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Research Article

Development of an Interventional Tool for Direct Reporting of Adverse Drug Reactions by Healthcare Users in South Africa

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ABSTRACT

The present policy in South Africa is for healthcare users to report adverse drug reactions through medical practitioners, pharmacists, nurses, dentists, or veterinarians. This study aimed to develop a web-based application as an interventional tool for reporting adverse drug reactions. The software will also serve as an educational program to create awareness and encourage reporting by healthcare users directly to the pharmacovigilance authority. Previous studies were carried out by reviewing directs reporting in Africa to survey the view of healthcare users on direct reporting in South Africa and methods of direct reporting. Findings from these studies resulted in the development of a user-centred web application. Heuristic evaluation (n=3) and small-scale usability testing was carried out. The objective (task success rate) and subjective (system usability scores) metrics were used to test the usability of the application among participants (n=22). This was followed by redesigning the application before the final presentation. An easily accessible digitalised adverse drug reporting web-based application named SA-VigiApp® was developed. It has health information tips as an educational intervention. The initial heuristics evaluation affirmed that the web application has Six (6) out of the 10 items on Nielsen's Heuristic checklist. A total of 22 participants aged 18 and above were recruited for small-scale usability testing. Majority of the participants (n= 11; 50%) accessed the web application with the use of android mobile phones while others used computer laptops (n=6; 27.3%), iPhones (n= 4; 18.2%) and tablet (n=1; 4.5%). The mean task success rate was 84.2% with 7 out of 11 tasks completed successfully. The usability score was 76.7%. The application was redesigned following the responses and comments from the usability testing. Results suggest that participants rated this application as usable. The redesigned application has all the main features for adverse drug reaction reporting and user's acceptability that will be useful for a prompt rate of report submission. It will also serve to create awareness and inform users on medication-related issues.

Keywords: *Adverse drug reactions, direct reporting, healthcare users, web-based application*

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INTRODUCTION

The prevalence of diseases in Africa with poor health-seeking behaviour has led to high consumption of prescribed and over-the-counter drugs. The resultant effect has been an increase in the frequency of adverse drug reactions (ADR) (Isah *et al*., 2012). Worldwide, there has been under-reporting of these unwanted reactions which is a challenge to the pharmacovigilance system (Anderson *et al*., 2011b). The individual case safety report (ICSR) submitted by African countries is less than 1% of the global total in VigiBase (Ampadu *et al*., 2016). Improvement and positive impact have been recorded in countries that have adopted the direct method of reporting ADR (Wilson and Amma, 2015, Jha *et al*., 2014, Anderson *et al*., 2011a, Basch *et al*., 2009, Blenkinsopp *et al*., 2007a). Healthcare users have been able to report directly to the pharmacovigilance authority through various means adopted by different countries, which include paper or faxed base, electronic (web-based, email, online media), telephone, and use of a combination of these methods(van Hunsel *et al*., 2012). Few African countries have formally launched a direct method of ADR reporting to pharmacovigilance authorities (Adedeji-Adenola and Nlooto, 2020a). To improve surveillance on medications and strengthen pharmacovigilance activities, all African countries have been urged to adopt newer methods and technologies to document and investigate adverse events to medical products (Ndagije *et al*., 2018).

Biomedical informatics is rooted in technologically based methods of improving the management of patient data and other information relevant to patient health. It has significantly contributed to the infrastructural development of pharmacovigilance (Åserød, 2017). A web-based monitoring

system which is a form of biomedical informatics has been reported to be an advanced method for a useful source of information in signal detection, an additional type of information, and ADR reporting (Yamamoto *et al*., 2015, Härmark *et al*., 2015). The internet has become a novel source of health data that has enabled users to monitor and share personal information including medication information. It has been used over time as an educational tool for information, response to enquiries, react to health-related news, discourage the public from unethical health behaviour, and so on. Governments have been urged to adopt and apply internet technologies for the assessment, protection, and promotion of public health. It was estimated that 75-80% of the worldwide web have searched for health information (Taylor *et al*., 2011). The use of smartphones and mobile applications has improved the telecommunication sector. This technology also holds great promise for safety surveillance and pharmacovigilance in Africa (Dodoo, 2018). Studies have shown the benefit of mobile technology and application software in healthcare management including pharmacovigilance (Santos, 2015, de Vries *et al*., 2017). Studies carried out to evaluate and demonstrate how healthcare consumers can be a useful source of information in signal detection and ADR reporting showed web-based monitoring system as an advanced methodology in pharmacovigilance that can generate an additional type of information (Yamamoto *et al*., 2015, Härmark *et al*., 2015). A report of a survey carried out among 50 countries showed the highest rate of healthcare consumers directly reporting in countries with online reporting systems (Margraff and Bertram, 2014).

Presently, there is no policy for healthcare users to report ADR directly to the pharmacovigilance authority in South Africa. Consumers are advised to report through medical practitioners, pharmacists, nurses, dentists, or veterinarians (MedicinesControlCouncil, 2014). Reports of ADR per million of inhabitants in South Africa was approximately 62 in 2015 as against a minimum of 200 ADR per million inhabitants in a year proposed for a functional pharmacovigilance system by the World Health Organization (Osakwe *et al*., 2013, Mehta *et al*., 2017). There is a need to develop and evaluate tools that are easily accessible for healthcare users in South Africa to report ADR. This can also serve as a medium to educate on medicine safety issues.

In 2018, when the global digital population surpassed four billion, 51% of South Africans were online and 31% were on social media. Sixty per cent (60%) of those online use smartphones while 24% appeared on laptops and computers (KayaFM, 2019). In January 2020, out of more than 59 million population of South Africans, 36.54 million were internet users with 34.93 million mobile internet users (Statista, 2020). This shows great potential for ADR reporting web-based application usability in South Africa.

This study aims at developing an internet web-based mobile compatible application; a framework to serve as an interventional tool for digitalised reporting of ADR by healthcare users and as an educational/ awareness platform to inform and encourage ADR reporting. The web-based application is expected to improve the rate of ADR reporting, prompt feedback, and safety intervention, as well as to strengthen pharmacovigilance activities in South Africa.

MATERIALS AND METHODS

Ethical approval: This study was approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee with BREC REF: BE091/18. Informed consent was obtained from all participants surveyed in the usability testing.

Literature search on direct reporting of adverse drug reactions: Literature search guided by Cochrane handbook was conducted in scientific databases: PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Cochrane library, a website for the regulatory resources for Africa and World Health Organisation – Uppsala Monitoring. Search engines such as google scholar and general google search engines were also searched for relevant information on guidelines, documents, and publications on direct reporting in Africa. The review period was January 1992 to October 2019 (Adedeji-Adenola and Nlooto, 2020b).

A study conducted in eThekwini and King Cetswhayo districts of KwaZulu-Natal on views of healthcare users on direct reporting of adverse drug reactions: The questionnaire contains five sections and administered to eligible healthcare users from Municipality A (eThekwini district) and Municipality C (King Cetswhayo district) in South Africa between October 2018 – October 2019. This was carried out at the five levels of care in the two districts. A total of 10 public health facilities were used to conduct the survey. Section 1 describes the participants' sociodemographic. Section 2 documented the knowledge of ADR and awareness of the pharmacovigilance system. Section 3 recorded the attitude towards ADR reporting. Section 4 recorded the motivation and barriers for reporting ADR on a 5-point Likert Scale. Section 5 identified the preferred method of participants for reporting ADR directly to the pharmacovigilance authority. Information sheet on the study was presented and signed informed consent was received before the survey (Adedeji-Adenola H, 2020).

Economic evaluation of direct reporting methods by healthcare users: Methods used in developed and developing countries to report adverse drug reactions by healthcare users were identified through a review of the literature. Statistical analysis of the previous study on views of healthcare users on direct reporting methods was carried out. A decision tree that was consistent with the pathway of direct reporting was developed. A cost minimisation analysis was carried out from the healthcare users' and providers' perspectives and data obtained in April 2021. All costs were reported in Rands (ZAR, South Africa monetary value).

Development and usability testing of the improved web application for reporting adverse drug reactions from healthcare users

The developmental process of the adapted web application: A progressive mobile compatible web application was developed. This was adapted from the ADR reporting form designed for health workers by the South African Health Products Regulatory Authority (SAHPRA), previously known

as the Medicine Control Council (MCC) (Medicines ControlCouncil, 2014). The web application also adapted the Web-Recognizing Adverse Drug Reactions (RADR) developed for The Netherland, The UK yellow card, Burkina Faso, and Zambia for direct reporting by healthcare users (Ghosh and Lewis, 2015, Agency, (MHRA), intelligence, 2017, WEBRADR, 2017). In addition, the electronic reporting platform in France was carefully studied (eVeDrug). This is to give an insight into a new website with better design and features.

The web application was developed using the approach, principles, and framework that guides the design and redesign process of an end-users-centred system, that will ensure a useful and usable web application (Taylor *et al*., 2011, Pierce *et al*., 2019). Validated models for assessment of healthcare usability testing of applications were used during the developmental process (J., 1996, Albert and Tullis, 2013, Bevan, 2008).

Initial design phase: The design team consisted of two (2) researchers [project supervisor with a Ph.D. and a Ph.D. student at University of KwaZulu-Natal (UKZN) who also have experience in pharmacovigilance activities] and a Microsoft certified information technology specialist.
The development of the mobile compatible web application started with identifying the end-users (healthcare users), task analysis (functionality in terms of user's goal and how the goals can be achieved with the web application to be developed, user platforms, input and output formats, information flow and communication needs of end-users), identifying design requirements (visual graphical representation, features, and information display that clarifies website content). An initial design was drafted and translated into a design document.

Development Phase: During this phase, the web application was developed and named SA-VigiApp®. The application has two graphic user interfaces (GUI) namely, the health care user's GUI and administrator's GUI. Visual Studio Code by Microsoft was used as the programming text editor. HTML, Bootstrap, and CSS were used for the user interface design. JavaScript and Angular JS were used for the logic of the application. Google firebase was used for the hosting, storage, user management, and authentication platform. The application has cross-platform functionality. It can be run on android, IOS, Linux, and Windows devices.

Usability testing

The extent to which a product can be used by targeted users to achieve specified goals with effectiveness, satisfaction, and efficiency in a specified context of use has been described as usability (Albert and Tullis, 2013). Usability testing of the web application developed included two (2) components which are heuristic evaluation by experts and small-scale usability testing (objective and subjective) by healthcare users.
Heuristic evaluation: Two informatics and a pharmacovigilance expert were recruited as usability evaluators as recommended by Nielsen (Nielsen, 2005) to include three to five evaluators in usability testing. Experts included a technology support practitioner at UKZN - also a Ph.D. student with published articles and book chapters in the field of information technology, the second expert is a business engineer, an application developer, and a project manager. The third heuristic evaluator is a professor/ pharmacovigilance consultant with many publications on adverse drug reactions/ pharmacovigilance.

Usability experts were briefed about the aim and objectives of the application and were provided with links to the graphic users and administrative interfaces of the developed web application. They were asked to complete a session in the application by going through all the tasks while thinking aloud. Verbal comments were documented by note-taking. They also completed the heuristic evaluation form provided. Each question on the 10 item checklist was scored as "yes", "no" or "not applicable".

End users small scale testing: A measure of the web application usability, functionality, and content-based testing was carried out among eligible participants (n=22) between July and August 2019. Eligible criteria for participation were: 18 years of age or older, healthcare users that have taken medication at least once in a lifetime, and participants willing to be enrolled in the survey.

Exclusion criteria included respondents that declined to participate or those that do not fall into the eligibility criteria. Potential respondents were approached with an initial introduction to the aims and objectives of the survey. Interested participants were screened for eligibility and a detailed explanation of the web application and functionalities was provided. Recruitment continued until twenty-two (22) individuals agreed to participate in the survey. Objective, subjective, and open-ended usability testing were used.

The objective usability of this web application was assessed using 11 task activity items to measure task success. These were observed and documented using pen and paper notetaking. The task success was carried out to evaluate the effectiveness of the web application. The subjective usability testing was carried out with a post-test questionnaire to assess the end user's satisfaction with the application. The post-test questionnaire consisted of a system usability scale (SUS) statement (Grier *et al*., 2013) and additional open-ended questions. The questionnaire consisted of 3 sections. Section 1 seeks the demographic characteristics of participants. Section 2 presented the SUS statements on a 5-point Likert scale of strongly disagree, disagree, not sure, agree, and strongly agree. Section 3 collected comments and opinions on the design technology in an open-ended style.

Redesigning phase and final modification: The web application was redesigned following the result of the heuristic evaluation and small-scale usability testing. Some of the modifications included the addition of privacy policy and about the app in a separate link, adjusting the ADR form to a page, making the link to some features colourful, improving on the layout and aesthetics of the desktop and mobile version, acknowledgement after submission of adverse reaction profile and a drop-down option for types of adverse reaction.

Data analysis

Descriptive statistics such as a measure of central tendencies were used to analyse the heuristic evaluation responses, frequencies were used to analyse the demography and task success in objective usability testing while the subjective usability scale testing was analysed using the procedure by Brooke (Brooke, 2013). Comments from the heuristic evaluation, open-ended questions under the subjective questionnaire, and final expert review were analysed by the research team to identify areas of usability concern that need improvement. Common concerns were discussed and deliberated until consensus was reached.

RESULTS

Outcome of literature survey on direct reporting of adverse drug reactions: Sixteen (16) African countries were identified to have included healthcare consumers as stakeholders in reporting adverse drug reactions in their policy/guidelines. Eight (8) African countries out of thirty-six (36) that are members of the World Health Organisation Programme for International Drug Monitoring have formally launched direct reporting by healthcare consumers. These countries include Nigeria (2012), Kenya (2013), Ghana (2015), Zimbabwe (2016), Zambia, and Burkina Faso (2017). There is low awareness of healthcare consumers on pharmacovigilance systems. There is also a wide range of differences between the rate of adverse drug reactions report submitted by health care consumers as compared with healthcare workers. Paper-based, text messages, telephone, and web application-based reporting systems have been used by different countries that have launched direct reporting. The challenges affecting direct reporting methods in Africa include poor infrastructure, low awareness, lack of a reporting culture, and so on while the presence of these reporting methods is a potential opportunity of promoting direct reporting in African countries (Adedeji-Adenola and Nlooto, 2020b).

Healthcare users views on direct reporting of adverse drug reactions; analysis of eThekwini and King Cetswhayo districts of KwaZulu-Natal: The survey has a response rate of 94.1% (n=1084). There was average knowledge on adverse drug reactions (603; 55.6%) and low awareness of pharmacovigilance programs (286; 26.4%). It is important to note that sixteen participants (16; 7.3%) and 4 (1.8%) of the female respondents have had a disability and congenital abnormality at birth, respectively which is due to adverse drug reactions. Respondents have a positive attitude (947; 87.4%) towards reporting and participants from municipality A prefer the online (website) option of reporting while participants from municipality C have a preference for the telephone option of reporting.

Health economics evaluation of direct reporting methods: Five common methods of direct reporting were identified as a web-based application, mobile application, telephone (toll-free text message with a phone call), e-mail, and drop box in hospitals. Web-based and mobile applications have the lowest cost of reporting by healthcare users (1.19ZAR) followed by telephone (5.40ZAR), e-mail (5.69ZAR), and drop box in hospitals (50.90ZAR). The investment cost by the provider is at no cost with creating email (0ZAR) method of reporting followed by telephone (1800ZAR) and web-based application (26200ZAR). Developing a mobile application on average was 149000ZAR while providing drop boxes (365893ZAR) in 407 public hospitals in South Africa was the most expensive.

Step 4: Development and usability testing of the adapted web application to report adverse drug reactions from healthcare users

Based on previous findings, we developed a simplified digitalised mobile compatible web application named SA-VigiApp® with administrative and users' interfaces. The links to the respective interfaces are http://bit.ly/vigiappadmin and https://vigiapp-f4692.web.app. Screenshots of the redesigned interfaces are shown in Figures 1 and 2, respectively. The administrative interface has two main features which are, "feedbacks (users submitted report link)" and "post health information". The users' interface has "login", "home screen navigation" that also has the following features "language selection", "health status feedback" and "health information", "report (adverse drug reaction form)", "about the app", "frequently asked questions (FAQ)", and "privacy policy".

Responses from the usability scale testing of the web application

Heuristic testing: Heuristic means score ranges from 1.00 – 3.00 on the 10 items on the heuristic checklist as summarized in Table 1. Scores closest to 0 have been shown to indicate a more usable product (Stonbraker *et al*., 2018). The areas identified in need of improvement were "user control of freedom" (ability to move forward and backward), "error prevention" (the ability of the system to warn users if they are about to make a potentially serious error), and "flexibility and efficiency of use".

Table 1:
Mean response from heuristic testing

Nielsen's Heuristic checklist	N	Mean	SD
Visibility of system status	3	1.00	0.00
Match between system and the real world	3	1.00	0.00
User control and freedom	3	1.67	0.58
Consistency and standards	3	1.00	0.00
Error prevention	3	1.33	0.58
Recognition rather than recall	3	1.00	0.00
Flexibility and efficiency of use	3	2.33	0.58
Aesthetic and minimalist design	3	1.00	0.00
Help users recognize, diagnose, and recover from errors	3	3.00	0.00
Help and documentation	3	1.00	0.00

According to the evaluators, "help users recognize, diagnose, and recover from errors" is not applicable in the developed web application. Experts also recommended; "description of ADR could have a drop-down option", "workflow to indicate acknowledgement of ADR report after submission by users". Addition of separate link for privacy policy and accessibility

statements were also suggested. The evaluators gave positive feedback such as "The ability to report adverse reaction when offline is an added advantage and will prevent missed report that may be due to poor network" "the numerous language option is good" "the application is simple and easy to use".

End user's small-scale testing: The usability testing was carried out among 22 participants with more females (n = 15, 68.2%) than males. Majority are between the age range of 18-24 (SD= 0.79). Most of the participants were in high school/ university (n=17, 77.3%), students (n=19,86.4%) and unemployed (n=19, 86.4%). Majority of the participants (n= 11; 50%) access the web application with the use of android mobile phones, other devices used were computer laptops (n=6; 27.3%), iPhones (n= 4; 18.2%) and tablet (n=1; 4.5%). The participants were Indians (n=10, 45.5%), Black Africans (n=7, 31.8%), Asians (n=2, 9.1%), Coloured (n=2, 9.1%) and white (n=1, 4.5%) (Table 2).

Table 2:
Demographic characteristics of end-users surveyed for small scale usability testing (N=22)

Variables		N (%)
Gender	Male	7(31.8)
	Female	15(68.2)
Age (years)	18-24	17(77.3)
	25-31	3(13.6)
	32-38	1(4.5)
	39>	1(4.5)
Education	High school/ University	17(77.3)
	Postgraduate	5(22.7)
Working status	Employed	3(13.6)
	Non employed	19(86.4)
Occupation	Student	19(86.4)
	Researcher	2(9.1)
	Customer service personnel	1(4.5)
Tribe	Black African	7(31.8)
	Indian	10(45.5)
	Asian	2(9.1)
	Coloured	2(9.1)
	White	1(4.5)
Device used	Android	11 (50.0)
	Computer laptop	6 (27.3)
	iPhone	4 (18.2)
	Tablet	1 (4.5)

Task success: The percentage of participants who completed a task and their success rates are summarised in Figure 3. The result of the success rate of a given task was categorised into "completed with ease" when participants can finish the task on their own, "completed with difficulty" when participants could not complete the task on their own, and "failed to complete the task" when the participant could not complete the task despite help.

Objective usability testing: The objective usability testing (Table 3) recorded a mean task success rate of 84.2% with 7 out of 11 tasks completed successfully. Seventeen (17, 77.3%) of the participants were able to submit adverse drug reaction forms through the link. Tasks 5, 7, 9, and 10 which are adverse drug reaction form, Health tips, second log-in, and second session respectively were the task items few participants (n= 7, 31.8%) failed to complete.

Table 3:
List of tasks and activities

Task	Task Item	Test activity
1	Log-in	Logging into the web application with individual e-mail and password
2	Home screen navigation	Navigate to the home screen of the application to view various features
3	Select language	Select out of the one hundred and three (103) language option
4	About the App	Finding and reading about the application
5	Report	Click to view the form and submit adverse drug reactions
6	Health status feedback	Click onto "my health status feedback" link to access the Pharmacovigilance admin contacts, send additional information through email as video, note, or picture
7	Health information	Finding and reading the health information and news of the application
8	Log-out	Log out of the App
9	Second Log-in	Log back into the App using an already given user account
10	Second session	Complete second session
11	Second Log-out	Log out of the App completely

Subjective usability testing

System usability scale: The mean SUS score was 76.7%. Nineteen (19) out of twenty-two (22) which is 90.91% of participants had a score above 68%. A score above 68% means on average, participants were satisfied with the usability of the web application (Brooke, 2013). The 10 questions with a 5-point Likert scale answering scheme of the SUS are summarised in Table 4.

End users provided open-ended comments such as, "the web application needs a better user interface", "the display should be properly categorised", "it needs more colour", "make the app more presentable and user friendly". Generally, participants stated that the web application was simple to use, the language option is good, and will encourage wide usage, A participant wrote, "the tool is user friendly and happy about this initiative for reporting medicines adverse effects".

Table 4:
Usability questions and summary of responses (N= 22)

Answer option	Strongly disagree n(%)	Disagree n(%)	Not sure n(%)	Agree n(%)	Strongly agree n(%)
I think that I would use this App frequently	0(0)	0(0)	4(18.2)	10(45.5)	8(36.4)
I found the App unnecessarily complex	1(4.5)	12(54.5)	2(9.1)	3(13.6)	4(18.2)
I thought the App was easy to use	0(0)	0(0)	1(4.5)	9(40.9)	12(54.5)
I think that I will need the support of a technical person to be able to use this App	4(18.2)	15(68.2)	3(13.6)	0(0)	0(0)
I found the various functions in this App were well integrated	0(0)	0(0)	3(13.6)	11(50.0)	8(36.4)
I thought there was too much inconsistency in this App	8(36.4)	14(63.6)	0(0)	0(0)	0(0)
I would imagine that most people would learn to use this App very quickly	0(0)	0(0)	0(0)	14(63.6)	8(36.4)
I found the App very cumbersome to use	3(13.6)	12(54.5)	5(22.7)	2(9.1)	0(0)
I felt very confident using the App	0(0)	2(9.1)	4(18.2)	13(59.1)	3(13.6)
I needed to learn a lot of things before I could get going with this App	11(50.0)	8(36.4)	3(13.6)	0(0)	0(0)

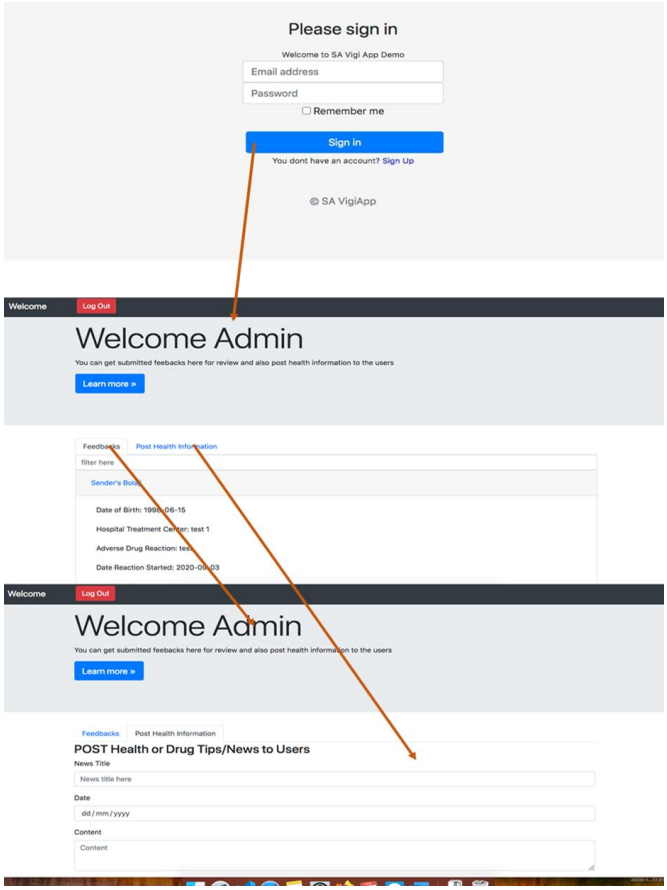

Figure 1
Screenshot of the redesigned administrative interface of the SA-VigiApp®

DISCUSSION

The web-based monitoring system has been reported to be an advanced pharmacovigilance system that can be useful to generate additional information on ADR (Yamamoto *et al*., 2015, Härmark *et al*., 2015). In previous studies assessing the preferable method of reporting ADRs by healthcare users, the majority of respondents preferred the electronic (online) reporting of ADRs as the most convenient method (Adedeji-Adenola H, 2020, Pahuja *et al*., 2014).

This study developed a web-based application named, SA-VigiApp® as an intervention for direct reporting of ADR reporting by healthcare users in South Africa. It also serves as an educational tool for informing healthcare users about vital health tips and to create awareness of ADR reporting.

The administrative interface of this web application is only accessible to the administrators with a confidential password. It has the link to post educational and health information. This is tagged as "post health information". Once the information is submitted on the administrative dashboard, it can be viewed by all healthcare users on the user's interface. All submitted ADR reports from the user's interface can be viewed by the administrator from the administrative interface and the information can be extracted in pdf or excel formats. The administrative interface can be accessed by authorized persons for analysis purposes only. This is to ensure confidentiality by conforming with the principles of the data protection act of the South African Protection of Personal Information Act (POPI). POPI states that 'processing of collection, recording, organisation, storage, updating or modification, retrieval, consultation, use, dissemination through transmission, distribution or making available in any other form, merging, linking, as well as blocking, erasure or destruction of personal information, can only be used for specified purposes and must not be used beyond the original scope that was agreed.' (De Bruyn, 2014).

Figure 1:
Screenshot of redesigned users' interface of the SA-VigiApp®

The design of the "report" link which is the ADR reporting electronic form adhered to the principles of a valid case report according to the guideline of post-market reporting of the South African Health Products Regulatory Authority. This is based on the four minimum criteria. These are; a patient, adverse reaction, a suspected drug, and a reporter (MedicinesControlCouncil, 2014). The electronic form developed is also able to provide information that is required by classical methods of reporting in pharmacovigilance.

Healthcare users will be able to access useful knowledge and other vital health information through the health information link of SA-VigiApp®. This will increase their awareness of the pharmacovigilance system as the main reason for under-reporting has been reported to be ignorance, lack of knowledge of ADR, indifference, and complacency (Lopez-Gonzalez *et al*., 2009).

The user's interface was developed to have features for healthcare users to log in with their e-mail addresses. It has up to one hundred and three (103) language options. There are five (5) out of the eleven (11) official languages in South Africa (Nel *et al*., 2012) available on the integrated google language of this application. These are isiZulu, isiXhosa, Sesotho, Afrikaans, and English languages. The numerous language options ensure healthcare users from a different country of origin resident in South Africa can use the application with ease. An individual can select a language of choice to be able to access vital health information and be able to report ADR through the "Report" link. A qualitative study that identified the factors influencing the use of a mobile application for ADR reporting stated that the application needs to be available in the languages of intended users and needs to be visually attractive (de Vries *et al*., 2017).

Technical and quality features were put into consideration in the development of this application to further enhance usability. When there is no access to the internet, the web application was integrated with progressive application technology that ensures that the submitted data while offline would be pushed to the database automatically once the internet is restored on the device. This would make an efficient usage for users in remote areas where internet provision is erratic. Users can also access health information offline after it has been accessed online. Feedback from the pilot of the web

application launched in Zambia and Burkina Faso in 2017 showed the importance of offline functionality for reporting ADR and news (Pierce *et al*., 2019).

The web application was programmed to give feedback. Upon submitting a report, an automatic message confirming the successful submission comes up. This is like the direct reporting platform of The UK online yellow card. It has been reported to automatically generate an acknowledgement letter to those that submit reports. They also have the opportunity to have access to drug safety updates and electronic monthly bulletin once they submit their report (van Hunsel *et al*., 2012). SA-VigiApp® has a "health status feedback" link that has the contacts of the administrators. Enquiry and follow-up through email, telephone, or text message can be made. Images or videos as additional information can also be sent through the administrator's contacts. This mechanism ensures the submission of the accurate report as low-quality reports have been documented with ADR reports by healthcare users (Blenkinsopp *et al*., 2007b). The concept of sending images such as dermatological reactions or medication package is like the design of eReport® which is the ADR online reporting platform in France. The platform has a link to upload images as additional information to the ADR report (eVeDrug).

To ensure that the intervention can be presented with a design and content that reflects an end user's opinion and acceptability, usability testing of the web application was conducted with informatics, pharmacovigilance experts as well as end-users to identify usability concerns and provide recommendation for redesigning of the application before the presentation. Findings from the result of the heuristic evaluation as well as small-scale objective and subjective usability testing carried out suggest satisfactory and acceptable usability of the web application.

Findings from this study through the small-scale usability testing showed that the web application can be accessed on mobile phones such as android, iPhone as well as tablets and laptops. SA-VigiApp® was designed as a cross-platform application that can be run on any platform including android, IOS, Linux, and Windows devices. It makes use of a responsive web design approach that renders it well on a variety of devices, windows, or screen sizes. Hence, it can be downloaded on a mobile phone or mobile devices (tablets, laptops, or desktops). This is very important as recommended by Pierce *et al*., 2019 on the use of applications for collection and communication of pharmaceutical products' safety information (Pierce *et al*., 2019). Previous studies on the use of applications to report ADR showed that most healthcare users prefer an application that is efficient and realistic in reporting adverse events (Wilson *et al*., 2016).

Study strength and limitation

This study developed a digitalised reporting portal for healthcare users in South Africa to be able to submit any ADR experienced after the use of medication. This will improve and increase the rate of ADR submitted. It will also strengthen the pharmacovigilance program in South Africa. Furthermore, the study is focused on the use of an innovative tool; a web application by healthcare users in real-life conditions to share their experience.

Participants surveyed for the small-scale usability testing were from the University of KwaZulu-Natal, they may have been more motivated and comfortable with using web applications on their devices for addressing their health issues including reporting ADR due to their level of literacy. Thus, this sample may not be representative of the general population. Although the results of this study suggest that the response of participants to SA-VigiApp® was positive, to counter these limitations, further research will be carried out to trial this technology among a larger population after launching the application. This will come after the official launch of the web application with the approval of the pharmacovigilance authority in South Africa.

Conclusion

This research developed SA-VigiApp® as an interventional tool and educational program for healthcare users to report ADR and access health information, respectively. The result from the usability testing showed it is acceptable, usable, and will be a method to increase and improve the rate of reporting of adverse reactions to medications. This technology will serve as a feedback medium to the public after submitting ADRs.

The next step will include sharing the results with pharmacovigilance authorities in South Africa and future work is to launch the web application on play stores, evaluate the outcome on a large population and make it available for direct reporting of ADR.

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