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Covid-19 Vaccination Advantages of Opting for an Active Pharmacovigilance Model

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Abstract

Background: To measure vaccination`s risks it exists the term "events supposedly attributed to vaccination or immunization" (ESAVI). ESAVI monitoring usually consist in passive surveillance based on voluntary notifications done either by beneficiaries or by health professionals. The spontaneous reports are scarce compared with active surveillance. Unfortunately; active methods performed by health service are expensive, laborious and unfeasible due to the few health personnel available.

Objective: to evaluate the efficacy of an active method for ESAVI reports associated to COVID19- vaccines performed by university students.

Methods: a research comparing two Pharmacovigilance methods for COVID-19-ESAVI was performed (passive vs active surveillance with participation of university students) from May to September 2021.

Results: At the end of the study period, in Argentina 52.786.324 anti-COVID-19 vaccines were applied (1st dose 56, 86%; 2nd dose 43, 14%), and 102.358 ESAVIs were validated (1st dose 74, 75%; 2nd dose 23, 96%; other dose 0, 5%; No data 1, 24); 2, 16% among them were considered severe. Although female/male vaccination/ratio was similar (50.31% vs 49.67%), ESAVI were much more reported by females (72.8%). The active pharmacovigilance experience was performed by 933 students-volunteers. They contacted 56,824 vaccinated people; obtaining 39,952 "positive" calls (either "no events" or "potential ESAVI" results). The monthly contacts performed by students were 14,206±1124; among them, 1186±436 calls were "refused", while in 3,032±741 cases existed wrong phone number. From 6.652 potential ESAVI reported; 1,037 were validated, which means 1.82% of vaccinated people contacted, certainly a better result than the 0.121%obtained by passive reports ($p < 0.0001$).

Conclusion: An active method of pharmacovigilance performed by health students was able to increase 15 times the validated ESAVI reports after COVID-19 vaccination.

Keywords: COVID-19; Vaccine; ESAVI; Pharmacovigilance

Abbreviations: ESAVI: Events Supposedly Attributed to Vaccination or Immunization; ADRs: Adverse Drug Reactions; PV: Pharmacovigilance; VPV: Vaccine Pharmacovigilance; CIOMS: Council for International Organizations of Medical Sciences; AEFIs: Adverse Events Following Immunization; VAERS: Vaccine Adverse Event Reporting System; PAHO: Pan American Health Organization; WHO: World Health Organization; UMC: Uppsala Monitoring Center.

Introduction

Medicines are essential keys to prevent and modulate the natural history of numerous diseases, and due to their use, a notable increase in life expectancy has been achieved at the population level during the last century. However, drugs are not free to generate harmful and unintended responses even in therapeutic doses, event called Adverse Drug Reactions (ADRs), which are recognized as a frequent clinical problem, an important cause of morbidity or mortality and of great negative impact on public health [1]. For this reason, at the same time that drugs are been registered, there are particular efforts to report their unwanted actions, following the WHO recommendation for constant monitoring of all drugs traded in a modality called "pharmacovigilance". Pharmacovigilance (PV) is then a process that encompasses the monitoring, research, collection, analysis and evaluation of information provided by patients and health professionals on adverse effects related to health technology (drugs, vaccines, medical devices, etc.). These PV studies, also called post-marketing or phase IV studies, constitute the recommended methods to determinate the quality and safety of the drugs once they are already in the market [2].

Pharmacovigilance Methods

There are several methods for the development of pharmacovigilance activities. The ideal method does not exist, since it is nearly impossible to monitor the entire population and assess the different medications that each individual regularly takes (Table 1).

Classic Methods	Type of Report
Pasives	- Spontaneous or anecdotal notification
	- Voluntary notification (yellow card)
Epidemiological	- "Case-control" studies
	- "Cohort" studies
	- Vital or morbidity, mortality and birth statistics.
	- Cross-sectional studies
Intensive	-Intensive monitoring of hospitalized patients.
	-Diagnosis of ADR from the hospital diagnosis.

Table 1: Methods of Pharmacovigilance.

The classic spontaneous or voluntary notification methods are techniques in which the researcher (usually, members of the health care team) does not control the variables, but simply remains attentive on the use of drugs and the consequences of their use. The weaknesses of this method is that its depend on the willingness of the person to report, that it has little sensitivity, its monitoring is difficult, and it is generally associated with low quality of information and false alarms. Epidemiological methods are designed to determine the adverse reactions of drugs before or after their commercialization, and are generally carried out in a limited group of individuals.

Intensive methods are used in health institutions where data collection performed in a systematic way is available and where adverse effects of drugs can be collected without major problems. Unfortunately, because a great number of staff members are needed to develop a follow up of drug utilization at population levels, these active methods are usually unviable for the majority of the health systems.

Pharmacovigilance of Vaccines

Vaccines are drugs with certain characteristics that make them special for the specific protection against certain diseases. Immunizations are on the top among the most successful and cost-effective public health interventions of all time. As important as the benefit that vaccines provide, is to guarantee their safety, considering that these drugs, like any other medicines, can generate adverse events and that they are used by a large number of healthy people. The definition of Vaccine Pharmacovigilance (VPV) was generated in 2012 by the Council for International Organizations of Medical Sciences (CIOMS) [3], being defined as the "detection, evaluation, understanding and communication of adverse events that occur after immunization or problems related to immunization".

These "Adverse Events Following Immunization" are defined as side event that occurs long after immunization and does not necessarily have a causal relationship with the use of the vaccine. The adverse event can be any unfavourable or unwanted sign, abnormal laboratory finding, symptom or disease. All of these signs or symptoms are called by different ways: Adverse Events following immunization (AEFIs), Vaccine Adverse Event Reporting System (VAERS); etc. For this same concept in the Americas region [4] the term "Event Supposedly Attributed to Vaccination or Immunization" (ESAVI) has been coined, and since the present research was performed in Latin-America, this will be the acronym use along this paper.

As any other drug, one of the most used systems in ESAVI monitoring is passive surveillance, which consists on the voluntary notification of these events, whose main utility is the detection of potential safety signals of a particular vaccine; allowing the identification of new risks, new information on little- documented risks, being easily accessible at a low-cost. The World Health Organization

(WHO) and the Pan American Health Organization (PAHO) have generated tools to support the implementation of pharmacovigilance systems both at the regional level and in the different countries of each region. One of these tools is an indicator that is used in passive surveillance to establish whether a vaccine reaches a minimum of safety. According to this indicator, if a country has a reporting rate of at least 10 ESAVI per 100,000 vaccinated (0.01%), it is considered that it has reached the minimum capacity threshold regarding vaccine safety [5].

In general, the regulatory authorities of each country are in charge of collecting the information from the ESAVI, and subsequently notifying it to the Uppsala Monitoring Center (UMC), which is a WHO Collaborating Center in Pharmacovigilance where VigiBase was installed. This base is the only database recognized by WHO Global Safety Notifications for Individual Cases. Each country enters its reports in their Vigi Flow system, validates them and connects their information with VigiBase for global consolidation [6]. From these data, it is possible to know the different expected events of each vaccine and collaborate in making decisions about the best immunization options In many Societies, it that not exist a "culture" of self-report. This problem should be added to the wrong feeling that health professionals have, believing that if they report an adverse event of the prescriptions they made, these data can harm them. Unfortunately, passive notification methods performed by patients and doctors achieve poor results with very few records in relation to the number of vaccines administered [7]. In order to evaluate the efficacy of an alternative surveillance method for ESAVI related to COVID-19 vaccines, the present study was started.

Materials and Methods

Type of study

Cohort observational study that compared two methods of pharmacovigilance of ESAVI data recruitment.

Period of Study

From 2nd of January to September 30th2021 (occasionally interrupted due to student`s vacations in July).

Groups of Study and Methodology

Two methods of pharmacovigilance of events related to COVID-19 vaccination were applied to people that received any kind of vaccine against SARCoV-2 virus in Argentina. One of these methods was based on the classical passive ESAVI reports (with occasionally active calls to certain patients), and the other method was based on a process of active routine calls to patients that received COVID-19 vaccination 3 or 4 weeks after their immunization, with a protocol of contact in order to explore data related to ESAVI (table 2).Due to the limited number of staff, it is usually difficult to opt for active pharmacovigilance by contacting each vaccinated person. To mitigate this limitation, the Ministry of Health of the Province of Buenos Aires made a collaboration agreement with the Chair of Pharmacology of the Faculty of Medical Sciences National University of La Plata, so that 1.000 advanced students were trained to carry out active surveillance either by telephone or social networks, in relation to the ESAVI detected during the study period. The number of ESAVI obtained in each state/district was compared with the number of the applied vaccines. This ratio was used has a measure of efficacy obtained by each method.

Students Training Process

All 1.000 students were separated in sub-groups of ten members in order to received training. The training process included how the conversation should be started; what questions should be asked and how to managed negative response or special situations. After the training, the students were assigned to one of the twelve regions that Buenos Aires State is divided. Each Region had several coordinators that monitored the calls and provided back up for special situations that might appeared.

ESAVI

For the present study, only the validate ESAVIs were taking into account. The validation was performed by the National Committee of Vaccination Security, depending on the National Ministry of Health in Argentina. This Committee studied each one of the notifications and confirmed it truthfulness (in severe ESAVIs the patients/families were always contacted). After the confirmation, this data was uploading to the international databases (VigiBase).

Vaccination

To determine the amount and type of vaccines applied in the study period in each province, the public database of open data of the Ministry of Health of the Nation (NOMIVAC) was used (available at:http://datos.salud.gob.ar/dataset/vacunas-contra-covid19-dosis-aplicadas-en-la-republica argentina/archivo/e4515c25-e1fd-4f02-b1c1-5453c36eada6)

Data Management

All data obtained from calls was registered in a database especially developed for this project, based in the National

Formulary of ESAVI registration. In order to obtain much purer data, reports of patients residing in another district that vaccination or notification was carried out, were excluded from the analysis.

Data Analysis

Results obtained from the active surveillance experience performed by Buenos Aires State together with the National University of La Plata, were uploaded to database and then compared with the information extracted from other states of the country during the period of study. "R" software was used for the data analysis.

Results

At the end of the study period, 52, 786, 324 anti-COVID-19 vaccines were applied in Argentina (of which 20, 166, 920 vaccines were applied in the state of Buenos Aires, 38.33% of the total country), destined for 29.978.754 people (11.498.789 from the state of Buenos Aires). After screening and exclusion of the failed reports, 102.358 ESAVIs were confirmed and validated. From this universe of ESAVI 74, 75% corresponded to the first dose, 23, 96% to the second dose,0,5% to other doses, and 1,24% with no information (Figure 1). The severe cases were 2, 16% (range 0-15.67). Excluding one of the States located in patagonian region that reported 15.67% of severe cases, the range of serious events in the country were 0% to 8, 62%. In Buenos Aires State, ESAVI considered severe were 1, 68%. These data allow calculating the vaccination/ESAVI average ratio, which was 193, 91 ESAVI per 100,000 vaccinated from the total vaccines applied; 189, 33 ESAVI from 100.000 vaccines administrated in Buenos Aires State and 194, 64 ESAVI due to vaccination given in the rest of the country.

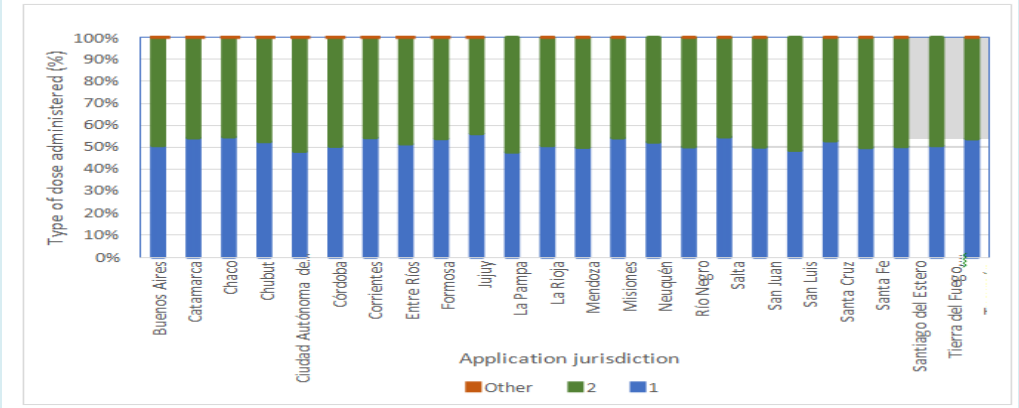

Figure 1: COVID-19 vaccination according to type of dose and district.

Although female/male ratio was similar in terms of vaccination (50.31% vs 49.67%), ESAVI were much more reported by females (72.8%) than males (27.2%) (Figure 2). The age plot shows a distribution skewed to the left. The average age of those who reported an ESAVI was 43 years old (SD=14, 05).50% of cases are in an age range between 32 (Q1) and 50 (Q3) years. In the case of women the average age is 42 (SD=13, 67), while among men is 44 (SD=15, 03).

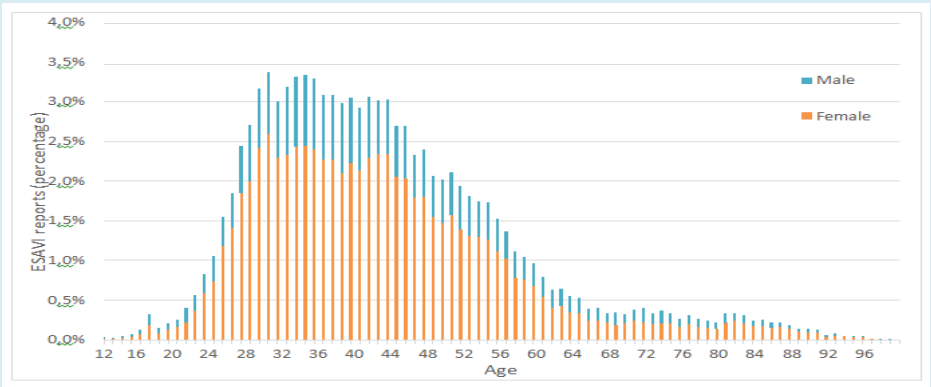

Figure 2: Events Attributed to Vaccination or Immunization distributed by gender an age.

Concerning to the number of vaccines administrated in each district and the percentage of ESAVI detected in relation to those vaccines, it can be said that there was a direct correlation between both parameters. (Table 2).

VA in Argentina (n)	ESAVI Argentina (n)	ESAVI Argentina (%)	VA in Arg. without BA (n)	ESAVI Arg. without BA (n)	ESAVI Arg. without BA (n)	VA in BA (n)	ESAVI in BA (n)	ESAVI in BA (%)	VA in Study (n)	ESAVI in Study (n)	ESAVI Study (%)
4,43,85,727	53,814	0.12	2,73,72,477	37,234	0.13	1,70,13,250	16,580	0.1	56,824	1,037	1.82

VA: vaccines applied; ESAVI: Event supposedly attributed to vaccination or immunization; BA: Buenos Aires State; Arg.: Argentina
Table 2: Level of vaccination and ESAVI reported in each district.

Concerning the study group, the results obtained shows that one thousand students were initially enrolled in the project. From them, 933 (93.3%) were still active by the end of the research. A total number of 56,824 calls were performed during the period, with an average of 14,206±1,124personal contacts with vaccinated persons per month (excepted for the period July 15th-August15th where the calls were interrupted due to student`s vacations).Of these monthly calls, 1,186±436 of the people refused to answer the questions from ESAVI formulary while 3,032±741 lack of response or had wrong number. That means that the positive contacts of the vaccinated people during the period were 39,952 (either stating that they had no events or confirming the existence of a potential event).

Noteworthy, if we just consider the 56,824 people vaccinated and contacted by the students during the study period, it could be established an overall number of 6,652 potential ESAVI reported. From them, 1,037 ESAVI were finally validated by the National Committee of Vaccination Security which means 1.82% of the total amount of people contacted after vaccination. From these events, only 38 (3.66%) were categorized as "severe" or "serious" while the other 999 were considered "non-serious". Although there is no significant difference between the vaccine/ESAVI ratio obtained in Argentina versus the data obtained in Buenos Aires State when classic method was applied (0.121 vs 0.104% p 0.7), certainly, it was detected significant differences between vaccination/ESAVI ratio extracted from overall reports in Argentina vs. this same ratio obtained by the active method of reports extracted from our research. The ratio of "vaccines administrated/ESAVI reported" obtained from the active method of pharmacovigilance, highly increased the rate of notifications (1.82 vs 0.121 p < 0, 0001) (Figure 3).

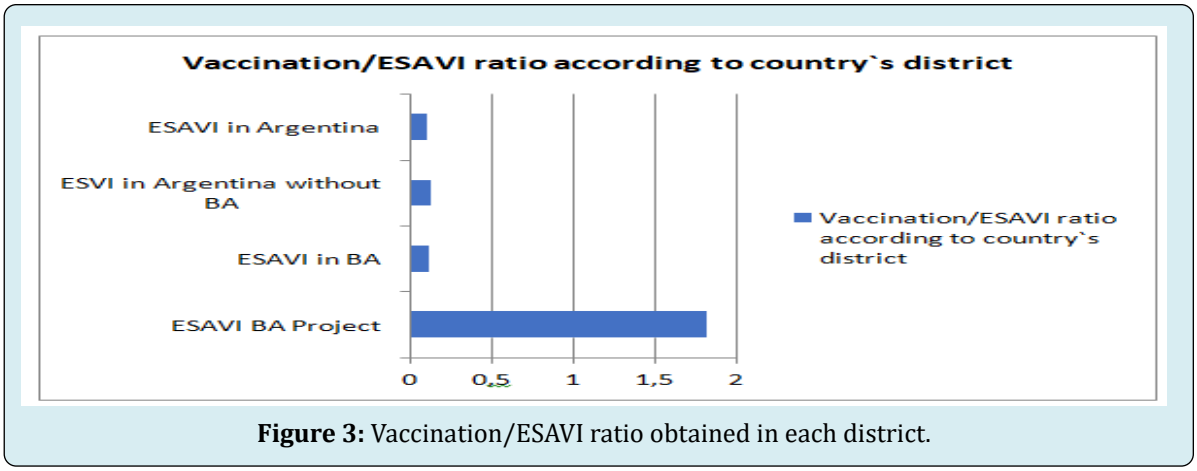

Figure 3: Vaccination/ESAVI ratio obtained in each district.

Discussion

Pharmacovigilance has four major stages: detection, deduction, decision, communication/dissemination. However, "detection" is a key point, since it is the beginning of the process and the others steps will depend on this stage. Without detection it is not possible to develop the other phases. Most commonly detection stage employs observational/ pharmacoepidemiological methods like spontaneous reports, case series, cohort studies or case–control studies; which mean that either patient's self-report or health professional reports are needed. However, these spontaneous reporting depends on country`s culture. Unfortunately, Latin-American countries do not in the habit of self-reporting. This low ratio of reports is due for many reasons, some of them are associated with people`s lack of time, lack of will and commitment, fear of being identified or due to the population discredit in their own health authorities

and in how they can use the information properly [8]. On the other hand, health professional culture of reporting is low mainly due to the belief that it exist a potential risk in being personally involved with the ESAVI reported [9].

The present study was performed considering the amount of vaccines applied in the country; hence, the type of vaccine administrated was not analyze. This is because initially, when the study started, all vaccines applied were Sputnik V, but also because the focus was on ESAVI's reporting methodology and not on the events themselves. However, a second study is now in process, concerning ESAVI according to the types of vaccines approved and used in the country: Astra Zeneca ChAdOx1 nCoV-19 vaccine -AZD1222-; CovishieldChAdOx1 n CoV-19; Sputnik V; Moderna; Pfizer-BionTech; Sinopham; Cansino - Ad5-nCoV. Concerning this topic, it should also be noticed that Local Public Health authorities designated certain vaccines to a special population (i.e. Sputnik in elderly, Sinopham in children, Moderna in immunodeficient population; etc). This element might bias the results obtained, therefore the special study which is now taking place will be able to show the difference level of ESAVI according to the vaccine applied.

When the classical form of reporting is considered, we can observe that in Argentina there is a lower rate of ESAVI reports compared to international data [10-12]. However, it should be noticed that the ESAVIs extracted from public database and then included in our study were already analysed, passed through a screening process, and then confirmed its validation by infectious experts; an aspect that must be considered as a distinctive aspect with respect to other publications. However, the comparison between the regular reports obtained by classical pharmacovigilance system in Argentina, versus the active model used in this research, showed statistical significant differences. The active call (system that contacts people and it does not expect for an spontaneous report) and personalized contact made to each vaccinated after a period of 3 to 4 weeks after receiving the vaccine, allows a net reminder of the events suffered, and a greater reporting rate, increasing the ESAVI rate by more than 15 times in relation to classic reports.

This type of active pharmacovigilance method is usually unfeasible for health authorities, either from a managing or economic point of view, since it will usually need a large staff, aspect the health systems usually do not have. However, in this experience, health sciences students were invited to participate, receiving training in exchange for their homework. This academic institutions/health authority relationship is symbiotic, since some of them obtain training and experience that will be useful for professional life; while the health system not only enhance its active pharmacovigilance system, but also is changing the culture of ESAVI reporting among future health professionals.

Conclusion

An active pharmacovigilance experience performed by the Staff of Ministry of Health with the help of university students from Health Careers was able to increase in 15 times the validated ESAVI reports after COVID-19 vaccination. This symbiotic interaction between Health and Educational public sectors helps to reduce the economic impact that usually have the active pharmacovigilance methods, and transforms it, in a viable option available to be adopt by other country`s authorities.

Conflicts of Interest

Authors declare no conflict of interest.

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