



RESEARCH ARTICLE

Assessment of educational intervention impact on improving pharmacovigilance knowledge among health care providers: A study from different hospitals in Tanzania.

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ARTICLE INFO ABSTRACT



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Safety, anti-tuberculosis, monitoring, e-blended learning.

Introduction: Under-reporting of adverse drug reactions is a major challenge in Tanzania. It is important to educate the health care providers about pharmacovigilance in order to improve the reporting rate.

Objectives: We conducted a study with the objective of evaluating the impact of an educational intervention based on the knowledge on pharmacovigilance among healthcare providers in Tanzania.

Methods: A pharmacovigilance e-blended learning method was used. Pre and post-test, courses were the basic concepts in Pharmacovigilance and the safety of Anti-Tuberculosis Drugs. Descriptive analyses were run to determine the proportions of the correct and wrong answers for pre and post training.

Results A total of 118 (72%) completed the pre-and post-test for both the first and the second courses. There was an increase in the correct answers in the post-test to every question. The median score of pre-intervention for knowledge about basic pharmacovigilance increased from 5 (range 4-7) in pre-test to 8 (range 7-9) in post-test. The median score for anti-TB drug safety issues monitoring and management increased from 4 (range 4-6) in pre-test to 7 (range 7-9) in post-test.

Conclusion: The findings of this study showed that knowledge scores and correct answers were increased following an educational intervention among HCP.

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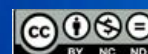
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Introduction

A wide range of essential drugs has become available in low- and middle-income countries (LMICs), including sub-Saharan Africa (SSA) (Isah et al., 2012). SSA countries, such as Tanzania, bear the highest burden of diseases in the world (WHO, 2019). In a huge effort to bring under control highly infectious conditions that are widespread in these countries, such as AIDS/HIV, malaria, tuberculosis (TB), emerging and reemerging diseases, vaccines, newer and established medicines have been extensively deployed. Performing post-marketing surveillance requires comprehensive, robust Pharmacovigilance (PV) systems to be in place. SSA countries notoriously lack the financial and technical resources necessary to establish and maintain such processes (Olsson et al., 2015). Training the health care workers will help to increase efficiency in these areas.

Traditionally, literature has mentioned shortages and poor retention of skilled healthcare professionals (HCPs), inadequate infrastructures, low level of knowledge and awareness of PV among HCPs, weak regulatory and legal frameworks as some of the major issues that remain to be addressed in African countries (Barry et al., 2020; Khadem Broojerdi et al., 2020). Notably, the lack of staff trained in PV has been identified as one of the most serious limiting factors affecting the development of PV in resource-constrained settings (Olsson et al., 2010). Under such circumstances, targeted interventions are urgently needed to scale up training and mentoring of local HCPs and PV stakeholders in Tanzania as well as in other SSA countries.

PhArmacoVigilance Africa (PAVIA) is a consortium of 13 international partners funded by the European Developing countries Clinical Trials Partnership (EDCTP). The PAVIA Project is led by the Amsterdam Institute for Global Health and Development (AIGHD) and it aims at improving drug safety monitoring and strengthening PV processes in four SSA countries (Tanzania, Kingdom of eSwatini, Nigeria and Ethiopia). Central to the strategy designed by PAVIA to enhance post-marketing surveillance capacity in these countries, it is also fostering of a PV culture through training of HCPs (Karolinska Institutet S., 2018).

One of the strategies adopted within the PAVIA Project to strengthen pharmacovigilance in these countries was the implementation of a blended e-learning programme which was developed by the University of Verona. Blended learning, a process that mixes elements derived from face-to-face training with elements taken from e-learning, represents a suitable alternative to both traditional methods and pure e-learning. Previous experiences suggest that blending learning programs can be successfully implemented in resource-limited SSA countries to train HCPs with remarkable gains in terms of

cost reduction and knowledge acquisition (Barteit et al., 2019; Manyazewal et al., 2017).

To rapidly scale up effective training of HCPs, a blended e-learning approach was fully integrated with a Training of Trainers (ToT) scheme that included a first and a second level. Due to its cost-effectiveness and its potential to reach out to a huge number of learners, the ToT scheme is often applied to achieve rapid, effective and extensive up-skilling of HCPs in resource-constrained settings (Mormina et al., 2018; Makanjuola et al., 2012). The blended-learning-based on ToT on two courses designed to mentor HCPs on PV general principles and anti-TB drugs safety was implemented in Tanzania. The aim of this study was to evaluate the impact of an educational intervention on the knowledge and practice of adverse drug reporting among health care providers who participated in the second level of ToT-based training at the Kilimanjaro Christian Medical Center (KCMC) and other Regional hospitals in Tanzania.

Methodology

Study design and population

The study was a pre-post intervention. The blended-learning programme integrated with the ToT approach was implemented at KCMC and other hospitals. The training programme was offered to all the HCPs of the center. The training programme was part of the second level of the ToT approach.

Participants

The healthcare professionals were from different healthcare facilities in different Regions in Tanzania. The team included doctors, pharmacists, nurses, laboratory and pharmaceutical technician.

Description of the e-learning courses

We conducted the e-blended teaching method comprised of two courses: the first course was on the basic concepts in Pharmacovigilance (Time: 3 hours) with 11 modules and the second course on the safety of Anti-Tuberculosis Drugs (Time: 3 hours) with 5 modules. A self-study through e-learning mixed with face-to-face lectures, interactive clinical cases, and PowerPoint presentations was used for the training. Both courses were comprised of an introductory, non-country-specific part and an additional country-specific part. Each part was further subdivided into a subset of educational modules designed in a self-study format. Both courses were made available on Schoolroom, a web-based e-learning platform developed by the University of Verona.

Scoring system

A pre-test and a post-test was given at the beginning and at the end of each of the two e-learning courses, to assess

the HCP on their pre-existing and acquired post-course knowledge. Both courses used 10 identical, multiple-choice questions randomly generated by the web-based application where e-learning materials were uploaded. Each response was evaluated to be either correct or incorrect. Healthcare providers were given 1 point for each correct answer and zero points for each wrong answer. A final knowledge score was calculated for each healthcare provider out of 10 for each course. The pass mark for each course was 7.

Statistical analysis

Data were analyzed using the statistical package for social science (SPSS) version 22 (SPSS Inc., Chicago, IL, USA). Descriptive analyses were run to determine the proportions of the correct and wrong answers per question in both courses. Normality of the data were checked using the Shapiro-Wilk test (with a P value > 0.05 indicating a normally distributed continuous variable). Wilcoxon signed-rank test was used to observe the difference between the two (pre-post-test) variables in knowledge in basic pharmacovigilance and TB and anti-TB drug safety issues monitoring and management (continuous data). For all statistical analyses, a P-value of less than 0.05 was considered statistically significant and all tests were two-tailed.

Ethical approval

Research and ethical approval were provided by the Kilimanjaro Christian Medical College Research Ethics and Review Committee (CRERC) in Moshi, United Republic of Tanzania (Certificate No. 2297), and the National Health Research and Ethics Review Committee (Nat-HREC) (Certificate No. NIMR/HQ/R.8a/Vol.IX/2883). The participants were asked by the trainer to accept the attendance of the training, then the email with password were sent. The training was performed according to the given guidelines.

Results

The pre and post-test data were available from five health facilities, including Dodoma General Hospital 12 participants (10.2%), Kilimanjaro Christian Medical Centre 51 participants (43.2%), Ligula Regional Referral Hospital 8 participants (6.8%), Mbeya Zonal Referral Hospital 23 participants (19.5%), and Tanga Bombo Hospital 24 participants (20.2%) (Shown in Table 1). A total of 164 HCPs were invited to the training and only

118 (72%) completed the pre-and post-test for both the first and the second courses which were included in the analysis.

Table 1: Demographic characteristics of the participants (N=118)

Study variables			Frequency (n)	Percentage (%)
Gender				
Male			70	59.3
Female			48	40.7
Health Facility				
Dodoma General Hospital			12	10.2
Kilimanjaro Christian Medical Centre			51	43.2
Ligula Regional Referral Hospital			8	6.8
Mbeya Zonal Referral Hospital			23	19.5
Tanga Bombo Hospital			24	20.2
Qualification of the participant				
Intern Pharmacist			23	19.5
Laboratory Scientist			5	4.3
Medical Doctor			15	12.7
Pharmaceutical Assistant			3	2.5
Pharmaceutical Technologist			22	18.6
Pharmacists			42	35.6
Research Nurse			3	2.5
Resident Doctor			5	4.3

Table 2 also shows responses to various questions given pre and post-test to the HCPs. The knowledge of HCPs had improved significantly for all questions.

Table 2: Comparison of responses pre and posttest training among health care providers.

Qn no.	Knowledge related questions	Healthcare professionals (n, %)	
		Pre-test correct response (n, %)	Post-test correct response (n, %)
The basic concepts in pharmacovigilance - Tanzania			
1.	What is the definition of an unexpected reaction?	60(50.8)	95(80.5)
2.	According to the scientific literature, what is the percentage of preventable ADRs	66(55.9)	101(85.6)
3.	Clinical studies conducted on a limited number of patients fail to identify:	59(50)	93(78.8)
4.	Type B reactions:	61 (57.7)	95 (80.5)
5.	What does CEM mean?	56 (47.5)	102 (86.4)
6.	What effects did thalidomide cause?	92 (78)	112 (94.8)
7.	A systematic review of randomized clinical trials (RCTs) has a degree of evidence:	60 50.8)	74 (62.7)
	A) Pre-clinical tests assess the pharmacokinetics, pharmacodynamics and toxicology of new drugs.		
	B) Clinical tests assess safety, tolerability and efficacy of drugs		
8.	The most reliable estimate of the incidence of ADRs in the general population is:	52 (44.1)	100 (84.7)
9.	A) Pre-clinical tests assess the pharmacokinetics, pharmacodynamics and toxicology of new drugs. B) Clinical tests assess safety, tolerability and efficacy of drugs	34 (28.8)	82 (69.2)
10.	One of the following is a descriptive epidemiological methodology:	77 (65.3)	102 (86.4)
An overview on tuberculosis and on anti-tuberculosis drug safety's issues, monitoring and management (aDSM) - Tanzania			
1.	The tuberculosis is a disease difficult to treat. Why?	23 (19.5)	90 (76.3)
2.	What's the globally incidence of TB disease?	53 (44.9)	117(99.2)
3.	A: First line are more effective than second line medications B: Second line medications are less toxic than the first line medications.	113(95.8)	113 (95.8)
4.	Some people are known to have a higher risk of becoming ill with TB. Who?	97(82.2)	80 (67.8)
5.	What does MDR-TB mean?	25 (21.2)	69 (58.5)
6.	Which is the most hepatotoxic drug?	56 (47.5)	96 (81.4)
7.	What's the effect of this interaction: concurrent use of nevirapine and rifampin?	63 (47.5)	86 (72.9)
8.	In which situations the risk of QTc prolongation may be higher in people taking delamanid?	41(34.7)	108 (91.5)
9.	A: Ototoxicity is more common with amikacin than kanamycin B: All of the injectable agents have potential for renal toxicity	76 (64.4)	71(60.2)
10.	What's the half-life of bedaquiline?	89(75.4)	107 (90.7)

Figure 1 shows that out of 118 HCP, only 31(26.3%) obtained scores between 7 and 10 and 87 (73.7%) were below 7 in the pre-test on basic pharmacovigilance. These scores were improved in the post-test by 110 HCPs who obtained scores between 7 and 10 (93.2%), while 8 (6.8%) got scores less than 7. For the TB and anti-TB

drug safety issues monitoring and management out of 118 HCP, only 25(21.2%) obtained scores between 7 and 10, and 93(78.8%) were below 7 in the pre-test. These scores were improved in the post-test by 115 (97.5%) obtained scores between 7 and 10, while 3 (2.5%) got scores less than 7.

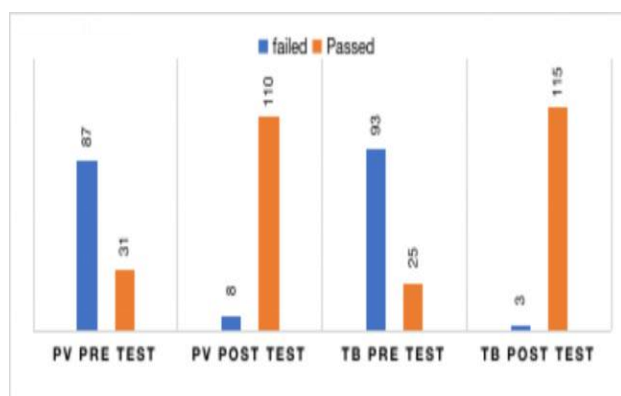


Figure 1: Comparison of the correct answers of the knowledge pre- and post-education intervention.

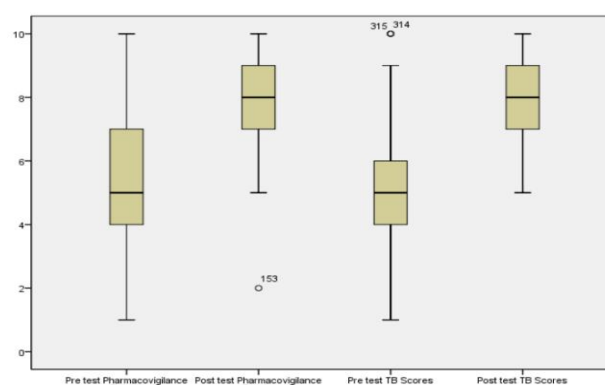


Figure 2: Effect of the educational intervention on healthcare providers on the improvement of knowledge

Table 3: Assessment of knowledge median scores before and after the educational intervention.

			Median	Range	p-value
Knowledge	Pharmacovigilance concept				
Basic training	PV		5	(4-7)	< 0.001*
		Total score before education intervention			
			8	(7-9)	
		Total score after education intervention			
Anti-tuberculosis drug safety					
TB training	Total score before educational intervention		5	(4-6)	< 0.001*
	Total score after the educational intervention		8	(7- 9)	

Table 3 shows the median scores on the knowledge of basic concepts in pharmacovigilance and an overview of tuberculosis and anti-tuberculosis drug safety issues, monitoring, and management (aDSM) before and after an educational intervention. The median score of pre-intervention for knowledge about basic pharmacovigilance increased from 5 (range 4-7) in the pre-test to 8 (range 7-9) post-test. The median score for TB and anti-TB drug safety issues monitoring and management increased from 4(range 4-6) pre-test to 7 (range 7-9) post-test. The educational intervention showed improvement in both courses (Wilcoxon signed rank $P = 0.001$). Figure 2 shows the impact of the educational intervention improvement in scores among healthcare providers.

Discussion

Tanzania has taken substantial steps to improve the operational capacity of its PV system, including defining a budget for PV, adopting a communication plan for the

dissemination of PV information and introducing an electronic reporting system to facilitate spontaneous reporting (Barry et al., 2020). Recently, the WHO has classified the Tanzania Medicine and Medical Devices Authority (TMDA), previously known as Tanzania Food and Drug Authority (TFDA) into maturity level 3, implying that the organization has stable, well-functioning regulatory and PV systems with a defined budget for pharmacovigilance (Khadem Broojerdi et al., 2020). Nevertheless, Tanzania's national PV system still faces significant challenges. To our knowledge, this is the first e blended learning training assessing basic knowledge of pharmacovigilance among healthcare professionals in Tanzania. In this present study, healthcare professionals had poor knowledge of basic pharmacovigilance and TB and anti-TB drug safety issues monitoring and management before the educational interventions. A significant improvement in the knowledge score was observed after the educational interventions. Similar findings were observed in a study

at Nepal hospital where a pre-post intervention questionnaire-based study was conducted amongst eighty-nine HCPs and after the educational intervention, the mean score for knowledge about PV and ADR increased from [mean $\pm$ S.D] 6.90 ± 2.527 (pre-test) to 11.36 ± 1.189 (post-test, $p < 0.001$) (Shrestha et al., 2020). The same study showed a significant improvement in correct answers after educational interventions in the post-test amongst HCP (nurses and pharmacists) (Shrestha et al., 2020). Overall the knowledge of HCP increased soon after the educational intervention. The findings of this study showed that knowledge scores and correct answers were increased following an educational intervention among HCP.

Another study in India showed an increase in the mean knowledge score in the post-intervention phase (11.65 ± 2.14) as compared to the pre-intervention phase (6.98 ± 2.46) among nurses (Abu Farha et al., 2018).

Similar findings were observed also in a study done in South Africa on a one-day decentralized pharmacovigilance training of 129 HCP using a pre/post-test self-administered multiple choice questionnaire (Mukesh et al., 2018). However, a further study needs to be conducted to investigate whether this increase remains steady in the long term.

Conclusions

The findings of this study proves the impact of training as the knowledge scores and correct answers were increased following an educational intervention among health care providers.

Strength

This is the first blended e-learning training to be conducted to health care workers involved in reporting adverse events. More than 70% of invited members were trained and the knowledge improvement were seen from different topics based on pre and posttest.

Study Limitations

In our study we were not able to evaluate the differences of ADR reporting after the training in comparison with the ADR reporting before the training.

In several health centers the improvement of ADR reporting lasted just few months after the training, hence more training is encouraged.

The participants might not be representative of the health care professional population of Tanzania as statistical basis of selection was not used.

Declarations

Ethics approval and consent to participate.

Research and ethical approval were provided by the Kilimanjaro Christian Medical College Research Ethics and Review Committee (CRERC) in Moshi, United Republic of Tanzania (Certificate No. 2297), and the National Health Research and Ethics Review Committee (Nat-HREC) (Certificate No. NIMR/HQ/R.8a/Vol.IX/2883). The participants were asked by the trainer to accept the attendance of the training, then the email with password and logging credentials were sent. Privacy and confidentiality were maintained as each trainee was given unique number and they were informed that the results will be used for study purposes only. Hence informed consent was obtained from the health care workers.

Consent for publication

The trainees were informed that the results will be published as part of the deliverables of the main study PAVIA (EDCTP grant number 1627 PAVIA CSA2016S)

Availability of data and material

The data available are the analyzed results from the trainee questions both pre and posttest. They will be provided by corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interest.

Funding

The e-learning activities was not funded. However the development of the blended-learning programme was facilitated by the PAVIA project ((EDCTP grant number 1627 PAVIA CSA2016S)

Authors' contributions

Eva Muro and Hadija Semvua were pharmacovigilance focal person of the project and was involved in the training of health care professional at Kilimanjaro Region. They prepared the manuscript for submission. Kissa Mwamwitwa, Adam Fimbo, Seth Kisenge, Mtani Njegere and Nellin Shiletiwa were involved in data collection from the other Regions which were trained. They reviewed the manuscript for publication. Linda Harmark, Ugo Moretti, Riccardo Lora, Alberto Sabaini and Francesco Schievano were involved in designing the blended eLearning programme and questions. Mauro Veregoni and Lara Magro were involved in teaching the train of trainers group which were then used to train the health care workers. Blandina Mmbaga were involved in the designing, supervision and reviewing the manuscript for publication.

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