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Original Article

SiddAR (Siddha Initiative for Documentation of Drug Adverse Reaction): Android Mobile App for AYUSH Pharmacovigilance Programmes: An Efficient and Easy Way of Assessing ADR

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ABSTRACT

Background: *Mobile phones have become integral part of human life. A mobile application helps in Delivering food and also helps to conduct Delivery. Apart from connectivity android and iPhone make ease of all activities. One area of those applications is healthcare applications. "SiddAR" (**S**iddha **I**nitiative for **D**ocumentation of **D**rug **A**dverse **R**eaction) Android Mobile App is a pioneer app of its kind in AYUSH which helps in documenting, reporting and improve the communication of safety issues related to adverse drug reaction. Siddha Central Research Institute, Chennai is a Peripheral Pharmacovigilance Centre developed "SiddAR", a free smartphone app available on Android stores, for reporting adverse drug reactions and requesting drug safety information instantaneously.*

Aim: *In AYUSH pharmacovigilance, contemporary documentation process involves in submission of reports through filled in physical forms / online forms. Rapidity in Reporting would be lifesaving and also helps to prevent mortality and Morbidity.*

Methods: *25 single questionnaires in the report form were combined in the App. Algorithms were written and mobile app was designed using Android Studio with Eclipse plug-in along with SDK tools and manager. The app runs on android based Operating System of version 2.1 or higher.*

Results: *This Android app helps in real time documentation, lessening the time consumption and promotes the habit of being vigilant with drugs in market and their defects in manufacturing process. This App enhance the Researcher to document ADR in Clinical trials. This app would be a boon to the AYUSH health professionals and support team like nurses, AYUSH pharmacy persons and allied AYUSH persons to report the adverse events caused by drugs and to stream line the process of ADR reporting and analysis.*

Conclusion: *"SiddAR" ADR android mobile app can be an effective alternative method to manual ADR analysis and can become an important tool in strengthening the AYUSH Pharmacovigilance programmes.*

Key words: *"SiddAR", Android mobile APP, ADR, Siddha, AYUSH, pharmacovigilance.*

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INTRODUCTION

I Siddha and Other traditional Medicine is assumed to be Natural, Safe even in Long term usage. The drugs were studied in ancient days according to their Properties, Uses, Dose, Drug Reactions / Side Effects, their Management, Compatibilities & Incompatibilities; Interactions etc. The Pharmacovigilance system is prevalent from ancient days. Validation with suitable documentation is the need of the hour. Adverse Drug Reactions are the integral part of drug Pharmacology. Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). Pharmacovigilance system is in infant stage in India. The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health. Pharmacovigilance includes drug and Therapeutic procedures (Varmam & Thokkanam, Karanool, Detoxification procedures in Siddha).[1]

As compared to the modern systems, adverse events in the AYUSH systems of medicine adverse events are not reported widely.

தீயள வன்றித் தெரியான் பெரிதுண்ணின்
நோயள வின்றிப் படும்.
Theeyala Vandrith Theriyaan Peridhunnin
Noyala Vindrip Patum

Unlimited eating beyond one's measure Leads to unlimited number of ills stated in thirukural stanza – 947.

அளவுக்கு மிஞ்சினால் அமிர்தமும் நஞ்சு

Too much of anything is good for nothing is a proverb which stated by Saint Avvaiyar.

In Kannusamiyam ennum vaithiyasekaram[2] clearly mentioned "adverse events" related information in Siddha system of medicine. The following stanza says,

கொள்ளும்மருந்தொன்றில்கூறும்நலிதீர்ந்து
கள்ளப்பிணிவேறுகண்டிடின்கேள்-உள்ள
மருந்தாகதென்றேமருத்துவத்திலான்றர்
கருத்தமைத்துக்கூறினார்கண்டு (Prose 11)

'According to the stanza, if a drug (medication) cures an illness for which it was prescribed and subsequently causes another illness as result of taking that drug, then even if it is a superior form of drug, it should not be considered as a drug/medication'. This prose uses the Tamil term *'Kallappini'* referring to occurrence of an illness as a 'consequence' or 'adverse event' of the drug that goes beyond its indication. Hence, it is noteworthy to appreciate that the authors of ancient systems of medicine were mindful of unintended effects of medications. Finally, it is important note an imperative message underlying the text. It calls for a physician to have clinical acumen to identify, differentiate and manage the intended and unintended consequences of treatment. [3] Adverse drug reactions (ADRs) cause substantial mortality and morbidity in patients. [4-9] The World Health Organization (WHO) defines an ADR as a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function. [10] It is recognized that information technology (IT) has entered and altered the health care and clinical medicine in which the work of doctors and the care of patients with high quality, efficacy and lower cost. Earlier studies have shown that the mobile apps in health care provided various benefits to end users which include Doctors, patients and various stake holders. [11-15] Mobile technology facilitates effective delivery of services to patients and also improves quality of life of patients. [16-17] The "SiddAR" App is an android based mobile application, works on system with androidV6 OS 2.0 or higher. This Android app helps in real time documentation, lessening the time consumption and promotes the habit of being vigilant with drugs in market. This app would be a boon to the AYUSH health professionals and support team like nurses, AYUSH pharmacy persons and allied AYUSH persons to report the adverse events caused by drugs and to stream line the process of ADR reporting and analysis. Using of the app is made very simple with the help of user-friendly user interface (UI). The user has to fill the information in the required fields for the completion of ADR reporting. The user will then send the ADR form to the peripheral pharmacovigilance centre. Where a staff will follow up the reported ADR for further analysis. The user is free to send the ADR to peripheral pharmacovigilance centre by E-mail. This is the monopoly app first of its kind for AYUSH systems. Even though it is in siddha domain it can be customised and easily converted to other AYUSH stream like Ayurveda, Unani and Homeopathy by changing the list of medicines enlisted in the box. Pharmacovigilance has undergone some major changes. Here, the patient's active role in identifying and describing adverse drug reactions (ADRs) has gained recognition. This app has increasingly incorporated information and communications technology (ICT). Patients can now upload their own reports of ADRs online. Physicians used to dispense medicine which may have created ADR in which physicians are convicted instead of company manufactures, this app provides a role for taking pictures and to upload. Data on intensive medication monitoring are now collected via the Internet and smartphones.

METHODS

Assessment Tool for Adverse Drug Reaction (ADR) Currently no gold standard assessment tool has been proven for ADR therefore, the widely used National Pharmacovigilance Coordination Centre (NPvCC) tool were selected for the development of our app. The designed tool has been validated. The "SiddAR" ADR app was developed using the National Pharmacovigilance Coordination Centre (NPvCC) tool[18] This is a questionnaire-based tool for suspected ADRs using an algorithm built by a Siddha team from the Siddha Central research Institute in 2018. Development and Publishing the App into Google Play Store. The app was developed using the android application development. The development processes are divided into two main phases which are alpha and beta versions. For the development of the "SiddAR" ADR app Windows 10 by Microsoft was used as the operational system. Android studio was used during the alpha and beta version process and Android Emulator were then used to provide communication between running browser and android mobile Android studio is a free downloadable version with official integrated development environment (IDE) for Android application development. It is based on the IntelliJ IDEA, a Java integrated development environment for software, and incorporates its code editing and developer tools. After all the production phases were completed, the app was then saved in an APK file and then uploaded into the Google Play Developer Console. Once the "SiddAR" ADR app was published in Google Play Store, it could then be downloaded and installed for free by Android OS users. The app was designed without storage capacity to avoid issues regarding patient confidentiality or personal data. Therefore, information input into the system is not available to anyone.

https://play.google.com/store/apps/details?id=siddha.drug.documentation.

RESULTS

APP DEVELOPMENT AND PUBLICATION

The developed app was published in Google Play Store on March 05, 2018. "SiddAR" ADR app fulfilled the objective of the development. The app was freely downloadable from Google Play Store from March 2018. Architype screenshots for "SiddAR" app are shown below in figures1-10 Upto until August 20, 2019, a total of 150+ users have downloaded the app. The total installer, installer by country, and ranking statistics for "SiddAR" app are shown in Table 1. The installers were mainly from India and other parts of the world.

DISCUSSION

The health care professionals that used the apps concluded that the apps were convenient and they would choose them over conventional paper-based assessments. Previous studies have found that the use of apps in health care is effective, faster, easier, and more interactive due to factors of mobility, convenience, and involvement of active touching of the screen to perform the assessment. [19-20] The app is also secure, as they do not store any information from the data inputted into the app. [21-22] The use of medical app by health care professionals and researchers, and the numbers of this app are increasing rapidly. This App can give additional advantages at the point of care such as in diagnosis, monitoring, reporting, or follow-

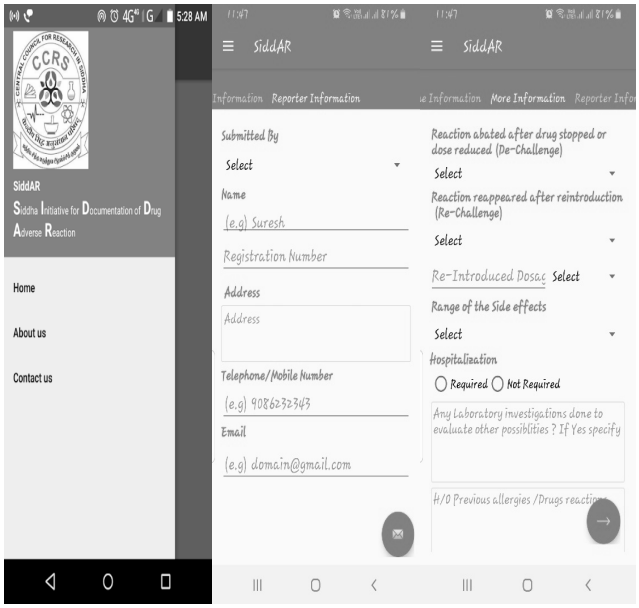
up of treatment. [23] The increased usage of mobile phone or mobile device apps warrant further studies evaluating their utility and effectiveness on a larger scale.

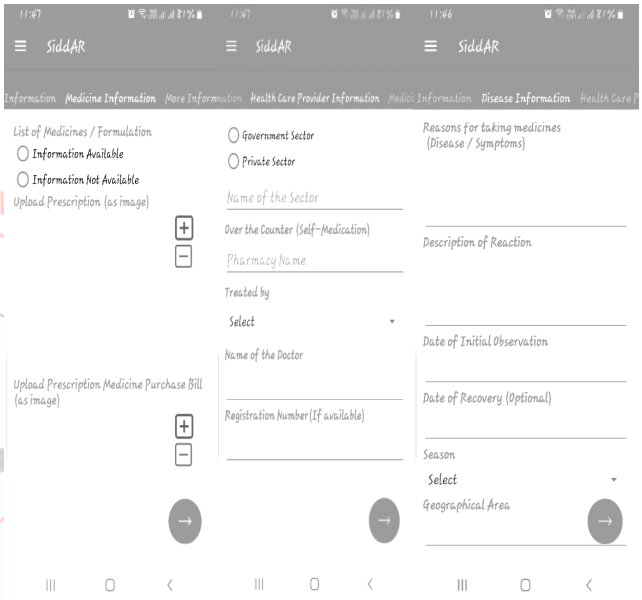
Limitations

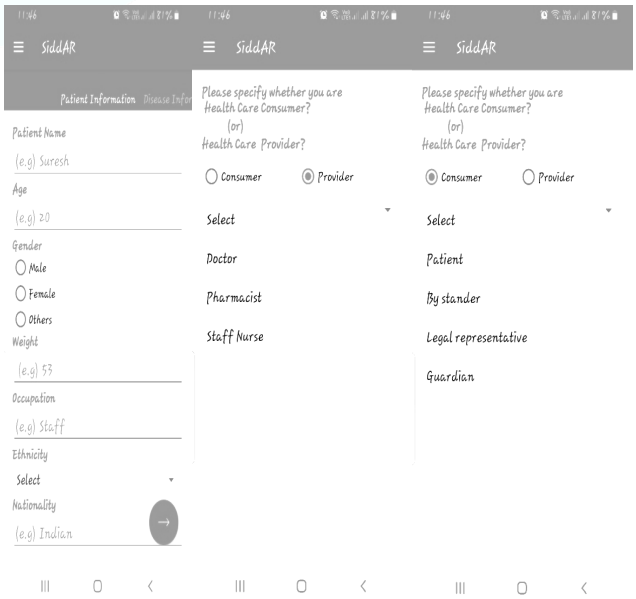
We have identified a few limitations of the app. On a basic level, there is no gold standard assessment tool for AYUSH ADR. We chose the National Pharmacovigilance Coordination Centre (NPvCC) TOOL to develop the apps; Further evaluation is necessary to gain more feedback from a wider range of users. Finally, the aesthetics of the app contents in terms of colour, text letters, and pictures have been optimized; however, there is room for improvement to make the app more attractive. We are continuously working to update and upgrade the app. Future research is needed to test the usability of the apps in varying populations and to add several other commonly used algorithms or tools in ADRs assessment. Research to highlight the context and content of the app should also be designed specifically, for health care professionals, researchers, and regulators.

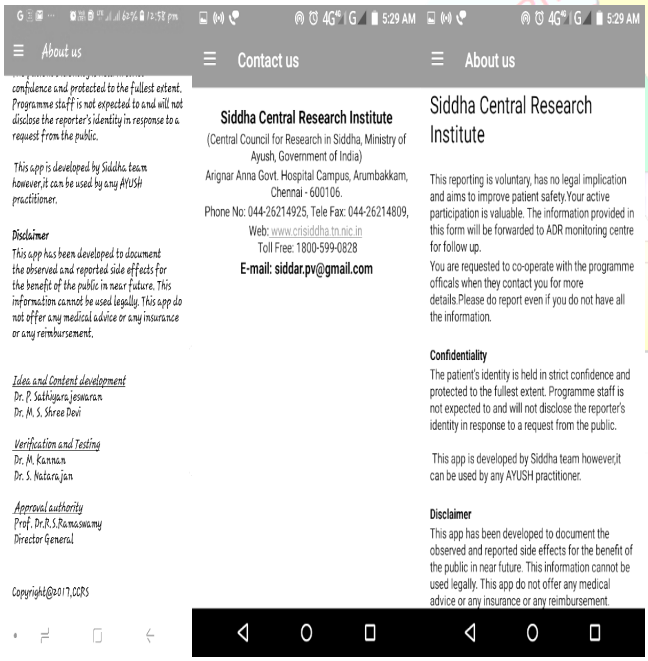
CONCLUSION

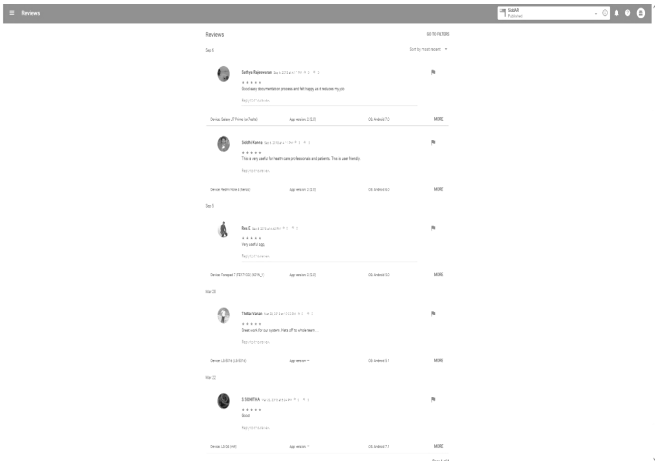
"SiddAR" app will aid health care professionals in determining the ADRs. This is aimed to contribute toward efforts to reduce the burden of ADRs on patients. the app have acceptance usability among health care professionals. They will also support future research to enhance overall safety relating to drugs given to patients.

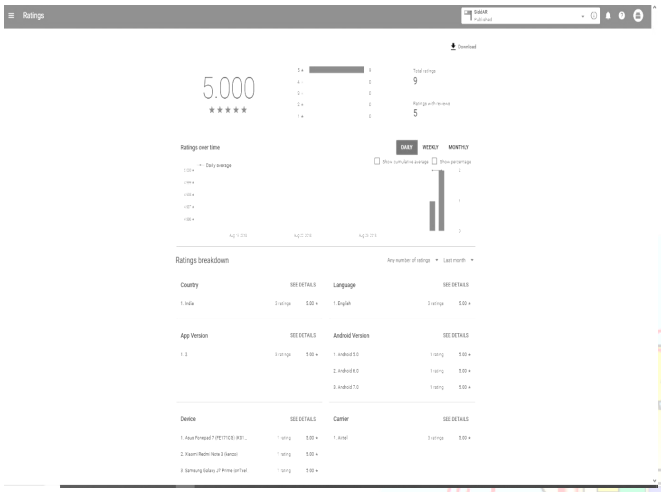


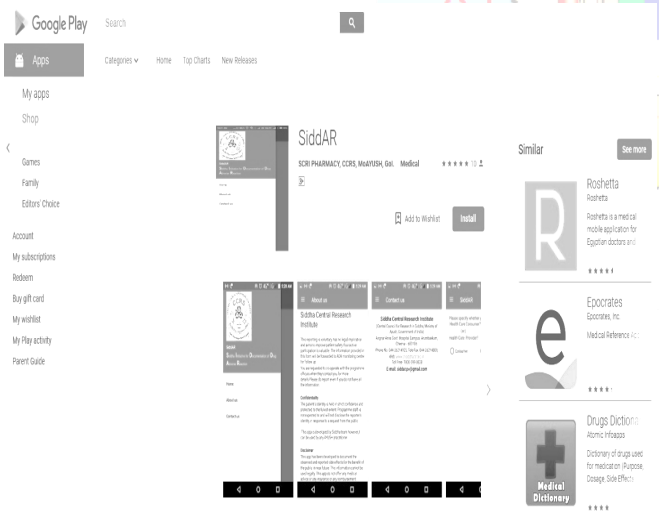












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