Use of medical safety apps for drug reaction reporting by health workers

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Abstract:

Adverse drug reactions (ADRs) are an important public health challenge worldwide; however, pharmacovigilance systems are plagued by under-reporting. Mobile technologies, including mobile applications such as Med Safety, could strengthen ADR reporting. We explored the acceptability, and factors that could influence uptake of, Med Safety for ADR reporting by health workers in Uganda. The study took place between July and September 2020 in 12 HIV clinics in Uganda and employed a qualitative exploratory research design. We conducted 22 in-depth interviews and 3 mixed-gender focus group discussions (49 participants) with a diverse range of health workers. We analysed the data using a thematic approach. There was goodwill among the health workers to adopt Med Safety for ADR reporting and the majority would recommend the app to other health workers. Training with practice increased acceptability of the app. Uptake of the app was favoured by the younger, technology proficient, health worker demographic; the app's offline and two-way risk communication functionalities; availability of free internet hotspots at some health facilities; goodwill and willingness of health workers to report ADRs; and the cumbersome nature of conventional ADR reporting tools. Potential barriers to the uptake of Med Safety were the perceived lengthy processes of initial app registration and completion of multiple screens during ADR reporting; challenges with health workers' smartphones (incompatibility with application, no space for more applications, low battery charge); high cost of internet data; poor internet connectivity; difficulty in recognising ADRs, language barrier and poor feedback to ADR reporters. There was goodwill among the health workers to adopt Med Safety for ADR reporting and the majority would recommend the app to other health workers.

Key words: Drug Reaction, language barrier, Med Safety, communication, technology proficient

1. Introduction:

Globally, adverse drug reactions (ADRs) are associated with high morbidity, mortality and economic costs. Timely prevention, detection, reporting and management of ADRs is essential for patient safety. Although ADRs are an important public health challenge, they are widely under-reported, which underestimates the risks of medicines and impedes actions to improve medication safety. Under-

reporting of ADRs is underpinned by complex interactions between patient-related factors, drug-related factors, and health-system barriers, among others.

Recent advances in mobile technologies allow for two-way exchange of medication safety information between ADR reporters and National Drug Regulatory Authorities (NRAs). Reporters submit safety reports to NRAs using mobile applications, or apps, and NRAs simultaneously transmit new safety information through the same apps to ADR reporters. An app programmed for the two-way exchange of medication safety information increases engagement of ADR reporters with their respective NRAs and could reduce the time lag between an ADR onset and its registration in both national and World Health Organization (WHO) drug safety databases. The Web-Recognising Adverse Drug Reactions (Web-RADR) project developed and implemented a prototype Web-RADR app for ADR reporting in European nations. The WHO subsequently adapted the prototype into the low-cost Med Safety app, for low- and middle-income countries (LMIC). Med Safety has two-way risk communication functionality to promote efficiency in ADR reporting and transparency of NRAs to ADR reporters and can be used by both patients and health workers.

Factors that influence the use of mobile apps in health care in high-income countries include the lay-out of the app, ease of use, and data security if the data are held in the app. In LMIC, however, little is known about factors that could influence the uptake of Med Safety for ADR reporting by health workers. Engaging potential end users in implementing an app is important to ensure that their views are taken into account, which improves the app's uptake and utilisation. There is particular interest in Med Safety to promote active drug safety monitoring of newer antiretroviral therapy (ART) (e.g., dolutegravir-based regimens) and tuberculosis preventive therapy (e.g., isoniazid preventive therapy [IPT]), which are widely rolled-out in LMIC.

We conducted this qualitative study to inform the feasibility of implementing a planned large-scale multicentre pragmatic cluster-randomised controlled trial to evaluate the effectiveness of Med Safety. The trial aims to assess the ability of Med Safety to improve the rate and quality of ADR reporting by Ugandan health workers, with particular focus on ADRs associated with dolutegravir-based HIV treatment and IPT. The study explored the acceptability of rolling out Med Safety for ADR reporting to frontline health workers in HIV care in Uganda. The specific objectives were to i) explore acceptability of Med Safety for ADR reporting by health workers at ART clinics in Uganda and, ii) identify factors that could influence the uptake of Med Safety in Uganda.

2. Methods:

2.1. Study design:

The study employed a qualitative exploratory research design. We sought to understand factors that could influence the uptake of Med Safety from the perspective of health workers in their operational context and health-system setting(s).

2.2. Qualitative analytical framework:

Our analytical approach was guided by the Consolidated Framework for Implementation Research (CFIR), which has five domains: *intervention characteristics, outer setting, inner setting, characteristics of individuals, and process of implementation*. The CFIR is a comprehensive implementation research framework compiled from more than 20 sources and has been applied across more than 13 disciplines. The CFIR informed study conceptualisation and development of data collection tools. We used the updated CFIR to elicit barriers and facilitators to implementation of Med Safety for ADR reporting by health workers. The updated CFIR framework has sub-domains under each of the five domains.

2.3. Study sites and sample selection:

We aimed to recruit a diverse sample of health workers from multiple contextual settings, i.e., geographical sub-regions of Uganda (northern, eastern, western, central), levels of health care (tertiary, secondary, primary) and health worker cadres (medical doctor, pharmacist, clinical officer, nurse, midwife, lay worker/expert client, medical statistician, laboratory technician). In each of the four geographical sub-regions, we purposively selected three health facilities—one facility at the tertiary level of health care (regional referral hospital), one at the secondary level of health care (health centre IV) and one at the primary level of health care (health centre III); thus, 12 health facilities in all (Table 1). The purposive sampling of health facilities enabled us to have a diverse range of health workers who are involved in the care of people living with HIV receiving combination ART. We selected a minimum of three health workers from each of the 12 nominated health facilities thereby targeting a minimum sample of 36 health workers.

Table. 1: Characteristics of participating health facilities in Uganda

Health facility	**Level of care**	**Geographic sub-region**
1. Jinja Regional Referral Hospital	Tertiary	Central
2. Mbale Regional Referral Hospital	Tertiary	Eastern
3. Lira Regional Referral Hospital	Tertiary	Northern

Health facility	**Level of care**	**Geographic sub-region**
4. Mbarara Regional Referral Hospital	Tertiary	Western
5. Bugembe Health Centre IV (Jinja)	Secondary	Central
6. Namatala Health Centre IV (Mbale)	Secondary	Eastern
7. Ogur Health Centre IV (Lira)	Secondary	Northern
8. Bwizibwera Health Centre IV (Mbarara)	Secondary	Western
9. Kakira HC Health Centre (Jinja)	Primary	Eastern
10. Maluku Health Centre III (Mbale)	Primary	Eastern
11. Amuca Health Centre III (PNFP, Lira)	Primary	Northern
12. Rubindi Health Centre III (Mbarara)	Primary	Western

PNFP private not-for-profit

3. Results:

3.1. Characteristics of health workers:

The study interviewed 49 health workers, 24 females (49 %) and 25 males (51 %). The backgrounds of the health workers (age range of 22–59 years) are outlined in Table 2.

Table. 2: Cadres of health workers who participated in the study

Cadre of health worker	***n***
1. Medical doctor	6
2. Clinical officer	15
3. Nurse	10
4. Pharmacist	4
5. Midwife	2

Cadre of health worker	*n*
6. Data analyst	2
7. Laboratory technicians	2
8. Lay worker/expert patient	8
Total	49

3.2. Uptake of med safety for ADR reporting:

We describe the major themes within sub-domains of each of the five CFIR domains according to the updated CFIR framework, with exemplar quotes. Facilitators, barriers and recommendations to the uptake of Med Safety are summarised in Tables 3 and 4.

Table. 3: Facilitators and barriers to the uptake of Med Safety for adverse drug reaction (ADR) reporting by health workers in Uganda

Five CFIR domains	**Sub-domains**	**Factors that influence uptake of Med Safety**	
		Facilitators	**Barriers**
Innovation characteristics	Innovation relative advantage	Easy to use—interface and layout uncomplicated Offline functionality Cumbersome nature of alternative/conventional ADR-reporting tools	Lengthy app registration processes
	Innovation cost		High cost of internet data
Outer setting	Local conditions	Willingness to report ADRs to new HIV medicines	
Inner setting	Information technology infrastructure	Awareness of Med Safety app High smartphone coverage Free internet hotspots	Internet connectivity constraints
	Relational connections	Two-way risk communication functionality	
	Recipient-centredness		Poor feedback to ADR reporters
Individuals	Implementation facilitators	Young demographic of health workers	Difficulty in recognising ADRs Language barrier

Five CFIR domains	**Sub-domains**	**Factors that influence uptake of Med Safety**	
		Facilitators	**Barriers**
Project implementation process	Engaging innovation recipients	Goodwill from health workers	Challenges with health workers' smartphones

CFIR Consolidated Framework for Implementation Research, *HIV* human immunodeficiency virus

Table. 4: Recommendations from health workers on the uptake of Med Safety in Uganda

Barrier	**Recommendation**
Lengthy app registration processes	Simplify the app registration process by reducing the requirements believed to prolong the process, e.g., the complex app password and email account In future rollout efforts, it should be clarified to health workers that the app registration password is distinct from the personal email account password
Language barrier	Translate the app into local languages because the workforce that provides HIV care in our setting varies dramatically to include lay workers and expert clients with limited formal education and command of the English language
Laborious reporting process	Introduce a voice recording function in the app to simplify ADR-reporting Programme the app with sections dedicated to specific diseases, e.g., malaria, tuberculosis, HIV, etc. Link other internet-based tools like WhatsApp and email to Med Safety Quicken paper-based reporting via electronic transmission of scans and photos of filled out paper forms
Cost and connectivity of internet	Promote other purely offline platforms, e.g., SMS alerts, toll-free telephone lines and the Unstructured Supplementary Service Data (USSD) platform. The USSD is an SMS-based interface for reporting by dialling a defined code with stepwise prompts In severely resource-restricted settings where smartphone coverage and internet connectivity are low, health facilities could provide a desktop computer or other suitable electronic device dedicated to ADR reporting

ADR adverse drug reaction, *HIV* human immunodeficiency virus, *SMS* short message service

3.3. Innovation characteristics:

In this study, the innovation was the use of Med Safety for ADR reporting by health workers. The major derived themes were in two sub-domains; namely innovation relative advantage and innovation cost.

3.4. Innovation relative advantage:

Innovation relative advantage describes whether or not Med Safety is better than conventional methods of ADR reporting.

Easy to use after introductory training, the health workers reported that Med Safety was easy to use and the interface and lay-out were uncomplicated. With practice, the app was thought to be user-friendly and could be used without difficulty, as reported below by a nurse in an HIV clinic:

'The app is friendly, very user-friendly. Really, if you like gadgets… these technical things… it's good, you can type in and you are done. It is smooth. It can flow.' [Nurse, Central Region].

Health workers were excited about Med Safety and its potential to unblock barriers to ADR reporting posed by the paper-based ADR registers. The majority of health workers would recommend the app to other health workers.

Offline functionality A strength of the app commended by the health workers was the ability to enter data offline and transmit these data to the national pharmacovigilance database, once the smartphone is connected to the internet.

Lengthy app registration process and initial use Most health workers (44/49) found that the initial registration process was lengthy. Some health workers felt that registration on Med Safety was cumbersome because it required a complex password (with a figure, symbol, capital letters, etc.) and an email account. The app rejected attempts to register using the same password as the health worker's personal email account in the app, which frequently frustrated several health workers. After initial registration, most health workers felt that the multiple screens requiring input during ADR reporting made the process laborious as represented by the following excerpt:

'For me I think the app is very good. It is a very good innovation as it helps in enhancing the real time reporting and receipt of the report. However, we may need to see how we kind of shorten the time consumed. I don't know how. We should be cognizant of the time taken by whoever is reporting, the easier the format, and the shorter the time possibly the better" [Medical Officer, Northern Uganda].

After training, however, the health workers found it easier to use the app to report ADRs. Demonstration of the app to a health worker took 20–25 minutes. Nevertheless, some health workers thought it was faster to send scanned copies or photos of the paper forms via WhatsApp or email to the National Pharmacovigilance Centre located at National Drug Authority (NDA), Uganda's NRA.

4. Discussion:

We evaluated the acceptability, and facilitators and barriers to the uptake of Med Safety for ADR reporting by health workers in Uganda. There was goodwill among the health workers to adopt Med Safety for ADR reporting and the majority of health workers would recommend the app to other colleagues. Training with practice increased acceptability of the app. Uptake of the app was favoured by the younger, technology proficient, health worker demographic; the app's offline and two-way risk communication functionalities; availability of free internet hotspots at some health facilities; willingness of health workers to report ADRs; and the cumbersome nature of conventional ADR-reporting tools.

Potential barriers to the uptake of Med Safety were the perceived lengthy processes of initial app registration and completion of multiple screens during ADR reporting; challenges with health workers' smartphones (incompatibility with application, no space for more applications, low battery charge); high cost of internet data; poor internet connectivity; difficulty in recognising ADRs, language barrier and poor feedback to ADR reporters.

After introductory training and with practice, the health workers reported that Med Safety was easy to use and the interface and lay-out were uncomplicated. The training promotes proficiency on Med Safety and should be integral in all awareness campaigns to promote uptake of the app. Sufficient training on the app should be given initially and regularly to create a durable culture of ADR reporting among Ugandan health workers. In Ghana, acceptability increased if the training highlighted the app's benefits and the retention of those who downloaded the app required that new and exciting information is provided regularly. Keen interest in a mobile app for ADR reporting was reported in three European countries (Netherlands, Spain, UK) where country-specific apps were adapted from the same prototype Web-RADR app as the Med Safety app. As in our study, the perceived benefits of the app in the European setting included its convenience and efficiency over traditional methods of ADR reporting such as the paper-based form. The health workers' willingness to report ADRs with the app also coincided with the active drug safety monitoring programme for the newly introduced HIV drug dolutegravir. The NDA and Ministry of Health, Uganda conducted joint pharmacovigilance training workshops for health workers to promote the reporting of ADRs to dolutegravir. Med Safety was introduced to the trainees as one of the pharmacovigilance methods.

5. Future perspectives:

While it is important to use technology platforms to improve ADR reporting, the actual utility of such an approach, especially in LMIC settings, needs to be shown through a robust study design. This is underlined by the very low level of app awareness by health workers. We therefore plan a two-armed (mobile app, no mobile app) cluster-randomised controlled trial (RCT). Based on our experience, during rollout of the RCT; (1) mobile wireless routers should be supplied to field teams for internet hotspots to health workers at intervention sites, (2) power banks should be made available to circumvent the challenge of low phone battery charge, (3) wherever possible, software upgrades should be applied to older compatible smartphones that have technical support, (4) phone space should be created to ensure the successful download of Med Safety and, (5) for the first 6 months, monthly reminders to report ADRs should be sent to health workers to be enrolled in the large-scale RCT, e.g., by SMS and WhatsApp.

To promote the recognition and reporting of ADRs, health workers should be routinely trained to use the Ministry of Health (MoH) screening tool for active pharmacovigilance of ADRs to dolutegravir and IPT. Uganda's MoH consolidated HIV/TB prevention and treatment guidelines mandate screening for ADRs in every person living with HIV at each clinic visit. Training aids should be provided within Med Safety to give health workers the confidence to appropriately report ADRs based on suspicion alone rather than wait to be sure before reporting. Finally, the pharmacovigilance system should contribute to improved clinical care for people living with HIV by ensuring the timely referral of serious ADR cases for appropriate clinical management at health facility level.

6. Conclusion:

There was goodwill among the health workers to adopt Med Safety for ADR reporting and the majority would recommend the app to other health workers. Training with practice increased acceptability of the app and should be integral in all future rollout campaigns of the app. Uptake of the app was favoured by the high smartphone coverage; the young, technology proficient health worker demographic; the app's offline and two-way risk communication functionalities; availability of free internet hotspots at some health facilities; goodwill of health workers and their willingness to report ADRs to newly introduced HIV and tuberculosis medicines; and the cumbersome nature of conventional ADR-reporting tools, particularly paper forms. Potential barriers to the uptake of Med Safety included the perceived long process of initial app registration and laborious level of detail required to complete a single ADR report; challenges with health workers' smartphones (incompatibility with app, no space for more apps, low battery charge); high cost of internet data; poor internet connectivity; difficulty in recognising ADRs, language barrier and poor feedback to ADR reporters. These results will guide future research and implementation to promote the uptake of Med Safety for pharmacovigilance in LMIC.

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