with the Ministry, bringing these benefits to a growing number of patients that come from different specialities. The number of patients with special vaccines processed was increasing in time, the value of effective coverage of the programme could not establish be in this moment since the design describes those patients that were requested special vaccination and not an analysis of all the patients that are controlled in CAE, but provides an orientation in relation to this increasing demand that we have in pediatrics. Nevertheless, the relevance of disseminating of the procedure to improve our coverage in this population is evident and the challenge of knowing the vaccination status of all our patients in control in order to know the effective coverage is evident, which requires to count on the transversal contribution of the health team, ideally exclusive and trained human resource for these purposes in order to disseminate and train the clinical team. Proof of this are the few referred patients from neurology and the absence of request from cardiology, genetic, and endocrinology, among others. The high rate of approval of the requested vaccines reflects the coordinated work between the hospital team and the PNI, through the local in charge. The wide variation found in the latency of the response to the request could complicate the adherence to the vaccination, and the loss of opportunity would impact on the decrease of the immunogenicity in the cases in which the immunosuppressive therapy started before completing the scheduled vaccines, which must be considered by the team members to optimize the moment of request of special vaccines. The reasons for the wide dissemination of the response time from PNI are unknown to us, however, regularly we keep contact with them to activate the pending requests. The existence of children that had an effective vaccination over the 250 following days to the authorization was due to the geographical distance of some, those who coordinate the vaccination the day of the medical control. These situations could improve through a ministerial norm of recommendations for groups at risk or specific situations that do not require procedure of the central authorization, but local certification of health condition, which might decrease the necessity of re-

Table 2. Medical diagnoses and special vaccines recommended in HEGC patients during the period 2015-2016

Medical diagnoses[#]	Special vaccines recommended[&]
ESAVI to pentavalent vaccine	Hexavalent[1]
Son of an HIV mother or father	Hexavalent[1]
Candidate for solid organ transplantation	PCV 13[2] Pneumococcal polysaccharide 23 valent Meningococcal vaccine ACWY - TT[3] Hepatitis A HPV tetravalent[4]
Functional/surgical asplenia	PCV 13[2] Polisacárida neumocócica 23 valente Antimeningocócica ACWY - TT[3] / CRM $_{197}$[5]
User of biological therapies	PCV 13[2] Pneumococcal polysaccharide 23 valent Meningococcal vaccine ACWY - TT[3] Hepatitis B Hepatitis A
Pyoderma gangrenosum	PCV 13[2] Meningococcal vaccine ACWY - TT[3]
Juvenile idiopathic arthritis/Systemic lupus erythematosus	PCV 13[2] Pneumococcal polysaccharide 23 valent Meningococcal vaccine ACWY - TT[3] Hepatitis B Hepatitis A
Primary immunodeficiencies	PCV 13[2] Pneumococcal polysaccharide 23 valent Hepatitis A
Deficiency of specific pneumococcal antibodies	PCV 13[2]
Chronic lung damage	PCV 13[2] Pneumococcal polysaccharide 23 valent
Recurrent respiratory infections	PCV 13[2] Pneumococcal polysaccharide 23 valent
Severe asthma	PCV 13[2] Pneumococcal polysaccharide 23 valent
Cystic fibrosis	PCV 13[2] Pneumococcal polysaccharide 23 valent
Nephrotic syndrome	PCV 13 Pneumococcal polysaccharide 23 valent Meningococcal vaccine ACWY - TT[3] Hepatitis A
Chronic kidney disease	PCV 13[2] Pneumococcal polysaccharide 23 valent Hepatitis B Hepatitis A
Hematological neoplasms	Hexavalent PCV 13[2] Pneumococcal polysaccharide 23 valent Hepatitis B Hepatitis A
Long hospital stay	Hexavalent[1] IPV Pentavalent[6] Vacuna tresvírica[7]
Crohn's disease/ Ulcerative colitis	PCV 13[2] Pneumococcal polysaccharide 23 valent Meningococcal vaccine ACWY - TT[3] Hepatitis B Hepatitis A
Autoimmune hepatitis	Hepatitis A Hepatitis B
Neurofibromatosis	PCV13[2] dTpa
Cardiopathy	Pneumococcal polysaccharide 23 valent
Pulmonary hemosiderosis	PCV 13[2]

[#]Not applicable for victims of sexual violence. [&]Vaccinations against varicella were not requested because it was rejected the first time mentioning that the ministry did not have it for this program. *Includes sickle cell anemia and thalassemia. [1]Hexavalent vaccine Infanrix® (Glaxo Smith Kline): includes diphtheria, tetanus, acellular pertussis, hepatitis B, polio 1,2,3 virus and Haemophilus influenzae type b. [2]PCV 13 vaccine: Prevenar 13® (Pfizer): 13 valent pneumococcal conjugate vaccine. [3]Meningococcal vaccine ACWY-TT: Nimenrix® (Pfizer) tetravalent meningococcal vaccine against serogroups ACWY conjugated with tetanus toxoid. [4]HPV vaccine tetravalent: Gardasil® (Merk Sharp & Dohme): recombinant vaccine against human papilloma types 6, 11, 16 and 18. [5]Meningococcal vaccine ACWY-CRM$_{197}$ Menveo® (Glaxo Smith Kline) tetravalent semen anti-meningococcal vaccine ACWY conjugated with mutant diphtheroid CRM$_{197}$. [6]Pentavalent vaccine (Serum Institute of India): includes diphtheria, tetanus, cellular pertussis, hepatitis B and Haemophilus influenzae type b. [7]SRP vaccine: (Serum Institute of India): includes measles, rubella and mumps virus.

quiring analysis from PNI optimizing its response for most complex cases and improving the opportunity for the patients. While the study was not designed to evaluate the safety of the vaccines, for the analyzed period events supposedly attributable to vaccination and immunization (ESAVI) were not presented.

The promotion of ministerial guidelines for special scheduled vaccines is a need, since what is available in the PNI web does not contain clinical guidelines but the request procedure, to all those health professionals in charge of indicating vaccines to the patients at risk count with approval and supported schedules, that accelerates the flow diagram and the principal goal that is to protect the individual and also the community.

Table 3. Indicator result variables

Total of managed schemes	n = 367	
	n	%
Esquema de vacunación autorizados por el PNI	359	97,80%
Scheme of vaccination authorized by the PNI	122	52,8%
PNI response time (calendar days)	median	range
Total	15	0-174
2015	30	0-174
2016	4	0-119
Vaccination opportunity (calendar days)	median	range
Total	41	0/287
2015*	40	0/287
2016*	35	0/253

*Revised schemes as November 30th, 2016.

Our local goals to improve the vaccination service of patients is to count on medical staff and exclusive infrastructure for the execution of special vaccination. At the end of this article, a protocol of safe vaccination for special cases was developed, a technical paramedic was recruited exclusively for our patients vaccination, and infrastructure was compromised to carry out this activity. Furthermore, with the aim of improving the effective coverage, the clinical teams of bronchopulmonary and the child and adolescent with special necessities in health care (NANEAS) are working on a registry of their patients and their vaccination status to evaluate and program special schedules if they need.

In conclusion, the program of special vaccines of PNI is a benefit for our patients with high risk of immuno-preventable infections. In order to access it, there is a flow diagram that can and has to be implemented in each health center, public or private. The response time of PNI could decrease if there were preset recommendations for different morbid conditions. We must improve the dissemination of this program among health teams to optimize its coverage.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Financial Disclosure

Authors state that no economic support has been associated with the present study.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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