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Research and Applications

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Barriers to the success of an electronic pharmacovigilance reporting system in Kenya: an evaluation three years post implementation

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ABSTRACT

Objective: Electronic pharmacovigilance reporting systems are being implemented in many developing countries in an effort to improve reporting rates. This study sought to establish the factors that acted as barriers to the success of an electronic pharmacovigilance reporting system in Kenya 3 years after its implementation.
Materials and Methods: Factors that could act as barriers to using electronic reporting systems were identified in a review of literature and then used to develop a survey questionnaire that was administered to pharmacists working in government hospitals in 6 counties in Kenya.
Results: The survey was completed by 103 out of the 115 targeted pharmacists (89.5%) and included free-text comments. The key factors identified as barriers were: unavailable, unreliable, or expensive Internet access; challenges associated with a hybrid system of paper and electronic reporting tools; and system usability issues. Coordination challenges at the national pharmacovigilance center and changes in the structure of health management in the country also had an impact on the success of the electronic reporting system.
Discussion: Different personal, organizational, infrastructural, and reporting system factors affect the success of electronic reporting systems in different ways, depending on the context. Context-specific formative evaluations are useful in establishing the performance of electronic reporting systems to identify problems and ensure that they achieve the desired objectives.
Conclusion: While several factors hindered the optimal use of the electronic pharmacovigilance reporting system in Kenya, all were considered modifiable. Effort should be directed toward tackling the identified issues in order to facilitate use and improve pharmacovigilance reporting rates.

Keywords: pharmacovigilance, product surveillance, eHealth, adverse drug reactions, developing countries

BACKGROUND AND SIGNIFICANCE

Pharmacovigilance is the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems."[1] It gained prominence in the 1960s in response to the thalidomide tragedy in Europe, Australia, and Japan,[2] which was blamed on marketing pressures from pharmaceutical companies and on the lack of robust pharmacovigilance systems.[3]

Since then, drug safety monitoring agencies have been formed at different levels to enhance patient safety when using medicines and to continuously provide balanced and reliable information on the safety of medicines. Among the first was the World Health Organization Program for International Drug Monitoring, established in 1968, which works in collaboration with the Uppsala Monitoring Centre (UMC) to maintain a global database for Individual Case

Safety Reports (ICSRs) of adverse drug reactions reported from different countries.

Several developments in recent years have highlighted the need for robust pharmacovigilance systems capable of quick detection and reporting of suspected incidents. They include increased licensing and use of biologicals and biosimilars in health care,[4–8] increased off-label use of drugs,[9,10] growing concerns over a lack of coverage of children in drug safety monitoring during clinical trials,[11,12] and an increase in health conditions arising from drug-related incidents.[13]

Other factors include the increased use of herbal and natural products, many of which have unknown side effects[14,15]; the growing use of new combination therapies for the management of chronic conditions and coinfections[16,17]; and the rising incidence of poor-quality medicines and medical devices, particularly in low- and middle-income countries.[18] There are also growing calls for objective drug safety information to counterbalance the information published by the pharmaceutical industry, which in some cases is suspected of being biased.[19] Emerging dimensions, such as safety issues arising from self-medication[20] and safety concerns associated with medical applications[21] and medical devices,[22] further underline the importance of robust pharmacovigilance systems.

While the number of ICSRs in the global database has been steadily rising over the years, the rate of reporting has been skewed toward developed countries, whose cumulative ICSRs account for >81% of the reports at the UMC.[23] African countries in particular have disproportionately low reporting rates, accounting for only 0.88% of all reports despite having 15% of the global population, high disease burdens,[24] and poor-quality medical products.[18]

Various studies have been conducted to explore the causes of the low reporting and to make recommendations on how to optimize reporting. A consistent theme in the recommendations has been calls to incorporate information and communications technology and informatics to improve signal detection, reporting, data analysis, feedback communication, and response in pharmacovigilance.[25–29] Examples of such informatics interventions include integrating electronic pharmacovigilance systems into hospital information systems,[30] using Internet-based reporting systems,[31,32] and using desktop applications to improve access to reporting tools.[33] The use of natural language processing systems and event monitoring to aid in the detection of adverse events (AEs) in clinical databases[34,35] and of automated decision support systems to help detect and prevent drug-drug interactions[36] have also been explored. Others include using mobile applications[37,38] and social media to improve the detection of adverse drug reactions (ADRs).[39,40] Text messages for pharmacovigilance reporting have also been tested as a complementary tool to other reporting systems.[41–43]

Many organizations have invested in electronic systems to improve pharmacovigilance reporting, but as consistently observed in recent reviews, the desired effects have not always been achieved.[24,44–47] It has been argued that among the reasons for the failure of many e-Health interventions in developing countries is the fact that many are based on research performed in different contexts, usually in the developed world, where the sociocultural and organizational influences are different.[48] Consequently, studies on pharmacovigilance now increasingly recommend more context-specific research on ways to improve pharmacovigilance reporting systems.[24,25,45,49,50]

This study examined an electronic pharmacovigilance reporting system that was introduced in Kenya in 2013[51] with the intention of improving the efficiency and timeliness of pharmacovigilance reporting by health workers there. The system has a web application version, a stand-alone desktop application version, and a stand-alone mobile application version.

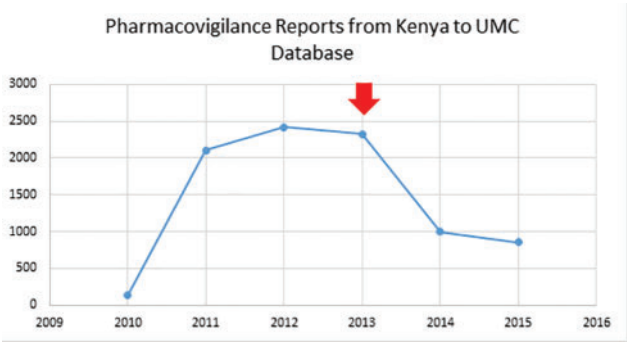

Figure 1. Pharmacovigilance reporting by Kenya 2010–2015 (the arrow shows point of introduction of the electronic reporting system).

Reports submitted through these sources are sent to servers at the National Pharmacovigilance Centre in Nairobi, where they are processed and further sent to a global database (VigiBase) at the UMC.[51] However, as seen in ICSR reporting data for the country,[24] the system has yet to achieve the desired objectives, and reporting rates have declined in the years following its introduction (Figure 1).

OBJECTIVE

The purpose of the study was to explore users' opinions of the potential barriers to optimal utilization of the electronic reporting system, establish the perceived modifiability of these factors, and identify other factors that may have been responsible for the decline in pharmacovigilance reporting in the country. Understanding these barriers would help in formulating recommendations for improving pharmacovigilance reporting rates in Kenya. This would have benefits for both Kenyan health care consumers and their global counterparts through ICSR data shared via the global drug safety database at UMC. Lessons from the study should also benefit other countries implementing similar electronic pharmacovigilance reporting systems.

MATERIALS AND METHODS

Two research techniques were employed in this study. The first was a literature review to explore available information on factors that could act as barriers to electronic pharmacovigilance reporting, and the second was an exploratory survey conducted among public sector pharmacists to collect complementary empirical data specific to the electronic pharmacovigilance reporting system in Kenya. Information from the 2 were then used to draw conclusions and guide the formulation of recommendations for the study.

The literature review was guided by the question: What are the barriers to using electronic systems for submission of pharmacovigilance reports to national pharmacovigilance centers? The specific search terms used in the literature search were {(barriers OR obstacles OR challenges OR hindrances OR impediments OR concerns OR hurdles) AND (electronic systems OR internet based OR online OR web based OR digital OR computerised OR computerized OR computer based OR information technology OR IT OR informatics) AND (reporting OR submission) AND (pharmacovigilance OR e-Pharmacovigilance OR adverse drug reactions OR ADR OR adverse events OR AE OR drug safety OR medicine safety OR

medication safety OR post marketing surveillance)}. The review was carried out on studies from both developed and developing countries and factors that could act as barriers in the study area selected to build the questionnaire.

The survey questionnaire had 4 sections, covering respondent characteristics, barriers to reporting, modifiability of the barriers, and a final open comment section. It consisted of a mixture of semi-structured questions and structured 5-point Likert scale questions, on which respondents rated the likelihood of the identified factors to act as barriers and how modifiable the factors were. Additional factors acting as barriers were captured in the free-text section, making this a mixed-methods study. The questionnaire was pilot-tested on 17 pharmacists working in counties not included in the study area. Input was also sought from the co-authors, and amendments were made based on the feedback and recommendations from the pilot test. The questionnaire was then entered into the Bristol Online Survey tool[52] and the relevant navigation and skip logic were incorporated before being retested to check for flow and clarity and to estimate the time needed for completion.

The study was conducted among pharmacists, because they are often expected to be leaders in the safety monitoring of medicines, owing to their expertise and their role as a source of critical information on medicine-related matters.[53] Pharmacists working in government hospitals were chosen because they were accessible through their respective county pharmacists, and also for a clear definition of the boundaries of the study.

Six counties close to each other that had a preexisting pharmacists' professional network (Central Kenya Region Pharmacists Network) were chosen by convenience sampling for the study. All 115 pharmacists working in the counties were invited to participate in the survey. A link to the survey, including a secure access control password, was sent to all potential participants by e-mail and through their respective professional WhatsApp™ groups. One of the authors was in Kenya to ensure rigor of the data-collection process and deal with local queries. The survey was sent out on August 12, 2016, and remained open for 60 days, with reminders sent out on the 20th (August 31, 2016) and 40th (September 20, 2016) days.

Excel 2016 and SPSS v21 were used to analyze quantitative data and generate tables, charts, and graphs. Qualitative data from the free-text sections of the questionnaire were analyzed by thematic analysis, which involved coding the data for key concepts, identifying themes based on the codes, and consolidating the resulting information into themes. The findings were then triangulated to draw conclusions for the study.

Ethical clearance to conduct the study was obtained from the University of Leeds School of Medicine Research Ethics Committee, approval number MREC15-121, and from the Kenya Pharmacy and Poisons Board (PPB). Consent was obtained from the respondents prior to their participation in the survey.

RESULTS

Databases included in the literature review were: PubMed, which generated 686 results on a 2006–2016 publication filter range; a combined search of Embase, Global Health, Health Management Information Consortium, International Pharmaceutical Abstracts, Ovid Medline, and PsycINFO databases using the same search criteria, which generated 457 results that were reduced to 374 results after deduplication; and the Cumulative Index to Nursing and Allied Health Literature database, which generated 30 results on a 10-year filter. Other complementary literature was searched in Google Scholar, the Google search engine, and textbooks, reports, and websites. From the search results, literature apposite to the study was selected based on recency, reliability, and relevance. Of the 25 factors identified, 16 factors applicable to the Kenya context were selected and used to build the questionnaire for the survey.

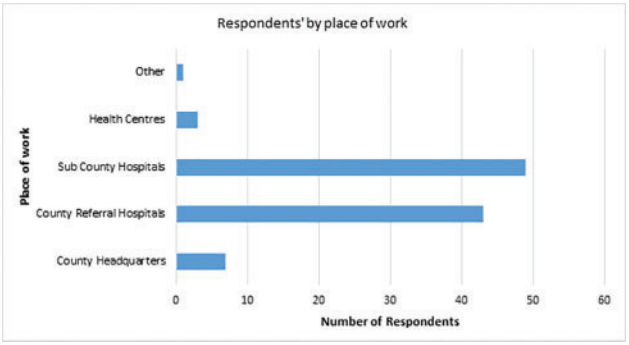

Figure 2. Respondents' places of work.

Of the 115 potential respondents to whom the survey link was sent, 103 returned the survey, yielding a response rate of 89.5%. The respondents comprised 62 men (60.2%) and 41 women (39.8%). A majority worked in sub-county and county hospitals (Figure 2), which are usually relatively busy, as they are the facilities most frequented by patients seeking both primary and specialist treatment services.

All respondents were familiar with the pharmacovigilance reporting process, with 84 (81.5%) reporting that they had submitted a report before, through either the paper reporting system (34, 40.5%), the electronic reporting system (9, 10.7%), or both (41, 48.8%). The numbers of male and female pharmacists who submitted reports were not significantly different. Most of them were comfortable or very comfortable with sending text messages, using smartphones, and using computers. This was regardless of the number of years worked as a pharmacist and not significantly different for male and female pharmacists.

Table 1 shows the factors that acted as barriers and the distribution of the responses in percentages. For each factor, a chi-squared test was carried out to test the hypothesis that responses were from a uniform distribution, that is, that respondents chose their response category at random. For all but 2 of the factors, respondents showed significant preferences for particular categories.

Table 2 shows the distribution of responses to the perceived modifiability of the same factors as Table 1, allowing a link to the perceived importance. Factors perceived as most modifiable included difficulty in navigating the electronic system when reporting, difficulty downloading and installing the application versions of the reporting system, and lack of awareness of the existence of the electronic reporting system. Conversely, factors deemed to be least modifiable included the perception that the electronic reporting system had no practical benefits, unreliable electricity supply at the workplace, and a dislike of computer technology. As with the previous table, for each factor, a chi-squared test was carried out to test the hypothesis that responses were from a uniform distribution, that is, that respondents chose their response categories at random. The results show that for all factors, respondents showed significant preferences for particular categories when questioned about the modifiability of the factor.

Additional factors acting as barriers that emerged from the free-text sections of the survey included tedious transcription process from paper forms to the online system, difficulty recovering

Table 1. Likelihood of factors to act as barriers (N = 103)

	Factors affecting electronic reporting	Respondent ratings in %					
		Very Likely				Very Unlikely	Chi-squared statistic on 4 degrees of freedom; *P*-value
		1	2	3	4	5	
Most Likely	Lack of Internet access provision at the workplace	36.9	37.9	4.9	13.6	6.8	54.04; <.001
	Unreliable Internet coverage at the workplace	37.9	31.1	10.7	13.6	6.8	38.31; <.001
	Existence of a paper-based system as an alternative for reporting	27.2	32.0	17.5	12.6	10.7	17.73; .001
	Lack of a culture of pharmacovigilance reporting	34.0	21.4	17.5	23.3	3.9	24.43; <.001
	Lack of support/incentives from management to use the system for reporting	22.3	37.9	19.4	11.7	8.7	26.85; <.001
	Extra cost of electronic reporting (Internet data costs)	24.3	35.9	8.7	16.5	14.6	22.68; <.001
	Extra time involved in using the system to submit reports	15.5	41.7	19.4	13.6	9.7	32.97; <.001
	Difficulty downloading and installing the app versions of the system	21.4	30.1	15.5	17.5	15.5	7.73; .102
	Difficulty accessing the system online	13.6	31.1	22.3	20.4	12.6	11.52; .021
	Lack of awareness of existence of the electronic reporting system	25.2	15.5	13.6	26.2	19.4	6.56; .161
	Difficulty navigating the system when reporting	10.7	32.0	21.4	15.5	20.4	13.07; .011
	Limited access to computers at the workplace	18.4	23.3	7.8	25.2	25.2	11.22; .024
	Lack of an option for anonymous reporting in the system	11.7	20.4	15.5	23.3	29.1	9.48; .050
	No practical benefits of using the electronic system	6.8	14.6	19.4	25.2	34.0	22.00; <.001
	Unreliable electricity at the workplace	5.8	17.5	10.7	28.2	37.9	35.01; <.001
Least Likely	Dislike of computer technology	3.9	8.7	11.7	31.1	44.7	61.13; <.001

Table 2. Likelihood of factors to be modified (N = 103)

	Factors	Respondent ratings in %					
		Very Modifiable				Not Modifiable	Chi-squared statistic on 4 degrees of freedom; *P*-value
		1	2	3	4	5	
Very Modifiable	Difficulty navigating the system when reporting	48.5	42.7	6.8	1.0	1.0	114.82; <.001
	Difficulty downloading and installing the app versions of the system	46.6	41.7	9.7	1.0	1.0	103.55; <.001
	Lack of awareness of existence of the electronic reporting system	46.6	42.7	2.9	6.8	1.0	105.69; <.001
	Lack of Internet access provision at the workplace	44.7	37.9	11.7	4.9	1.0	81.81; <.001
	Difficulty accessing the system online	44.7	38.8	8.7	5.8	1.9	83.26; <.001
	Extra cost of electronic reporting (Internet data costs)	39.8	35.0	17.5	6.8	1.0	59.67; <.001
	Lack of a culture of pharmacovigilance reporting	36.9	38.8	16.5	6.8	1.0	61.22; <.001
	Existence of a paper-based system as an alternative for reporting	41.7	35.9	15.5	1.9	4.9	67.05; <.001
	Limited access to computers at the workplace	47.6	24.3	13.6	14.6	0.0	30.86; <.001
	Lack of support/incentives from management to use the system for reporting	34.0	38.8	20.4	2.9	3.9	56.76; <.001
	Unreliable Internet coverage at the workplace	33.0	38.8	14.6	11.7	1.9	48.89; <.001
	Extra time involved in using the system to submit the reports	27.2	45.6	18.4	2.9	5.8	62.00; <.001
	Lack of an option for anonymous reporting in the system	34.0	38.8	13.6	7.8	5.8	48.51; <.001
	No practical benefits of using the electronic system	28.2	40.8	19.4	9.7	1.9	47.92; <.001
	Unreliable electricity at the workplace	28.2	36.9	17.5	12.6	4.9	33.07; <.001
Least Modifiable	Dislike of computer technology	32.0	32.0	21.4	8.7	5.8	31.90; <.001

forgotten passwords on the electronic reporting portal, too much "unnecessary" information displayed on the online reporting portal making the website "too busy," and the lack of an application version for iOS devices.

Other barriers identified by respondents were not specific to the electronic reporting system. They included lack of acknowledgment and feedback from the PPB after submission of reports, lack of dissemination of the outcomes of the reports to health workers and the

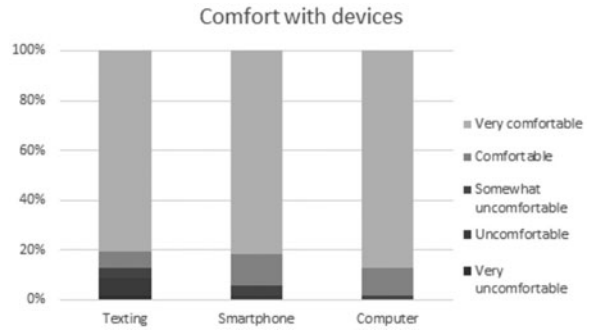

Figure 3. Comfort with devices.

public, poor coordination of pharmacovigilance activities at lower levels of care (health centers and dispensaries), poor access to pharmacovigilance reporting tools, and staffing shortages that led overwhelmed health workers to view pharmacovigilance reporting as extra "non-essential" work. Challenges associated with the devolution of Kenyan health services and the withdrawal of stavudine, an antiretroviral medicine that accounted for the largest proportion of ADR reports, from the HIV/AIDS treatment regimens in Kenya were also suspected to have an impact on overall reporting rates.[54]

DISCUSSION

This study achieved a high response rate of 89.5%, possibly attributable to the online questionnaire delivery method employed, which has been shown elsewhere to have a significant influence on survey response rates and average response times.[55] Moreover, the growing use of smartphones and applications such as WhatsApp™ among health care professionals[56,57] made it easier to reach out to respondents both individually and through their professional groups. Smartphones also allowed respondents to complete questionnaires outside of their work environments and possibly in areas with better Internet connectivity.

While both the electronic pharmacovigilance reporting system and the survey questionnaire were Internet-based, the higher survey response rate could be explained by the simple mobile-optimized design of the questionnaire, the fact that it was not viewed as work carried home, and the fact that no transcription of information from a paper form to an electronic form was required, unlike the case of pharmacovigilance reporting. Some pharmacovigilance reports contain sensitive patient information that should not be taken out of hospital/clinical environments, so if there are connectivity issues in the hospital, reporting may be difficult.

Most respondents worked in hospital settings and were familiar with pharmacovigilance reporting systems, with 81.5% ($n = 84$) having previously submitted a report either electronically or using paper forms. This high level of familiarity agreed with the findings of a Korean study among community pharmacists.[58] It contrasts, however, with the low levels of familiarity observed in other studies involving a mixture of pharmacists and other health professionals.[59–62]

Respondents also reported a very high level of comfort with sending mobile phone text messages and using smartphones and computers (Figure 3). This suggests that discomfort with such devices was probably not a barrier to using the electronic reporting system. Desktop and smartphone application versions of the electronic reporting system existed and links to downloading them were functional, though only Windows and Linux systems for the desktop application and Android devices for the smartphone application were covered. Other platforms, such as iOS and Mac OS, were not supported. With the growing role of applications in pharmacovigilance reporting,[63,64] this lack of coverage across all the major smartphone platforms used in Kenya could also have contributed to the underutilization of the electronic reporting system.

The factors acting as barriers to using the electronic reporting system cut across individual-level, organization-level, reporting system, and infrastructural barriers. The individual-level factor identified was the extra cost to the reporter associated with submitting reports to the national center via the Internet. This may include the cost of privately purchased Internet bundles where the organization does not provide workplace Internet, Internet access costs at cyber cafés, and sometimes the cost of transport from the work location to a shopping center where the Internet can be accessed. Similar barriers have been observed in a systematic review of m-Health in sub-Saharan Africa[65] and in a study that explored the access of information through information and communications technology among health workers in Kenya.[66] These costs can result in reporting being postponed or not done, and hence underutilization of the electronic system.

Key organization-level barriers that were identified included failure to provide Internet at the workplace, lack of support from management to use the electronic system, and lack of a pharmacovigilance reporting culture in the organizations. Health organizations that embrace the culture of pharmacovigilance reporting may make more effort to provide Internet access or support for electronic submission of reports via either Internet cafés or personal mobile data. Failing to provide Internet at the workplace, however, may not be within the control of management, especially in small government health facilities in rural areas, which often lack the financial capacity and influence of top management.[67,68] Also important, especially in a devolved health care system such as in Kenya, is the political will to provide and sustain Internet services in health facilities to facilitate important services such as electronic pharmacovigilance reporting.[69]

Barriers related to the reporting system included challenges associated with the coexistence of an electronic system with a paper-based system. As in many other electronic system launches, the launch of the electronic pharmacovigilance system in Kenya in 2013 was dubbed "going paperless,"[51] and this could have unintentionally painted the paper-based system as cumbersome and ineffective, leading to a reduction in the printing and distribution of paper-based reporting tools. It may also have led to a reluctance by county pharmacists to ask for paper forms from the national pharmacovigilance office, because they felt they were supposed to use the new electronic reporting system. This problem was highlighted in the free-text section of the questionnaire by some respondents, who complained of difficulties in accessing the reporting tools (both paper and electronic). A hybrid phase in which paper and electronic systems coexist is important not only to provide backup in case the electronic system fails, but also to use at sites where the electronic system cannot yet be accessed.

Extra time required to submit reports using the electronic system was also highlighted as a barrier. This may have been a result of the usability challenges associated with the electronic reporting tool, which can lead to underuse.[70] Comments from respondents confirmed the existence of usability challenges, including unnecessary information being displayed on the website, unnecessary information required during reporting, difficulties in resetting forgotten passwords, and the

poor website navigation system. These usability challenges meant that it possibly took longer to report electronically, which further contributed to underutilization of the system. The importance of usability design and testing prior to implementation of electronic systems in health care settings continues to be emphasized.[45,70]

Another possible reason for the extra time that respondents mentioned was the requirement to transfer information from paper reports – usually filled at lower-level health facilities and brought to the central hospital – into the electronic system before submission to the national pharmacovigilance center. Comments from respondents revealed frustrations with the lengthy transcription process, with the suggestion that the PPB also accept scanned paper forms, shown to be feasible and time-saving elsewhere.[71]

On infrastructural barriers, poor Internet coverage was identified as an impediment to the optimal use of the electronic system for report submission. The problem of unreliable/unavailable Internet and the potential that this could interfere with electronic systems in health care has been observed in previous studies.[72–74] Smartphone and desktop application versions of the electronic reporting system can, however, be used to capture reports in offline mode, then submit them when there is sufficient Internet coverage. For areas with no Internet coverage, the paper system may be the solution, or a text message reporting system could be developed.

A factor local to Kenya that had a significant impact on pharmacovigilance reporting was the devolution of health services from the national government to county governments. This transition led to a disruption of administrative functions at the county level, low staff morale, resignations of key health personnel, and confusion arising from politicization of the health function.[75] These affected pharmacovigilance reporting, as hospital financial flows were disrupted and low morale meant that reporting was no longer a priority. Staff shortages following resignations further worsened the situation.

Factors that were least likely to act as barriers included a dislike of computer technology, the perception that the electronic reporting system had no practical benefits, and unreliable electricity at the workplace. The first factor could be explained by the high level of comfort with electronic devices among the respondents, as shown in Figure 3. Comfort with technology among intended users of an electronic system is important in ensuring uptake, and the lack of it can result in system rejection or underuse.[38,76] Despite unreliable electricity not being viewed as a major barrier by respondents, it can be a serious impediment to implementation of electronic systems, particularly those running on desktop personal computers and local area networks.[77,78] Mobile devices using mobile Internet are less affected due to long-lasting batteries, and falling costs of solar power should reduce this barrier going forward.

All the factors were considered modifiable, possibly indicating respondents' confidence with their respective management. This should, however, be viewed with caution because of the possibility of social desirability bias and acquiescence bias in responses due to the manner in which the questionnaires were sent to the respondents and the use of Likert scale questions in the survey, respectively. However, it is likely that the anonymous nature of the questionnaire mitigated against social desirability bias, especially as this was explicitly communicated to the respondents prior to their participation. For all factors, the agreement that they were modifiable was statistically significant.

Based on the weighting of the distribution of responses, factors related to the reporting system were generally deemed more modifiable, while those perceived to be less modifiable included unreliability of the electricity supply and dislike of computer technology (Table 2). Interestingly, the factors considered least modifiable were also the ones considered by the respondents to be least likely to act as barriers. This was a positive finding that may need to be verified in a separate study, since this study was based on perceived rather than actual barriers to using the electronic system.

This study shows that it is challenging to successfully scale up important e-Health projects in low-income settings, but that users can have clear and consistent views about what the barriers to scaling up are and how to address them. It further shows than in an engaged group of health professionals such as pharmacists, high response rates can be achieved on surveys even in low-income settings.

This study had some limitations. There was sampling bias, as the surveyed participants were drawn from one region of the country and were public sector pharmacists only. A more general sample of staff in a national-level study would have been more powerful. The review done for the study was nonsystematic and was limited to English-language articles only. It was also performed in databases that may be biased toward studies from developed countries, and because of this, the results leading to the survey may have omitted some questions relevant to the study setting. The distribution of questionnaires to participants directly from their supervisors also may have introduced some social desirability bias, especially on aspects of the survey touching on the managers. Completion of the survey using mobile devices by some participants could also have affected the data quality, due to the relatively smaller screen size, which is thought to affect the length and quality of free-text answers.[79,80] Another potential limitation of the study is its timing 3 years into the implementation; this should give a good idea of long-term performance, but an earlier study could have shed more light on the implementation process. The final limitation is that the study examined perceived rather than actual factors that acted as barriers to electronic pharmacovigilance reporting. While the perceptions of users were important, it is equally important to establish the actual barriers to using the electronic reporting system.

CONCLUSION

The main barriers to using the electronic pharmacovigilance reporting system were access to the Internet, the system's design and usability problems, and challenges related to the hybrid system of reporting. All these factors were perceived by users of the system to be modifiable. Formative evaluation of the performance of such systems is necessary to allow for early detection of problems and for improvements and learning. With large numbers of health facilities in Kenya using electronic health record systems to support care and reporting, these systems could also make important contributions to the generation and submission of AE reports, potentially speeding the process and reducing workload and errors. We would encourage the PPB to address the problems identified in the current electronic pharmacovigilance system and institute follow-up studies to assess reporting rates and user experiences.

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COMPETING INTERESTS

None.

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