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ORIGINAL RESEARCH ARTICLE

Facilitators and Barriers to Uptake of the Med Safety Mobile App for Adverse Drug Reaction Reporting by Health Workers in Uganda: A Qualitative Study

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Abstract

Introduction 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.

Methods 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.

Results 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.

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 app roll-out campaigns. The identified facilitators and barriers could be used to appropriately guide future research and implementation to promote the uptake of Med Safety for pharmacovigilance in low- and middle-income countries.

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1 Introduction

Globally, adverse drug reactions (ADRs) are associated with high morbidity, mortality and economic costs [1–3]. Timely prevention, detection, reporting and management of ADRs is essential for patient safety [4]. 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 [4–6]. Under-reporting of ADRs is underpinned by complex interactions between patient-related factors, drug-related factors, and health-system barriers, among others [7, 8].

Key Points

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 Med Safety and should be integral in all future app roll-out campaigns.

The uptake of Med Safety was favoured by the younger, technology proficient, health worker demographic; the application's offline and two-way risk communication functionalities; availability of internet hotspots at some health facilities; goodwill and willingness of health workers to report suspected adverse drug reactions (ADRs); and the cumbersome nature of conventional ADR-reporting tools.

Potential barriers to the uptake of Med Safety included 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.

Recent advances in mobile technologies allow for two-way exchange of medication safety information between ADR reporters and National Drug Regulatory Authorities (NRAs) [9]. 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 [9].

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 [10–12]. In LMIC, however, little is known about factors that could influence the uptake of Med Safety for ADR reporting by health workers [13]. 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 [14]. 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 [15, 16]. 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 [17]. The updated CFIR framework has sub-domains under each of the five domains [17].

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.

2.4 Eligibility

We included consented health workers who attended to people living with HIV receiving combination ART at the selected health facilities.

2.5 Data Collection

2.5.1 In-Depth Interviews

We conducted 22 in-depth interviews (IDIs) with a diverse range of health workers at ART clinics in the 12 nominated health facilities. The objective of the IDIs was to gain in-depth insight into the acceptability of Med Safety from the perspective of health workers and from the vantage point of their operational contexts. On average, we conducted two IDIs at each of the 12 study sites.

At least one of the IDIs was conducted by the ART clinician-in-charge at the health facility who is privy to ADRs reported by clinicians in routine practice. We collected the data between July and September 2020. Face-to-face interviews were conducted by an investigator (HZ) with extensive experience in qualitative health services research, assisted by two research assistants (RAs). The RAs took notes during the proceedings and operated the recorder. In-depth interviews were conducted in the offices of participants at the 12 study sites. The average duration of each IDI was 60 minutes.

2.5.2 Focus Group Discussions

We constructed a Focus Group Discussion (FGD) guide (Supplementary material) based on the CFIR and used it to conduct three mixed-gender FGDs. Each FGD had 9 health workers with clinical roles at ART clinics in the 12 nominated health facilities. The FGDs were conducted by one of the investigators (HZ) assisted by two RAs. The average duration of each FGD was 90 minutes.

2.5.3 Procedures During Data Collection

We conducted the FGDs and face-to-face IDIs in three steps. First, we described the background and study objectives and obtained written informed consent from each participant. Second, we demonstrated how to download and use Med Safety to report suspected ADRs. Third, we conducted an open-ended discussion to elicit the perspectives of health

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
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

workers on the acceptability of Med Safety. We conducted the FGDs and IDIs until theoretical saturation. We collected data during the COVID-19 pandemic prior to the vaccines era and thereby avoided COVID-19 spread by social distancing, use of hand sanitisers and face masks.

2.6 Data Analysis

We followed the procedures recommended for qualitative data analysis by Miles and Huberman (1994) [18]. All IDIs and FGDs were audio-recorded and transcribed verbatim into text transcripts. Data analysis was performed through four steps. First, two authors (HZ, RK) read the transcripts multiple times for data familiarisation. Second, the two authors inductively devised a coding scheme from the data and applied it to all the transcripts, using Nvivo 10 software for data management. Third, two authors (HZ, RK) abstracted the inductively coded data into thematic matrices. Disagreements in assignment of codes and themes were resolved through consensus [18]. Fourth, all authors participated in the overall interpretation and synthesis of the results.

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
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 [17], with exemplar quotes. Facilitators, barriers and recommendations to the uptake of Med Safety are summarised in Tables 3 and 4.

3.2.1 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.

3.2.1.1 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

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
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

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.

Cumbersome nature of conventional ADR reporting tools The majority of participating health facilities had dysfunctional ADR reporting systems. Paper-based ADR forms were the most common reporting platform. However, the majority of completed hard-copy forms at the health facilities, never reached the NDA due to the lack of dedicated logistics to deliver the ADR forms. Also, health facilities sent completed ADR forms to multiple reporting centres, rather than directly to the regional and national pharmacovigilance centres. Forms were sent to District Health Officers, regional President's Emergency Plan for AIDS Relief (PEPFAR) implementing organisations at sub-national level, and non-governmental pharmaceutical suppliers, e.g., Joint Medical Store (JMS). The JMS receives ADR reports on new medicines like dolutegravir-based ART or IPT from faith-based

private health facilities in Uganda. From the perspective of participants, Med Safety is more convenient and efficient for ADR reporting than paper-based reporting:

'The app is so convenient for reporting ADRs. I can do it personally so I don't need anyone to be able to report. I can report (ADR) there and then and from wherever I am as long as I have a phone. So, that improves my efficiency in reporting so I can handle that issue there and then so that one improves my efficiency on reporting and also improves pharmacovigilance.' [Medical Officer, Western Uganda].

3.2.1.2 Innovation Cost *High cost of internet data* The high cost of internet data was frequently cited as a barrier to ADR reporting with the app:

'At the moment, it is (Med Safety App) internet-based. That makes it expensive. So now, going forward who sustains it in terms of logistics (paying for internet data for use)? Do I need to buy my own private data to report? It is not feasible. I can't pay the bills of this hospital.' [Nurse, Western Uganda].

Health workers with higher income status, for example medical doctors, were more likely to have private internet data on their smartphones than mid-level workers such as nurses.

3.2.2 Outer Setting

In this study, it refers to the pharmacovigilance and health care system across Uganda.

3.2.2.1 Local Conditions Local conditions refer to conditions in the outer setting that support the implementation of Med Safety.

Willingness to report ADRs to newly introduced medicines The desire by health workers to report ADRs linked to newly rolled-out medicines, namely the HIV drug dolutegravir and IPT, was high and offered a practical and illustrative backdrop for the study:

'We recently transitioned over 6000 of our clients to dolutegravir and as a result of introducing this new drug we have had over 200 complaints from patients with mild problems like general body weakness, headaches or even loss of libido but also serious ones like hepatotoxicity. With the 200 reports we need to send to the NDA, the Med Safety app is timely indeed given the reporting burden' [Medical Officer, Western Uganda].

Health workers viewed this study as an opportunity to report ADRs associated with dolutegravir-based ART and IPT; notable dolutegravir-linked ADRs included hyperglycaemia, erectile dysfunction and hepatotoxicity. For IPT, skin rashes and peripheral neuropathy were commonly cited.

3.2.3 Inner Setting

The inner setting in this study was the HIV clinics where Med Safety was implemented. The identified major themes were in three sub-domains, namely; information technology infrastructure, relational connections and recipient centeredness.

3.2.3.1 Information Technology Infrastructure *Awareness of the Med Safety app* Only three of the 49 health workers were aware of Med Safety; two were from tertiary care health facilities and one was from a secondary care health facility. Two of these health workers had previously installed Med Safety on their smartphones but had not used the app to report ADRs.

High smartphone coverage among the health workers The majority of health workers (43/49) owned smartphones and most (42/49) were aged < 44 years of whom 41/42 owned smartphones.

Internet connectivity constraints Internet connectivity was poor in some parts of the country, particularly in northern Uganda. Low internet speeds impeded the download and demonstration of Med Safety to new users as illustrated by the participant below:

'In this district, we have problems with our internet service provider. The internet connection is not stable. The quality of the internet connection here fluctuates a lot. On some days, it is too slow for you to do anything meaningful on a site that is internet-based. Sometimes the signal strength is very good, sometimes it is completely off. If I was to use the Med Safety App, internet connectivity in Lira would be a major constraint especially if you want to report in real time.' [Clinical Officer, Northern Uganda].

Availability of free internet hotspots Only 3 of the 12 selected health facilities provided free internet hotspots to their staff to support ADR reporting with Med Safety; these facilities included two regional referral hospitals (tertiary level of health care) and one health centre IV (secondary level of health care):

'We have an internet hotspot for staff near the outpatients section, which means we have access to internet any time we need to use the Med Safety app. I don't need to buy internet data from my pocket to be able to report' [Clinical Officer, Western Uganda].

3.2.3.2 Relational Connections *Two-way risk communication functionality* The two-way provision for communication in the app is a major incentive for ADR reporting that could lead to behaviour change and an increase in reporting. Med Safety is connected to NDA's website and users can receive newsfeeds directly to their phones from NDA. The newsfeeds provide general information across the entire

spectrum of NDA's activities, including information on medication safety and the actions taken to safeguard the public.

3.2.3.3 Recipient Centeredness *Poor feedback to ADR reporters* Some health workers were happy with the notification that the sent app report was received unlike paper-based reporting:

'I like this app because unlike the paper-based ADR forms, after submitting your report you receive confirmation that your report has been successfully received. This gives you morale to keep sending reports because they reach their destination and you receive notification.' [Clinical Officer, Eastern Uganda].

However, some health workers felt that NDA did not give sufficient details to ADR reporters on how they used the reported information; and others expected timely feedback with advice on the particular reported cases to more appropriately manage the affected patients. Inadequate feedback from NDA to the health workers therefore caused apathy towards the ADR-reporting system generally, and could be a major barrier to the uptake of Med Safety for ADR reporting.

3.2.4 Individuals

Individuals – the roles and characteristics of individuals.

3.2.4.1 Implementation Facilitators Implementation facilitators in this study, it refers to characteristics of individuals who promoted or impeded the implementation of Med Safety.

Young demographic of the health workers The young health worker demographic, which may be more technology proficient, favours the uptake of Med Safety.

Difficulty in recognising ADRs The recognition of ADRs by health workers was cited as a major barrier to ADR reporting. Many health workers conceded challenges in their ability to correctly recognise ADRs even when reported to them directly by patients. Also, some of the mid-level workers acknowledged challenges with correctly matching patients' reports of ADRs with those listed in Med Safety:

'Sometimes I find difficulty in correctly selecting the specific ADR in the drop-down menu provided in the Med Safety app. When a patient describes a severe side effect, accurately selecting it from the list provided in the app can be a real challenge. The medical terminologies are cumbersome for some of us. Some of the language used to describe ADRs should be simplified from advanced medical terms to simpler alternative words.' [Nurse, Eastern Uganda].

Several nurses indicated that they were constrained to refer patients reporting ADRs to clinicians, and as such could not provide advice to the patients. Other health workers reported that they advised patients to persist on the medication despite patient safety being in question.

Language barrier A number of lay workers and expert clients had limited formal education and command of the English language, which made it difficult to use Med Safety efficiently.

3.2.5 Project Implementation Process

In this study, project implementation process refers to the activities and strategies used to roll out Med Safety.

3.2.5.1 Engaging Innovation Recipients In this study engaging innovation recipients refers to the approaches used to encourage recipients to participate in the implementation and/or uptake of Med Safety.

Goodwill among the health workers We observed immense goodwill among health workers to adopt Med Safety for ADR reporting, which increases the potential for scale-up of the app among health workers in Uganda.

Challenges with the health workers' smartphones The lack of space for more apps, low battery charge particularly during afternoons and old incompatible phones were the main challenges to installing Med Safety on health workers' smartphones.

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 [19]. 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 [20]. 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 [21, 22]. 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 [4, 21]. 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.

Uptake of the Med Safety app was favoured predominantly by the young, technology proficient health worker demographic with very high smartphone coverage, which is consistent with the literature [22]. Older persons are not as optimistic about newer technologies as their younger counterparts and are therefore less likely to use Med Safety [23, 24].

The two-way exchange of information in Med Safety gives NDA the opportunity to be more transparent to ADR reporters. However, the nonspecific nature of information in the newsfeeds could overwhelm some users of the app. Vries and colleagues reported varying perceptions to the newsfeeds in a European setting; some ADR reporters liked to receive all kinds of information, while others felt bombarded with excess information [22]. Respondents who feel overwhelmed with lots of information could benefit from a function that customises the app to receive newsfeeds with only specific types of information [22]. In this regard, Med Safety already has a watchlist function with which users can specify the drugs of interest for which they would like to receive updates on submitted ADR reports [25].

Despite showing interest in the app, health workers perceived the initial registration process as lengthy. The strict registration requirements are necessary for security and confidentiality and it is important to emphasise that to the health workers. Perhaps after the initial registration, logging in using fingerprint or face recognition, as this becomes more common, could be a solution. Also, Med Safety has a guest feature which avoids the registrations. Guest use is quicker initially, although app registration saves time if one reports often. Health workers should not be discouraged by the seemingly complex app registration process because the actual process of using the app is simpler. Similarly, the details required to report a single ADR case in the app were thought to make reporting laborious and could be a challenge in the future owing to time constraints in busy clinics. Competing clinical demands are known barriers to the use of apps by health workers in clinical settings [19]. Thus, complementary innovative methods of ADR reporting thought to be quicker and more convenient could be encouraged, e.g., including a voice recording function in the app and submitting scanned copies of paper forms via WhatsApp or email.

The small number of health facilities with free internet hotspots is a barrier to the scaleup of the app among health workers who are unwilling to spend their own data on ADR reporting. Health workers ought to be notified that the app consumes very little internet data and is not exclusively internet-based. Once installed and registered, users of the app can create and save ADR reports offline and submit them later when connected to the internet [9]. Thus, health workers can utilise the app across diverse settings including in rural and hard-to-reach areas with poor or no internet connectivity.

In Uganda, it is common to find that mid-level workers such as nurses and midwives are drafted into roles of HIV clinicians due to a severe shortage of physicians, particularly in rural settings. This is important in terms of pharmacovigilance because some health workers found it difficult to detect ADRs. A compilation of important ADRs and their descriptors (e.g., a list based on national guidelines or literature review, e.g., ADRs to dolutegravir-based ART or IPT) coupled with regular training and support supervision could help health workers to adequately screen for ADRs and report them using Med Safety. Training aids should be made available within Med Safety, like a page where recognising ADRs is discussed. It is often impossible to be sure of an ADR; thus, the training aids could give a health worker the needed confidence to report an ADR based on suspicion alone.

Health workers were apathetic to the ADR-reporting system generally due to the poor feedback from NDA, which is not surprising. Feedback should be prompt, to motivate the health workers to continue to report ADRs and ought to be more than simple acknowledgement of successful submissions, particularly for serious cases [22]. Feedback could be too late, if a reported ADR were serious, leading to the failure to make timely decisions to safeguard the affected patients from medication-related harm [22].

4.1 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 roll-out of the RCT [26]; (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 [27].

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 [27]. Uganda's MoH consolidated HIV/TB prevention and treatment guidelines mandate screening for ADRs in every person living with HIV at each clinic visit [28]. 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.

4.2 Limitations

Only a small number of health workers was interviewed, which could affect generalisability. However, health workers were selected from all geographical regions, which makes the data representative.

5 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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Declarations

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Ethics Approval This study received ethical approval from the School of Biomedical Sciences Research and Ethics Committee, College of Health Sciences, Makerere University (SBS-REC-720) and Uganda National Council for Science and Technology (HS1366ES).

Consent to Participate Study participants gave written informed consent (Supplementary material).

Consent for Publication Study participants gave permission and they will not be identifiable.

Availability of Data and Material The data that support these findings will be made available by the authors on reasonable request.

Code Availability Not applicable.

Author Contributions RK and HZ designed the study. RK drafted the manuscript. RK, HZ, HBN, NM, RS, PT, KH and MP critically

reviewed and revised the final version of the manuscript. All authors read and approved the final manuscript.

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