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Developing an electronic mobile reporting modality for pharmacovigilance in Namibia

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ABSTRACT

Introduction

The need for up-to-date technology in the delivery of quality healthcare services cuts across every facet of the healthcare delivery system. Paper-based reporting is increasingly being seen as outdated. Thus there is a need for more innovative means of reporting to be introduced. Mobile electronic reporting platforms can improve the number of reports received by pharmacovigilance centres. The aim of this study was to develop an electronic mobile platform for reporting pharmacovigilance (drug safety and ADR – adverse drug reactions) in Namibia, with the aim of improving monitoring of the reporting system used by healthcare workers in Namibia.

Methods

An existing mobile data-gathering platform was populated with the information on the Individual Case Safety Report (ICSR) form used by healthcare workers in Namibia to report suspected adverse drug reactions (ADRs) to the Therapeutics Information and Pharmacovigilance Centre (TIPC). A face validity was carried out among prospective users of the electronic mobile reporting tool, to ensure accuracy of content, format and information flow.

Results

An electronic mobile reporting platform for ADR reporting and pharmacovigilance was developed. A face validity involving eight academic staff from the School of Pharmacy, University of Namibia, was carried out. Different aspects of the tool requiring updates and clarifications were identified.

Conclusion

An online electronic mobile platform for collection of health data may improve reporting habits of healthcare workers when they encounter ADRs in practice in Namibia, although this requires further evaluation. Policy makers, healthcare workers and social engagement with the community are vital to the success of an electronic intervention for pharmacovigilance in Namibia.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Electronic mobile application, Reporting system, Healthcare workers

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INTRODUCTION

Health systems need to develop rationales geared towards better outputs and improved patient management. In order to achieve the stated goals of health systems improvement, integrated platforms and patient information management such as electronic reporting platforms can be developed; such platforms can assist in ensuring inclusive reporting from healthcare workers and patients. A number of studies have explored different ways of optimizing pharmacovigilance systems and mitigating under-reporting of suspected adverse drug reactions (ADRs). Approaches include incorporation of electronic reporting modalities through internet-based desktop reporting systems,[1,2] mining ADR information from social media platforms,[3] and the use of mobile phone applications that interface with pharmacovigilance centre reporting platforms.[4,5] Developing innovative ways of capturing data from patient clinical records, or at the point of consultation with patients using information and technology platforms such as electronic health records, can improve the quality of data collection, reporting and clinical research; augment data management; and promote improvement of patient safety and quality of care.[6-8] New reporting modalities have to be locally appropriate and also recognize the need for buy-in from health policy makers and healthcare workers.

Pharmacovigilance in Namibia mainly relies on spontaneous ADR-reporting on events by healthcare workers using paper-based reporting, but this has limitations,[9] including the likelihood of under-reporting of adverse events experienced by patients.[10] Similar paper-based spontaneous ADR-reporting systems are critiqued in many settings with barriers identified by healthcare workers as possible reasons for under-reporting including workload, unavailability of the reporting tool when needed, the need for suitable record keeping, availability of ways to communicate collected reports to the pharmacovigilance centre through fax, scanning and emailing of reports, or the need for hand delivery in the absence of other means of conveying reports to the pharmacovigilance centre.[11-16] The Therapeutics Information and Pharmacovigilance Centre (TIPC) situated within the Ministry of Health and Social Services (MoHSS) is responsible for coordination of pharmacovigilance activities in Namibia. The centre was formed in response to evolving management of HIV/AIDS and drug developments, with subsequent changes in HIV/AIDS treatment guidelines. It is responsible for collection, collation, analysis and dissemination of reports received to both the healthcare workers locally and World Health Organization Uppsala Monitoring Centre (WHO-UMC), globally. Between January 2009 and September 2019, 650 Individual Case Safety Reports (ICSR) were submitted to TIPC, an average of 65 reports per year [unpublished data]. There were yearly fluctuations in the number of reports (Figure 1).

According to the World Health Organization, each national pharmacovigilance centre should receive at least 200 ADR reports per 1,000,000 inhabitants per year[17] suggesting, in Namibia, TIPC should receive at least 400 ADR reports annually. The number of reports received by a national pharmacovigilance centre is an indication of the strength and effectiveness of the pharmacovigilance systems within that country. ADRs that have been reported to TIPC include nevirapine-associated Steven-Johnson syndrome,[18] tenofovir disoproxil fumarate (TDF)-associated renal failure[19] and jaundice associated with initiation of atazanavir.[20]

The peaks in 2011 and 2017 have been attributed to the impact of signals generated through a spike in the number of ADRs due to nevirapine administration in both male and female patients on antiretroviral treatments (ART)[21] and pharmacovigilance training and awareness creation.[22] It is therefore likely that ADRs are underreported, especially considering the introduction of new antiretroviral (ARV) regimens in the country over the last few decades.[23–25] We also recently reported data from Namibia that suggested underreporting of ADRs due to some ARV regimens compared with neighbouring South Africa.[20]

Furthermore, studies have shown a skewed reporting pattern between developed and developing countries: ICSRs submitted to WHO Uppsala Monitoring Centre accounted for less than 1% of all reports on the global database compared to the developing countries

contributing more than 80%;[26] the example in Namibia is not an exception.[27,28] In order to ensure patients' safety, pharmacovigilance systems and reporting tools used to collect pharmacovigilance data have to be user-friendly and accessible to healthcare workers and patients. In a recent study carried out among healthcare workers in public healthcare settings in Namibia, electronic reporting was identified as a potential approach to optimize pharmacovigilance.[9] As part of health systems improvement initiatives, an electronic mobile application for ADR-reporting aimed at improving the quality, rate of reporting and number of reports submitted to TIPC, was developed and piloted.

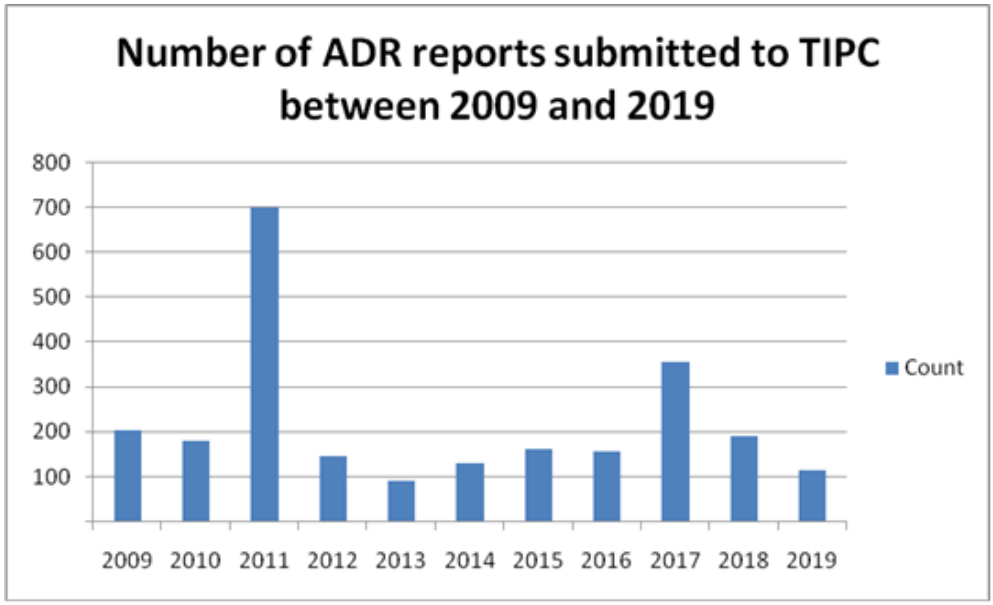

Fig 1 Number of reports submitted to TIPC per year, between 2009 and 2019

METHODS AND MATERIALS

Four continuing education (CE) events on pharmacovigilance were conducted in three different settings in the Namibian capital city, Windhoek, between June and December 2019. During the events, the electronic mobile application for ADR reporting was introduced to participants. The CE events deliberately targeted different practice groups including: an open event to encourage participation from the private sector; public sector training session with medical interns and medical staff; public sector training with pharmacist interns and pharmacy staff; and national awareness and training sessions including medical, pharmacy and nursing cadres.

An open access mobile data-gathering platform (Epicollect5®) was populated with the information contained in the ICSR form used by healthcare workers to collect and report ADRs to TIPC in Namibia. The data-frame was developed by researchers at the School of Pharmacy, Faculty of Health Sciences at the University of Namibia in February 2019 and tested by researchers prior to face validity, to check for any inconsistency and improve flow of information. The reporting tool can be installed on mobile devices of healthcare workers for ease and convenience of use.

We engaged 123 healthcare workers (HCWs) in this research, from different settings in the Namibian healthcare sector. The HCWs belonged to different professional groups (Table 1). They were followed up after one month to remind them about the application and the need for HCWs to report suspected ADRs using the application. The Research Ethics Board of the Ministry of Health and Social Services (Reference No. 17/3/3) and Ethics Committee of the University of Namibia (Reference No. SOPHA/209/2017) approved the study.

RESULTS

The platform was tested by 123 individuals. Most (n=84, 68%) were from the 18–29 years age group, with 15 (12%) aged 30–39, 14 (11%) aged 40–49, and 1 (1%) 50–69. More (59%) were female than male, reflecting the demographics of the workforce. Face validity was carried by eight academic staff from the School of Pharmacy, University of Namibia, to ensure the tool contained and conveyed the right information required by healthcare workers to make and submit correct ADR reports, in addition to ensuring that the reporting platform was able to capture data critical for TIPC reporting. The electronic reporting tool, at the time of conducting this study, was only compatible with mobile devices using Android or IOS operating systems. Healthcare workers were required to install the application on their mobile phones/devices and use it as an on-the-go reporting modality; all the study participants had smart phones capable of running the software. Seven participants identified issues such as duplicate entries, spelling errors, the need to include drop-down boxes for items such as medication name and laboratory tests, and follow up numbers; a total of 28 issues were identified by these seven participants (see Table 2).

Twenty-five (25) of the issues were identified by a single user. Three (3) issues (concerns over what to do if the inputter does not have all the information the form requires; concerns over spellings; and questioning the meaning of the term 'sequel') were common to more than one participant. The platform was reviewed and necessary corrections were made.

Table 1 Demographics of platform testers

Demographic variables	Categories	n = 123 (%)
Age, years (mean, S. D.)		32.51 (11.3)
Age, years categorised (n. %)*	18 – 29	84 (68%)
	30 – 39	15 (12%)
	40 – 49	14 (11%)
	50 – 69	1 (1%)
Years of experience (mean, S. D.)		6.1 (9%)
Gender	Female	73 (59%)
	Male	50 (41%)
Type of facility (n, %)	Intermediate Hospital	47 (38%)
	District Hospital	20 (16%)
	**Others	18 (15%)
	National Referral Hospital	12 (10%)
	Clinic	10 (8%)
	Health Centre	5 (4%)
	Medical Stores	5 (4%)
	NMRC	3 (2%)
	Private Hospitals/Practices	3 (2%)
Professional status (n, %)*	Medical student	18 (14.5%)
	Pharmacist	32 (26%)
	Medical intern	13 (10.5%)
	Medical doctor	20 (16%)
	Intern Pharmacist	10 (8%)
	Nurse	17 (14%)
	Alternative Medical Practitioner	1 (1%)
	Unspecified	12 (10%)

Missing data, NMRC – Namibia Medicines Regulatory Council, **Others – Community pharmacy, Wholesaler, National Health Training Centre, Private Hospitals/Practices

Table 2 Face validity testing for ADR e-reporting pilot – issues raised by participants

Participant	Comments	General/Unique	Action taken
1	Need to add DOB and age? Seems duplicative	Unique	None – retain
	Many of the fields are mandatory – what if you don't have all the information.	General	TIPC form content None
	Spelling will matter in some sections when you're downloading the results (i.e. medication name, laboratory results) Is there a process to help fix any problems? Maybe dropdown boxes.	General	It will be looked into
	Patient outcome – should only be able to choose 1?	Unique	Dropbox
	Died – should there be a N/A option	Unique	Dropbox
	Profession, Region – dropdown box	Unique	None
	Date of report – is there a reason this wouldn't be the date that it was submitted?	Unique	TIPC form content
	You don't need to ask it.	Unique	None
2	Age of patient?? months/weeks/years	Unique	None – retain
	Weight: state "unknown"	Unique	TIPC for content
	Type of report: Follow up#?	Unique	Format changed
	Description of event • Under date stopped: if not stopped (event ongoing) Medication • If ongoing (leave blank)	Unique	Follow up# line added.
	Medicine – if more than 6??	Unique	Event ongoing line added
	Profession: consider indicating professions	Unique	None
	Exclude field with "no answer given" in the summary	Unique	None - retain
	Weight – does not accept "unknown"	Unique	Dropdown
	Saving name – anonymity should be considered in the name of the report	Unique	TIPC form content will be looked into
	Date event stopped? – what if not ended	Unique	Ongoing added
	Labs reports – you can enter test date + result without entering test name	Unique	None
	What is sequel?	General	Defined
3	Asked about death even though not said patient died	Unique	Dropdown, made not compulsory
	Make phone number compulsory NB - "Sequela: A pathological condition resulting from a prior disease, injury, or attack. As for example, a sequela of polio. Verbatim from the Latin "sequela" (meaning sequel). Plural: sequelae". https://www.medicinenet.com/script/main/art.asp?articlekey=23895	Unique	Made compulsory
4	Consider populating with the list of medicines (NEMLIST) to mimize errors by reporters	Unique	Will be looked into
5	Ongoing event should be incorporated	Unique	Addressed
6	No Comment		
7	Age in patient – Make numeric	Unique	Addressed
	Weight in kg – Make numeric	Unique	Addressed
	Are there any more laboratory tests to report? – Ask first?	Unique	Will be looked into
	Died (if a patient died, what was the cause?) – Drop down	Unique	Addressed

DISCUSSION

The current project proposed an electronic mobile reporting system for pharmacovigilance, through a link between the pharmacovigilance centre and mobile telecommunication companies to support pharmacovigilance activities as a social responsibility service. Community engagement[29] through enlightenment and advocacy programmes delivered across various professional platforms, such as therapeutic committee meetings, or Continuing Professional Development (CPD) might be helpful in further encouraging healthcare workers to report through this functionality. Improved patient management can be achieved by healthcare workers being able to report suspected cases of ADRs using mobile electronic platforms including applications that can be installed on cell phones. Such platforms allow immediate data capture and reduce the time in relaying reports to TIPC. A data repository system to collect ADR reports more efficiently will assist physicians in patient management, and support manufacturers in improving their Summary of Product Characteristics (SmPC).

Considering the need for government buy-in, advocacy and stakeholder engagement, with the Namibian MoHSS being the primary stakeholder, the current project can be implemented on a stepwise basis. This will require identification of community entities with vested interests in patient safety. Government policies will need to legitimize such a platform and enforce its use. Healthcare workers need to be aware of possible ADRs while administering medicines or attending to patients and be able to detect such events when they occur. Development and use of electronic mobile platforms in reporting ADRs may improve reporting systems, awareness and interventions.[30] Such a system could be a part of a broader national e-health programme, incorporating broader aspects of clinical care.[31] Access to the internet is a barrier that may limit the use of such electronic platforms,[32] especially in areas with limited or no internet connectivity. Considering the costs accrued from sending messages via the internet or mobile networks, liaising with local stakeholders such as mobile telecommunication companies to subsidize or offset these costs may assist in encouraging healthcare workers and patients to report suspected ADRs.[33] We developed an electronic mobile reporting system for pharmacovigilance in Namibia based on an existing data gathering platform, with a computer application that can be installed on mobile devices, and without the need for immediate or continuous access to the internet. Uptake of this tool will rely on a systematic roll-out by the national medicines regulator underpinned by training; it will require this buy-in from key stakeholders to be successful.

Some limitations of this study are acknowledged. Our proposed electronic mobile application was introduced to healthcare workers, and training was provided, only in Windhoek, the capital city. Regional training, including the need for ADR reporting and introduction of the proposed electronic mobile reporting platform, will be conducted in the next phase of the study.

CONCLUSION

In order to ensure the uptake of the online mobile pharmacovigilance intervention, advocacy to the policymakers who can implement it and ongoing training of the healthcare workers is necessary. There may be a need for additional network coverage to be provided to some areas where internet coverage is currently limited; such an endeavour will require financial support for hardware, which may need to be sourced from donor funding organizations at the implementation stage. Implementation requires multi-sectoral contributions and thus the need for social engagement to evidence the need for pharmacovigilance and to demonstrate the impact that an on-the-go mobile platform will have on public health and the safety of the population in general. Key players in the sector such the WHO, USAID and NGOs will need to be engaged by the Namibian Government to realize the goals of pharmacovigilance, which include improved patient safety after the introduction of medicines into the market i.e. post-marketing surveillance or Phase IV clinical trials.

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