A Review of COVID-19 Vaccine Adverse Event Following Immunization Case Reports by four CARICOM Countries to VigiBase

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ABSTRACT

The World Health Organization declared COVID-19 a pandemic on 12 March 2020. One of the strategies to combat the pandemic was the development of novel COVID-19 vaccines. Once these vaccines were deployed, immunizations followed. The objective of this study was to identify the characteristics of case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines based on Individual Case Safety Reports (ICSRs) in VigiBase, submitted by four CARICOM countries: Barbados, Haiti, Jamaica and St. Vincent and the Grenadines. A review of the publicly available data on AEFIs with COVID-19 vaccines based on ICSRs in VigiBase was conducted from March 1, 2021 to December 14, 2022. A total of 1,582 AEFI case reports were identified for this period. Most of these were non-serious events, involving persons under 65 years (84.9%), and females (74.1%); 19% were classified as serious events. The top age group reported for AEFIs in VigiBase were 18-44 years (46.6%). The most frequently reported reactions were headache (29.3%), pyrexia (19.3%), dizziness (19.3%). Altogether for the four countries, the AEFIs per 100,000 doses was 64.1 and 12.2 serious AEFIs per 100,000 doses. Recommended actions identified were strengthening national pharmacovigilance regulatory frameworks, establishing robust national pharmacovigilance centres, capacity building of professionals, enhancing communication with key stakeholders and consider relying in a regional pharmacovigilance system.

Keywords: vaccine safety, pharmacovigilance, COVID-19

Introduction

The COVID-19 outbreak started in December 2019, was declared a public health emergency of international concern on January 30, 2020 by the World Health Organization (WHO). It was officially declared a pandemic on March 12, 2020. One of the strategies for pandemic control was the accelerated approval of safe and effective novel COVID-19 vaccines using different vaccine platforms. This approval for emergency use of these vaccines called for increased vigilance to ensure safety.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine-related problem as defined by the World Health Organization. (WHO 2023) An adverse event following immunization (AEFI) is understood as any untoward medical event that follows

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immunization and that does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. (WHO 2020)

The WHO defines a serious AEFI as an adverse event that results in death, hospitalization, or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, or is life-threatening or is a medically important event or reaction. (WHO 2020)

The World Health Organization Programme for International Drug Monitoring (WHO PIDM) is an international collaboration with the goal of ensuring timely identification of medicines-related safety problems. The WHO PIDM was launched by WHO in 1968, and 10 years later, the Uppsala Monitoring Centre (UMC) was established as a WHO Collaborating Centre for International Drug Monitoring to manage the technical and scientific aspects of the programme. (UMC, n.d.)

The WHO PIDM has over 170 full members and up to 2022 associate members. (UMC, n.d.) This covers about 99% of the global population. The Caribbean Community (CARICOM) member states include Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago. The associate members are Anguilla, Bermuda, the British Virgin Islands, the Cayman Islands, and the Turks and Caicos Islands.

From CARICOM, there are a total of 4 full members in the WHO PIDM: Barbados, Jamaica, Suriname, and St. Vicent and the Grenadines. Associate members include Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Guyana, Haiti, St. Kitts and Nevis, St. Lucia, Anguilla, British Virgin Islands and Montserrat.

The WHO PIDM has different global databases for use. VigiFlow is a web-based individual case safety report (ICSR) management system specifically for medicines and vaccines developed and maintained by the UMC. VigiBase is the WHO global database of reported potential side effects of medicinal products by PIDM member countries. During the COVID-19 pandemic, UMC expanded VigiFlow to include the WHO AEFI form. AEFI line listings can be extracted to help identify vaccine batch-related problems and immunisation-related errors at the local level.

In CARICOM, the Caribbean Regulatory System (CRS) is the regulatory unit within the Caribbean Public Health Agency (CARPHA). Within the CRS is a regional voluntary system, VigiCarib, that was rolled out in late 2017 to report suspected adverse drug reactions and substandard and falsified medical products. The Caribbean Regulatory System publishes a monthly newsletter known as VigiCarib News. This publication shares monthly updates on case safety reports with the VigiCarib network and its stakeholders. In 2021, VigiCarib started to include reporting adverse events following immunization (AEFIs).

Most of the Caribbean countries lack pharmacovigilance legislation. In Jamaica, the National Pharmacovigilance Centre is

the repository for suspected adverse reaction reports, which are spontaneous reports by healthcare professionals and marketing authorization holders. As for the national legal framework in Jamaica, the Food and Drugs Act, Regulation 70, 1975 indicates: "Where any person receives any report of any unexpected side effects, injury, toxicity or sensitivity reaction associated with clinical uses, studies, investigation and tests respecting any new drug, he shall immediately inform the Minister thereof, furnishing him with the full information available." Local adverse reaction reports are submitted via PharmWatch Drug Monitoring Reporting Forms available online to the National Pharmacovigilance Centre. These spontaneous reports are then submitted to VigiBase using the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline E2B (R3) format. (Ministry of Health and Wellness, 2023)

As for Barbados, the Barbados Drug Service is the National Pharmacovigilance Centre to which adverse event reports are submitted, which then submits it to the VigiBase. No pharmacovigilance laws or regulations exist; however, the Drug Service Act indicates as an offense: "Any person who maliciously commits an act that is likely to have an adverse effect on the operation of the Drug Service."

The Department of Pharmacy, Medicines and Traditional Medicine (DPM/MT) coordinates pharmacovigilance activities in Haiti. It includes all stakeholders within its health system, such as importers and distributors of pharmaceutical products, non-governmental organizations and humanitarian organizations, health professionals, and the public. (Ministére de la Santé Publique et de la population.,n.d.)

In St. Vincent and the Grenadines, there is no legal framework for pharmacovigilance despite the existence of a national pharmacovigilance centre and the submission of ICSRs to VigiBase. (Walker et al. 2023)

Importance of COVID-19 vaccine safety surveillance

One of the countermeasures to the COVID-19 pandemic was the development of vaccines with accelerated approvals. The emergency use authorization of various COVID-19 vaccines was made possible via the concurrent performance of multiple clinical trial phases and the presence of large patient cohorts in these studies. Large phase III trial has limitations, including a short post-authorization follow-up period and the inability to detect rare ($\geqslant$ 1 in 10,000 to $<$ 1 in 1,000 vaccines) and very rare ($\leqslant$ 1 in 10,000 vaccinees) adverse events that become apparent only when the vaccines are used widely. (PAHO, 2020) Therefore, the post-market surveillance of COVID-19 vaccines is pivotal to timely capture of safety data to prevent risks and ensure patient safety.

According to WHO, COVID-19 vaccines can cause side effects, most of which are mild or moderate, and go away within a few days. However, more serious, or long-lasting side effects are possible. In 2021, the typical side effects of COVID-19 vaccines included pain at the injection site, fever, fatigue, headache, muscle pain, chills, and diarrhea and this varies to the specific vaccine. (WHO 2023) Adverse Events of Special

Interest (AESI) have also been associated with Covid vaccines.

This study presents the publicly available COVID-19 AEFI data for selected CARICOM countries that was reported to VigiBase. It aims to provide key characteristics of this data and provide recommendations on vaccine safety surveillance in the Caribbean.

Objectives

The purpose of this study is to identify the characteristics of case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines based on publicly available information on Individual Case Safety Reports (ICSRs) in the global database, VigiBase - submitted by national pharmacovigilance centres in four CARICOM countries (Barbados, Haiti, Jamaica, and St. Vincent, and the Grenadines) with membership in the PIDM.

Methodology

A scoping review of the publicly available data on case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines based on Individual Case Safety Reports (ICSRs) from Barbados, Haiti, Jamaica, and St. Vincent, and the Grenadines in VigiBase was conducted.

Based on publicly published data, the study period was from 1 March 2021 to 14 December 2022. The only source of public information that was identified was VigiCarib News (CARPHA 2021). The data includes the consolidated number of reported COVID-19 AEFI and reporting rate, patient age groups reported for AEFIs, and top reported reactions for AEFIs in VigiBase.

Results

The ICSRs include the COVID-19 vaccines as appeared on the publicly available data as follows:

1. COVID-19 vaccine NRVV Ad (ChAdOx1-S recombinant) by AstraZeneca or Serum Institute of India (COVISHIELD)
2. COVID-19 vaccine NRVV Ad26 (Gam-Covid-Vac – Sputnik V)
3. Tozinameran (Pfizer-BioNTech COVID-19 vaccine)
4. COVID-19 vaccine NRVV Ad26 (JNJ 78436735) Johnson & Johnson
5. COVID-19 vaccine inactivated (Vero cell) HB02 – BIBP-Sinopharm
6. COVID-19 vaccine inactivated (Vero cell) WIV04 - Sinopharm-Wuhan
7. Elasomeran, COVID-19 Vaccine Moderna
8. Covid-19 Vaccine (unspecified)

Discussion

As of December 14, 2022, CARICOM countries and territories had seen 1,007,451 COVID-19 cases, 15,367 COVID-19 deaths, and 4,037,028 vaccinations with at least one dose and between 2.05% and 88.03% of persons had been fully vaccinated. (CARPHA 2022)

The presented AEFI data on the CARICOM countries was based on publicly available information published by the Caribbean Regulatory System in its monthly newsletter, VigiCarib News. The last published data for the year 2022 had a cut-off date of December 14, 2022. At the end of this period, there were 1,582 AEFI case reports on COVID-19 vaccines on VigiBase for the four selected CARICOM countries.

Based on the PAHO COVID-19 Vaccination in the Americas database (PAHO, 2023), at the end of week 52 of the year 2022, Barbados accounted for 53.9 completed vaccine schedule per 100 people, Haiti for 2.1 per 100 people, Jamaica for 25.0 schedule per 100 people and St. Vincent and the Grenadines 28.3 per 100 people.

In December 2022, CARPHA data showed that the COVID-19 vaccines deployed in Caricom counties as follows:

Haiti:

- Pfizer-BioNTech – Comirnaty -55.9%
- Janssen Ad26.COV 2.5 -25%
- Moderna - mRNA-1273.11 – 19.1% (PAHO Unknown)

Barbados:

- Vaxzevria
- BBIBP-CorV
- Pfizer BioNTec,
- Covishield

Jamaica

- Vaxzevria
- Janssen
- Pfizer BioNTech,
- Covishield

St. Vincent & Grenadines

- Sputnik V
- AZ – Vaxzevria
- Pfizer BioNTech
- Covishield
- Moderna.

Through December 2022, the public report on VigiCarib News indicates that the AEFI case reports on VigiBase also included the following vaccines: NRVV Ad (ChAdOx1-S recombinant) by AstraZeneca or Serum Institute of India (COVISHIELD), Gam-Covid-Vac – Sputnik V, Elasomeran, Tozinameran, JNJ 78436735, HB02 – BIBP-Sinopharm, WIV04 - Sinopharm-Wuhan, and unspecified Covid-19 vaccines, Although disaggregated data per vaccines was unavailable, the list of COVID-19 vaccines that were listed on the VigiCarib News – December 2022 coincides with those appearing as deployed in the four CARICOM countries.

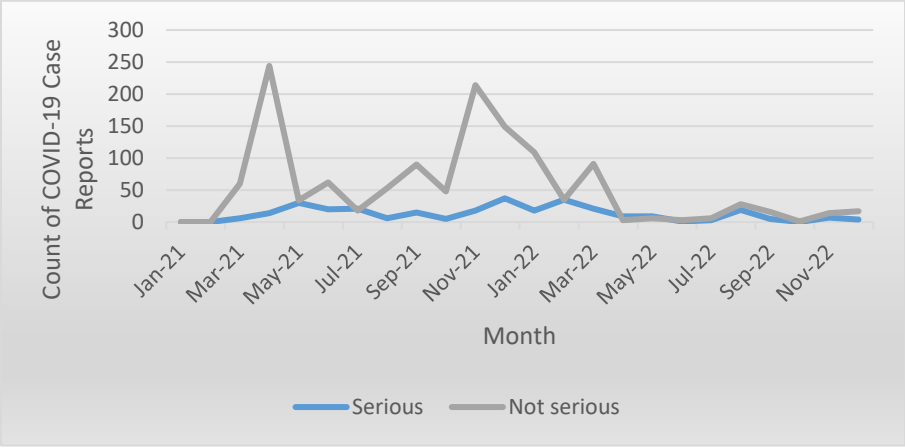

Figure 1: Case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines submitted to VigiBase by four CARICOM countries from 1 March 2020 to 14 December 2022 (N = 1,582). (CARPHA, 2022)

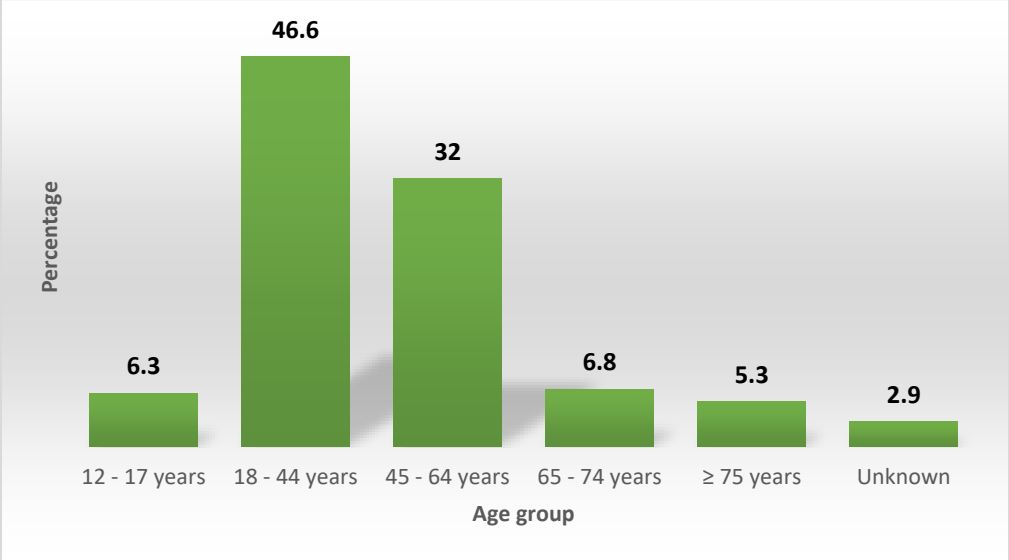

Figure 2: Patient Age Groups Reported for AEFIs in VigiBase from 1 March 2020 to 14 December 2022 (N = 1,582). (CARPHA, 2022)

Out of the 1,582 case reports (Figure 1), most were non-serious events involving persons under 65 years (84.9%) and females (74.1%). The top age groups reported for AEFIs in VigiBase from 1 March 2020 to 14 December 2022 were 18-44 years (46.6%), followed by 45-64 years (Figure 2). This may be attributed to the increased administration of the COVID-19 immunization in these populations, although older adults were the high priority-use groups to decrease death and severe diseases.

Table 2 - Top Reported Reactions by MedDRA preferred term in VigiBase from 1 March 2020 to 14 December 2022 (N = 1,582). (CARPHA, 2022)

Top Reported Reactions by MedDRA preferred term	Count	Percentage (%)
Headache	463	29.3
Pyrexia	306	19.3
Dizziness	305	19.3
Fatigue	250	15.8
Chills	244	15.4
Myalgia	224	14.2
Arthralgia	211	13.3
Nausea	178	11.3
Vaccination site pain	161	10.2
Malaise	150	9.5

The most frequently reported reactions in the four selected CARICOM countries were headache 29.3%, pyrexia 19.3%, and dizziness 19.3% (Table 2). In a study conducted by Ogar et al., based on VigiBase COVID-19 AEFI data for Africa, general disorders and administration site pain were the most frequently associated system organ class (SOC), at 34.7% and for the rest of the world at 26.5%. Headache was the most frequently reported adverse event, followed by pyrexia, and injection site pain. For the rest of the world, the most common adverse events included chills, headache, and dizziness. (Ogar et al., 2023) In the same study, the most reported AEFIs were fatigue, headache, and malaise. The most frequently reported reactions identified in the selected CARICOM countries also appear to be similar to those reported by other regions of the world.

Table 4: AEFIs per 100000 deaths

Region	Non-Serious AEFIs	Serious AEFIs	Death
CARICOM	64.1	12.2	N/A
PICS	129.8	5.7	N/A
Africa	11	5	2
Netherlands	3121	77	9.6

Altogether, for the four CARICOM countries, the AEFIs per 100,000 doses was 64.1 and 12.2 serious AEFIs per 100,000 doses up to 14 December 2022. The Pacific Island Countries (PICS) are small states similar to those present in the Caribbean, including its pharmacovigilance structure. In a study done by Amarasinghe, et.al. on COVID-19 vaccine-related AEFIs in the PICS, from 2021 to 2022, the reporting rates of total AEFIs was 129.8 events per 100 000 doses administered, and serious AEFIs were 5.7 events per 100 000 doses administered. (Amarsinghe et al., 2023)

Oosterhuis, et. al.(2023) stated that in 2021, the Netherlands Pharmacovigilance Centre Lareb, received 184,411 ICSRs, a reporting rate of 0.67% for vaccines given in the Netherlands - 6.4 ICSRs per million residents. While 887,954 AEFIs were reported, mostly well-known, non-serious AEFIs; 2.4% were serious and 0.3% were fatal. (Oosterhuis, et. al.2023) (See Table 3)

Based on the published data on VigiCarib News, in the CARICOM three hundred (19.0%) ICSRs were classified as serious, based on seriousness criteria: 4.2% (N=67) death, 1.3% (N=21) life threatening, 7.1% (N=113) caused/prolonged hospitalization, 3.4% (N=53) disabling/incapacitating, 6.7% (N=106) other medically important condition. Ogar, et.al., found that in Africa, serious adverse events accounted for 12.2% of AEFIs compared to 27.1% for the rest of the world, followed by death 10.1% of AEFIs from Africa compared to 9.6% for the rest of the globe. As for outcome, 61.4% of the adverse events in Africa were resolved at the time of reporting, while 58.2% have been resolved in the rest of the world. Based on the publicly available data on the selected CARICOM countries, the outcome of the adverse events was not

published. Despite these serious ICSRs, a study by Watson, et.al. estimate that COVID-19 vaccinations prevented 14.4 million deaths in 185 countries and territories between December 8, 2020 and December 8, 2021. (Watson et al., 2022)

Reporting in CARICOM Countries

In Barbados, suspected AEFIs to COVID-19 vaccines are reported to the National Pharmacovigilance Centre at the Barbados Drug Service. Both health professionals and the public can report electronically via its website. The pharmacovigilance officer reviews all COVID-19 AEFIs. When the AEFI report meets specific severity thresholds, it triggers an investigation as a serious AEFI. (UWItv, 2021) The national COVID-19 AEFI reports accounted for 38.0% of the total of CARICOM countries reporting to VigiBase (Figure 1).

In February 2021, the Barbados Drug Service (BDS) published a request to persons that have been administered the COVID-19 vaccine to report any suspected side effects by filling out the 'Reporting Form For Suspected COVID-19 AEFI' on their website and made available an active surveillance COVID-19 form for health professionals which uses the UMC eReporting Form. (Barbados GIS, n.d.)

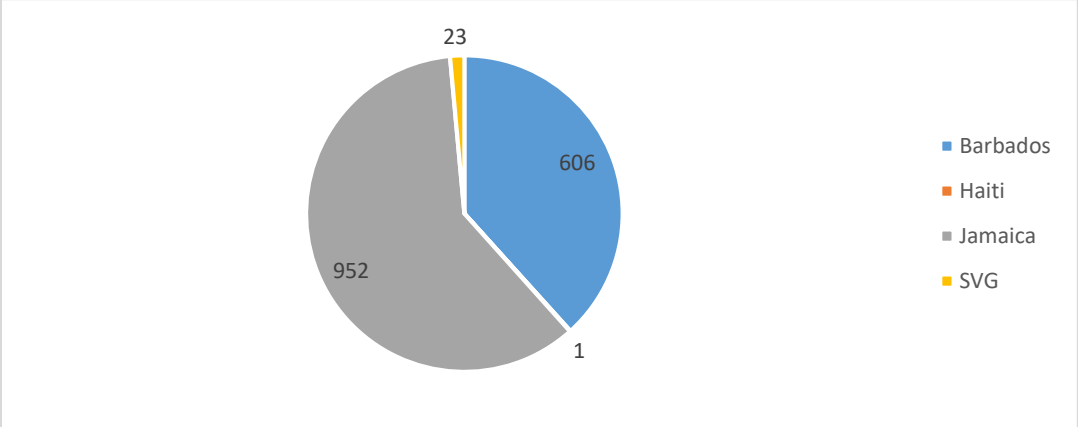

Figure 3: Case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines submitted to VigiBase per CARICOM countries from 1 March 2020 to 14 December 2022 (N = 1,582). (CARPHA, 2022)

Within Jamaica's Ministry of Health and Wellness, the Standards and Regulation (MoHW) Division is responsible of ensuring the safety, efficacy, and quality of medical products available on the Jamaican market. The Permit Approval and Products Registration Unit is responsible for post market surveillance programmes to monitor the safety and effectiveness of approved products, including vaccines. After the first month of starting the COVID-19 vaccination programme in April 2021, the MoHW reported two anaphylactic reactions. (JIS, n.d.) In 2022, since the introduction of COVID-19 vaccines, Jamaica saw a 633% increase in adverse events related to COVID-19. This indicates a need to strengthen the current pharmacovigilance

programme for the robust monitoring system required for the vaccines. (PAHO 2022) Data published by PAHO in 2021 also indicate that Jamaica has active surveillance occurring. (DIS TV, 2021) The national COVID-19 AEFI reports accounted for 60.1% of the total of CARICOM countries reporting to VigiBase (Figure 3).

Table 2: COVID-19 Vaccines AEFI Reporting Forms in the four selected CARICOM countries.

Country	Paper-based	Online	Voluntary Reporting
Barbados		x	Healthcare Professionals and Public
Haiti	x		Healthcare Professionals and Public
Jamaica	x		Healthcare Professionals and Public
St. Vincent and the Grenadines		x	Healthcare Professionals and Public

Although there is no identified legislation on adverse event reporting in St. Vincent and the Grenadines, the Public Health (Emergency Authorisation of COVID-19 Vaccine) Rules, 2021 listed the vaccines that were authorized for COVID-19. Saint Vincent and the Grenadines have used the UMC eReporting available via the VigiCarib website. Similarly, Haiti has an AEFI reporting form available online that needs to be downloaded and then submitted to the authorities: notification des évènements indésirables des médicaments et autres produits de santé. For a summary of the type of reporting used for AEFI of COVID-19 Vaccines in the four selected CARICOM countries. (Table 2)

In the study by Oosterhuis, et. al. in The Netherlands, 33.1% of all ICSRs were processed fully automatically. Lareb counted with a daily triage in which 4.2% were marked as 'high priority'; 62.7% as 'low-priority'. The study indicated that the automatic processing of well-known AEFIs, the daily triage, and signal detection meetings, resulted in 99.9% of the ICSRs being processed within the compliance timeframe to the European Medicines Agency's Eudravigilance online database. (Oosterhuis, et. al.2023)

For the four Caribbean countries, the month with the greatest number of AEFI reports occurred in April 2021, followed by November 2021, and generally a downward trend for the following months. The Caribbean Regulatory System indicated that this decrease in reporting of AEFIs may be due to multiple factors. It highlighted the reduction in vaccinations, lack of visibility of reporting systems, and reduced risk perception. However, additional studies at the national level would be needed to verify case reports, confirm causality, and identify other possible factors that may influence reporting.

COVID-19 further exposed the vulnerabilities in the health systems, particularly those in low- and middle-income countries. With the accelerated emergency use authorization of novel COVID-19 vaccines, vaccine safety surveillance was imperative. However, like

most of the world, these countries were unprepared for the COVID-19 pandemic.

Recommendations

It is imperative that Caribbean countries work towards establishing or enhancing their national pharmacovigilance systems for medicines and vaccines. The lack of proper legislation is a great challenge to develop and improve national pharmacovigilance systems. The limited human resources available for pharmacovigilance activities needs to be addressed, including capacity building of current staff and future professionals. This would also benefit the quality of the AEFI report review, investigation, causality assessment, and regulatory actions. This calls for allotting financial resources to the national pharmacovigilance centres so that they can conduct their activities adequately.

During the COVID-19 pandemic, underreporting was a key challenge in these low- and middle-income countries that lack the appropriate vigilance infrastructure and surveillance systems. Basic infrastructure, such as access to digital information systems from the local, regional, and national offices with staff and computer networks, is essential to have a functional system operating and to communicate and coordinate considering the surveillance cycle of AEFI.

There is also the opportunity to strengthen the engagement with key stakeholders, such as the relationship between national pharmacovigilance centres and expanded programme in immunization and national pharmacovigilance programme. In the Caribbean, the Expanded Programme in Immunization has led the way with AEFI investigation and reporting from pre-pandemic time, given that there are few established national pharmacovigilance centres.

CARICOM countries should use VigiCarib as a regional reliance mechanism for pharmacovigilance. Not only on the use of the AEFI online reporting form but also on other pharmacovigilance activities provided to support national systems. In addition, they can use the support provided by the CRS to submit adverse event reports to the global databases at the Uppsala Monitoring Centre. Countries such as those presented in the study can also benefit from pharmacovigilance capacity building provided by the CRS.

Although VigiCarib publishes safety data in its monthly newsletter, it was challenging to identify other sources of information, including data from the national Ministry of Health websites or other reliable websites. Healthcare professionals and others, who report AEFIs, must include the specific characteristics of the AEFI and vaccine safety data. This can contribute to building trust in the national pharmacovigilance systems and generally in the health authorities.

Conflicts of interest

The author has no conflicts of interest to declare.

Ethics statement

Ethical approval was not required for this study.

Funding

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