الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Establishment of Regional Pharmacovigilance (PV) Centers in Saudi Arabia: initiatives and challenges.

The National Pharmacovigilance Centre (NPC)
Data Capture Section

Introduction:

The World Health Organization has defined pharmacovigilance as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [1]. As part of Saudi Food and Drug Authority's (SFDA) responsibility, which includes the ongoing monitoring of the safety, efficacy and quality of pharmaceutical products in the kingdom. It initiated the establishment of regional pharmacovigilance centers to enhance pharmacovigilance activities among health institutions across the country. This is done as part of SFDA's strategic plan for early detection of adverse drug events (ADE) and to achieve the goal of medication safety. There are 25 regional pharmacovigilance centers that have been geographically distributed across the kingdom to maintain continuous activities of pharmacovigilance in all regions of KSA (figure 1).

The duties and responsibilities of the regional pharmacovigilance centers included:

- Reporting ADEs to the National Pharmacovigilance Center (NPC).
- Informing NPC about any clusters of ADEs.
- Performing awareness campaigns and workshops with health care providers
- Giving counselling on medicines at the request of NPC
- Serving as contact points between the patient and NPC
- Conducting follow-up for ADE reports in a timely manner
- Prompt response in case of emergency and crisis (Such as the Covid-19 pandemic)

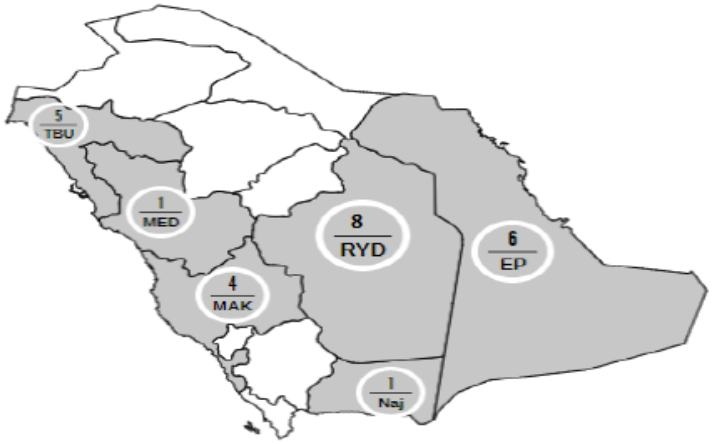


Figure 1: Geographical Distribution of the Regional PV centers

Objective:

To review SFDA's experience in establishing effective regional PV centers across the kingdom and their role in improving collaboration with healthcare providers as one of NPC crucial stakeholders.

Initiatives:

The national pharmacovigilance center (NPC) is responsible for collecting, analyzing and evaluating adverse drug event reports in the kingdom. Also, identifying signals of adverse drug reactions, and promotion of the reporting culture. Therefore, with the goal of patient safety in mind, NPC has taken several initiatives and plans with a number of collaborating regional PV centers to enhance patient safety.

These initiatives, which the regional pharmacovigilance centers participated in them very heavily, included the following:

1. **Workshops and Periodic Meetings**

The first milestone of the project was achieved on February of 2019 when training process was initiated by visiting each regional PV center. Numerous topics were covered during these training visits such as: introducing the role of NPC in receiving and evaluating ADE reports, discussing the desired objectives and outcomes for the regional centers, demonstrating how to use the online reporting system and receiving suggestions and inquiries. In addition to the effort of activating the role of the regional PV centers, NPC has held numerous meetings and visits with these varied and distributed centers throughout the kingdom. The primary objective of these periodic meetings was to enhance the quantity and quality of adverse drug reporting performed by each regional centers. As well as to receive inquires and suggestions regarding the reporting process. Due to the wide geographical distribution of the regional PV centers and the need of constant communication; technology was employed to stay connected with pharmacovigilance representatives by virtual meetings and a chatting group via smartphone application to make the communication as easy and as effective as possible.

2. **Educational Material**

Raising awareness of the public and health care providers regarding medication safety and pharmacovigilance is an important role of regional PV centers. Hence, different types of educational materials were provided to each center to display in their organization and hand out to their patients. These educational materials included, but are not limited to; roll-up banners to educate the public on adverse drug event reporting, when to seek medical attention and how to report adverse drug events. Also, educational posters to be showcased in patient waiting rooms. Another key material introduced by NPC was the short ADE

reporting cards, these cards could be handed-out during dispensing process in the pharmacy. The cards asked only for 4 essential information from the reporter. The 4 pieces of information were patient identifier, drug used, adverse drug event which occurred and contact information to obtain additional information if needed. The previous 4 pieces of information used in the shortened report cards are in compliance with the world health organization recommendations on reporting of adverse drug reactions.

3. Motivation

In order to motivate and recognize the efforts of the regional PV centers in maintaining the goal of ensuring medication safety. An appreciation event was organized and held on the world patient safety day. This event aimed to introduce the audience with the integral role of the regional centers in monitoring the post-marketing safety of pharmaceutical products throughout the country. It was an opportunity to present awards to the participating organizations and honor their achievement.

Impact on ADR Reporting:

1. Quantity:

The number of adverse drug event (ADE) reports that were received from health institutions at NPC gradually increased after the establishment of regional pharmacovigilance centers. This increase in numbers has been clearly noticed in the first quarters of 2020 as seen in figure 2. The increase occurred due to the completion of targeted number of regional centers in the project of regional centers and ADE promotion, which has been done during 2019.

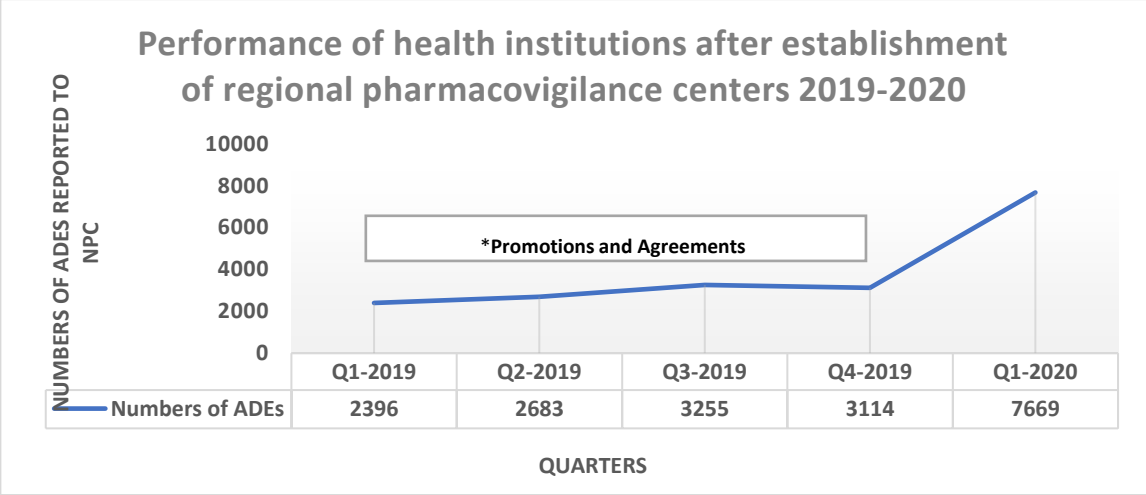


Figure 2: Performance of health institutions after establishment of regional pharmacovigilance centers 2019-2020

*The promotions of reporting and Agreements with regional pharmacovigilance centers have been done during 2019

Also, figure 3 -illustrated below- shows the significant increase of ADE reports in the first quarter of 2020. This occurred due to the success of all initiatives that were conducted during

2019 with the pharmacovigilance regional centers. As a result, the number of ADE reports received by NPC in the 1st quarter of 2019 was 1364 report, compared to a total of 4869 reports received during the 1st quarter of 2020. This increase in reports submission is estimated to be around 257%. Detailed report of regional PV centers performance will be conducted at the end of 2020 to assess the performance statistically.

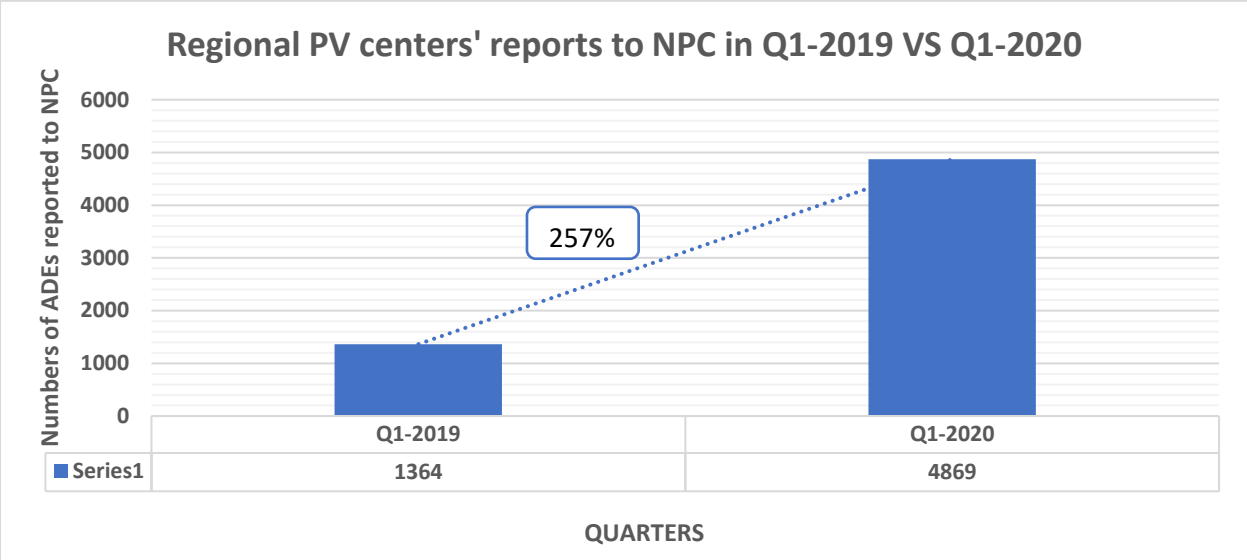


Figure 3: Comparison between numbers of ADEs reported from regional PV centers to NPC in Q1-2019 VS Q1-202

In a comparison between numbers of reporting in 2019 between PV centers versus all other health institutions across the kingdom as seen in figure 4; the number of ADE reports received from PV centers was slightly higher by 40 reports.

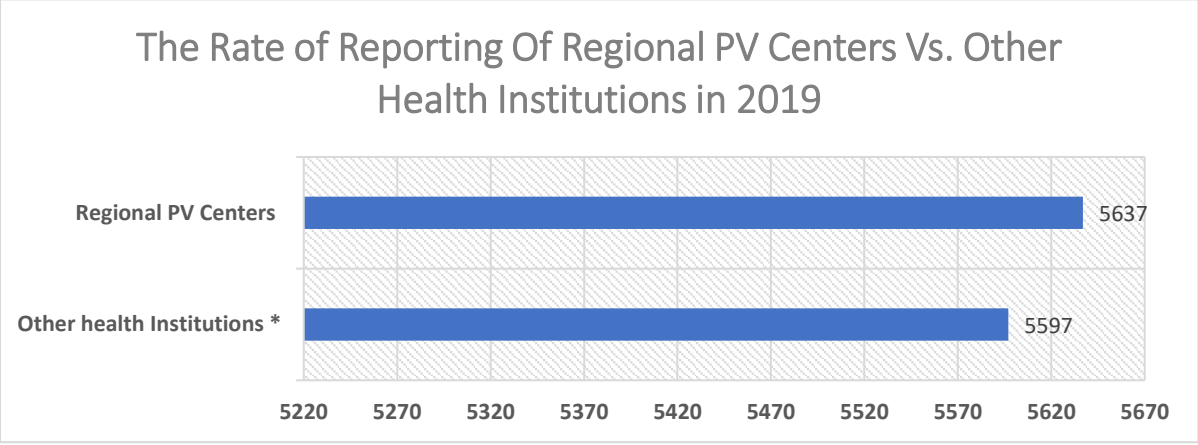


Figure 4: Reporting Of PV Centers Vs. Other Health Institutions in the year 2019.
*Hospitals do not have PV center

2. Quality:

The quality of ADE reports received from healthcare providers was improved significantly after the establishment of regional PV centers. Quality improved in terms of completeness, comprehensiveness, and their prompt response to follow-ups. This improvement was

attributed to the training sessions, workshops and distribution of educational materials done by the regional centers representatives in their institutions, which aimed to enhance the reporting culture among staff of their corresponding institutions.

Discussion:

The concept of pharmacovigilance and the culture of ADE reporting are still a devolving concept in Saudi Arabia. Thus, all efforts were maximized to enhance this culture. Targets and objectives were set for all regional centers to increase awareness. These targets included conducting a previously determined number of campaigns per year, in addition to, lectures given to hospital staff and trainees. Educational institutions were also targeted specifically to further enhance the reporting. This was done by conducting workshops, seminars and lectures within their university hospitals and collaboration with student clubs in colleges specializing health sciences.

The wide geographical distribution of the regional centers throughout the Kingdom presented unique communication challenge. Therefore, extra efforts were made to overcome this challenge by arranging monthly virtual meetings and periodic visits

Conclusion:

In conclusion, implementation of pharmacovigilance regional centers is still relatively new to the kingdom. However, the contribution of these regional centers has had a significant improvement in the reporting culture as evident by the increases in ADE reporting. Plans for pharmacovigilance regional centers include; further promotion of awareness regarding pharmacovigilance activities, further enhancement of the reporting culture and quality of reporting. Additional engagement in the evaluation of ADR cases received locally.

References:

1. WHO. Pharmacovigilance: Ensuring the Safe Use of Medicines. Geneva, WHO, October; 2004. www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/.