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Exploring the Efficacy of Mobile Applications in Adverse Drug Reaction Reporting

Helena Biju [a], Salva Barsath[b]

[a,b] Student,8th Semester, B Pharm, Chemists College of Pharmaceutical Sciences and Research, Varikoli, Ernakulam, 682308.

A B S T R A C T

The objectives of this study were to evaluate smartphone ADR-reporting apps, comprehend how they affect ADR reporting, and gather insights from app owners and developers. The study comprised a search of VigiBase, the global database of individual case safety reports maintained by the World Health Organization, an evaluation of ADR-reporting apps, and an online poll on app implementation. There were twenty-two applications total, eight of which were for the WHO's African area. The applications had E2B data components and feature that aided in user interaction and reporting. Positive experiences with the app's features and an increase in the number of ICSRs after launch were reported by 17 app creators and owners. Environment and user type were mentioned as factors influencing the use of apps. App usage was shown to be higher among younger and tech-inclined individuals than among older or tech-averse individuals.

Keywords: Adverse drug reactions, VigiBase, Case safety report, ICSR, Mobile Applications.

1. INTRODUCTION

In Pharmacovigilance, the voluntary reporting of adverse drug reactions (ADRs) has been a standard practice since the 1960s. Every year, the World Health Organization's global database vigibase receives an average of 2 million new individual case safety reports (ICSRs) from more than 100 countries. However, underreporting, inadequate documentation, and reporting delays have severely curtailed this reporting. Obstacles encompass inadequate understanding and consciousness of Pharmacovigilance, drive, indifference, unease, complacency, workload, and insufficient training. The main technique for gathering ADRs has historically been paper-based reporting; however, paperless methods, such as texting, calling, websites, and social media, have also been investigated.

Patients from high-income and low- and middle-income nations, as well as NRAs and medical professionals, have started taking an interest in smartphone-based solutions like Med Safety. In order to better understand the impact of accessible smartphone ADR reporting apps and get insights from creators and owners, this study will evaluate and define these apps.ne these apps

2. METHODS

• Worldwide available ADR reporting apps systematic assessment.

• Survey (online)

• An analysis of the quantity of reports that were filed to VigiBase both before and after the app's introduction.

- Worldwide available ADR reporting apps systematic assessment.

An evidence-based minimal set of items for reporting in systematic reviews was established using the PRISMA checklist. Rather of relying on academic references, this study concentrated on smartphone apps and modified the original checklist to include items linked to bias risk. Apps are software programs made specifically for cellphones that enable users to produce and send ADR reports to specific recipients. Applications in any language could be submitted, however those lacking the ability to submit an automated ADR report or with missing addresses could not be included. The study identified possible qualified ADR reporting apps using 17 search phrases from the Google Play Store and App Store.ps available Worldwide.

- Survey (online)

To evaluate the effect of app installation on the volume and quality of reports of adverse drug reactions (ADRs), a survey was carried out. The poll was directed at academic institutions, the pharmaceutical sector, and Pharmacovigilance professionals working for national regulatory agencies. The percentage of ADR reports received via the app among all reports since launch, trends in ADR reports following app launch, and answers to questions

about downloads were used to evaluate the quantitative impact. Responses to inquiries regarding the availability of the required minimum four information items for a valid safety report were used to evaluate the qualitative impact. Themes including ease of use, report quality, accessibility, inventiveness, data transferability, two-way communication, cost, and data security were developed from the app's experiences.

- An analysis of the quantity of reports that were filed to VigiBase both before and after the app's introduction

The quantity of ADR reports filed both before and after an app's release was analyzed using VigiBase, VigiLyze, and the analytical platform from VigiBase, was used for the analysis. Pre-launch period, timeline, and geographic breadth were among the search parameters. Apps that had been released for at least a year or two were the only ones included in the analysis, which was done on February 15, 2021. To compare the number of ADR reports in post-launch Periods A and B with the pre-launch period for each app, relative percentage changes were computed.

3. RESULT

2681 duplicate apps were eliminated from a study that involved 4126 and 1359 apps on the Google Play Store and App Store. 2144 and 660 apps were included in the initial screening round after duplicates were eliminated. Following the initial screening, selection criteria resulted in the exclusion of 2110 and 649 apps. Of the 34 and 11 apps that were screened in the second round, only Med Safety satisfied the requirements for admission. According to the study, Med Safety has 22 apps total that have been modified to fit the ADR reporting systems of eight different nations.

4. CONCLUSION

ADR reporting tools come in a variety of forms. Around the world, app-based ADR reporting technologies are growing in popularity and support ADR reporting through technological aspects. Because they are easier to report on and appeal to a larger range of reporters, they help enhance the culture of ADR reporting as a whole. Apps for ADR reporting have the potential to enhance Pharmacovigilance efforts. When launching an app, it is crucial to take into account features and functions that can enhance reporting both qualitatively and quantitatively. Additionally, it is important to take into account the intended user group, any training requirements, and the expenses associated with developing, launching, and maintaining the app. additionally, additional post implementation research would be beneficial in determining the long-term effects of app-based solutions and their sustainability.

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Acknowledgements and Reference heading should be left justified, bold, with the first letter capitalized but have no numbers. Text below continues as normal.

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