The Participation Of Private Healthcare Facilities In Pharmacovigilance Activities: A Case Study In Tanzania Mainland

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Abstract

Background: Poor quality products, adverse drug reactions (ADRs) and medication errors (ME) are reported to negatively influence health care cost, patients' treatment outcomes and quality of life. One way which can help in detection and prevention of their occurrence is through spontaneous reporting of these effects/events to the regulatory bodies. Despite the efforts done by regulatory bodies in different countries including Tanzania, the rate of reporting has remained low. This study therefore, assessed the participation of private healthcare facilities in pharmacovigilance (PV) activities in Tanzania Mainland.

Methods: A descriptive cross sectional study was conducted in selected regions in Tanzania from December 2017 to June 2018. A total of 169 healthcare facilities and 192 healthcare professionals were involved. Data was collected using questionnaires and standard checklist.

Results: Only (17%) of the respondents had good knowledge on PV activities and only (29.7%) of the participants had attended training on PV. Over 50% of respondents were not aware that PV activities reports are to be sent to a National pharmacovigilance center. Majority (89.7%) of the healthcare facilities assessed had no system for monitoring and reporting PV activities. About (55.7%) of the respondents said that they had observed ADRs in patients while (27.6%) had detected poor quality products and (51.1%) spotted medication errors in their practice, but none of them sent a report to the National pharmacovigilance center. Lack of PV tools (60.9%), poor knowledge on reporting procedures (69.8%) and lack of feedback and weak supervision from Tanzania Medicines and Medical Devices Authority (TMDA (93.3%) and (9.4%), respectively were the major obstacles for carrying out PV activities. Of the 47 respondents whereas, their healthcare facilities had systems for monitoring and reporting PV activities had a view that attending more training (74.5%), increase availability of PV tools (10.6%), frequent supervision from TMDA (12.8%), and inclusion of PV training in undergraduate and postgraduate training curricula (2.1%) may improve involvement in pharmacovigilance activities

Conclusions: Majority of private healthcare facilities participated poorly in PV activities, because of lack of pharmacovigilance training, knowledge on reporting and unavailability of systems and tools for monitoring and reporting on pharmacovigilance activities.

Background

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems (1, 2). Pharmacovigilance activities namely, adverse drug reactions (ADRs) poor quality product and medication errors, greatly influence healthcare systems by negatively affecting patient care and increasing treatment cost (3).

ADRs are among the global medical concerns, causing a considerable amount of morbidity and mortality (4, 5). Active and passive (spontaneous) reporting methods are commonly used in collecting data for PV. Spontaneous reporting is of importance in early detections and prevention of new, rare and serious ADRs,

ME and poor quality products, even though it is not routinely done in many sub-Saharan African countries. The level of under-reporting ADRs, ME and poor quality products is very high across the globe (6–9). Key causes of under reporting have been identified which include but not limited to uncertainty on what to report, lack of time, lack of knowledge on PV, lack of feedback on submitted reports, motivation and indifference (6, 9–11). Other causes includes, complacency, lawsuit concerns, concerns of implicating other healthcare professionals (HCPs) peer pressures and not being confident with reporting procedures (6, 10, 11). Under-reporting negatively affects treatment outcomes of individuals and government economy at large through unnecessary use of limited healthcare resources (10). In Tanzania under-reporting is still a pragmatic problem. According to the Tanzania Medicines and Medical devices Authority (TMDA) which is a national PV center, between 2002–2013 only 7,212 ADRs reports were received (12). These reports were only 2.5% of the annual recommended target. The received reports were mainly from public healthcare facilities (12). In resource limited countries such as Tanzania private healthcare facilities such as pharmaceutical drug outlets, hospitals, health centers and dispensaries are often patient's first point of contact with the health care system and they are preferred channels for purchasing medicines (13). The reason why majority of patients use private healthcare drug outlets lies on long opening hours, availability of medicines (including the possibility of credit and the option to purchase medicines in small quantities), geographical accessibility, personal familiarity and lack of physicians consultation fees (14). The extent of reporting of ADRs, ME and poor quality products within private healthcare facilities in Tanzania is not well documented and there is limited information regarding the potential barriers for reporting in these healthcare facilities (15). This study therefore, was aimed at assessing the involvement of private health facilities in pharmacovigilance activities in Tanzania.

Methods

Aim

This study was aimed at assessing the involvement of private health facilities in pharmacovigilance activities in selected regions of Tanzania Mainland.

Study design and area

This was a descriptive cross sectional study conducted in three regions namely Mwanza, Arusha and Mbeya in Tanzania.

Study population

Study participants were health care professionals (HCPs) such as registered nurses, assistant nursing officers, enrolled nurses, medical specialists, medical doctors, assistant medical doctors, clinical officers, pharmacists, pharmaceutical technicians, pharmaceutical assistants and Accredited Drug Dispensing Outlets (ADDO) dispensers. These HCPs were working in private healthcare facilities including private hospitals, health centers, dispensaries, pharmacies and ADDO.

Sample sampling

Participants were selected using a convenient sampling method.

Data collection

Data were collected from December 2017 to June 2018. In ADDO and community pharmacies one health care provider was interviewed per facility. In hospitals, health centers and dispensaries two health care professionals were interviewed per facility. The respondent interviewed was either the facility in charge or manager.

An interview was conducted using structured questionnaires to assess respondents' knowledge and attitude on PV activities. Likert scale was used to measure knowledge; whereby each question has one point, out the 12 questions, a score of 8 and above was considered good, 4 to 7 moderate and 0 to 3 poor. A checklist was used to assess practice in healthcare facilities. Pre-testing of the tools was done at five private healthcare facilities.

Statistical analysis

Data analysis was done using Statistical Package for Social Sciences version 20.0 software (IBM SPSS Statistics 20). Descriptive statistics test was used in the analysis wherever appropriate. Chi square test was also used to test for associations between the categorical variables. Results were presented mostly as percentages. A two tailed P-value < 0.05 was considered to be statistically significant at the 95% confidence level.

Results

A total of 169 private health care facilities and 192 healthcare professionals were assessed for their involvement in PV activities. Of the healthcare professionals included in this study (62.5%) were nurses, (15.1%) medical practioners and (22.4%) pharmaceutical personnel's, of which majority of them (70.3%) had never attended any PV training.

Regarding knowledge, over 50% of the respondents had poor knowledge on PV activities as depicted in Fig. 1.

Poor knowledge in PV activities, was more in HCPs working in ADDO (57.9%), compared to those working in community pharmacies, hospitals, health centers and dispensaries and the differences was statistically significant (P = 0.0017). A statistical significant differences in knowledge about PV activities was also observed between pharmaceutical and non-pharmaceutical personnel's (P = 0.0001). Of the respondents with poor knowledge majority of them (84.1%) had not attended any training on PV activities (P = 0.0001). These results have been summarized in Table 1.

Table 1
Pharmacovigilance knowledge among healthcare professionals working in private health care facilities

Type of the health facility	Good	Moderate	Poor	Chi square	P value
ADDO	9 (27.3%)	23 (44.2%)	62(57.9%)		
Pharmacy	15(45.5%)	16(30.8%)	21(19.6%)		
Formal health facility	9 (27.3%)	13(25.0%)	24 (22.4%)		
				12.021[a]	0.017
Training on PV					
Yes	18 (54.5%)	23(44.2%)	17(15.9%)		
No	15 (45.5%)	29 (55.8%)	90 (84.1%)		
				24.529[a]	0.0001
Professional cadres					
Pharmacist	10 (30.3%)	2 (3.8%)	1 (0.9%)		
*P'Technician	9 (27.3%)	13(25.0%)	3 (2.8%)		
**P'assistance	0 (0%)	4 (7.7%)	2 (1.9%)		
Medical doctor	3 (9.1%)	4 (7.7%)	11(10.3%)		
Clinical officer	0 (0%)	5 (9.6%)	6 (5.6%)		
Nurse	11 (33.3%)	24 (46.2%)	84 (78.5%)		
				72.231[a]	0.0001
Experience					
Less than a year	1 (3.0%)	5 (9.6%)	7 (6.5%)		
1 to 5 years	16 (48.5%)	23 (44.2%)	60 (56.1%)		
6 to 10 years	5 (15.2%)	13 (25.0%)	19 (17.8%)		
11 to 15 years	4 (12.1%)	5 (9.6%)	3 (2.8)%		
More than 15 years	7 (21.2%)	6 (11.5%)	18 (16.8%)		
				9.675[a]	0.289

***P'Technician = Pharmaceutical Technician**

**P'assistance = Pharmaceutical Assistant Technician

About (46.9%) of the participants did not know who is responsible for reporting ADRs, ME and poor quality products and only (37.5%) of respondents were aware that PV activities reports are sent to Tanzania Medicine and Medical Devices Authority (TMDA) which is a national pharmacovigilance center for Tanzania. These results are summarized in Table 2.

Table 2

Knowledge of respondents on reporting ADRs, ME and poor quality products (N = 192)

Mention people who are required to report ADRs, ME and PQPs Frequencies		Percentage
Nurses	1	0.5
Clinicians	1	0.5
Drug dispensers	11	5.7
All health care workers	74	38.5
Don't know	90	46.9
Patients	1	0.5
HCW and Patients	14	7.3
Where should the reports be sent		
TMDA offices	72	37.5
District Medical Officer offices	18	9.4
At the facility	6	3.1
Don’t know	95	49.5
Pharmacy council	1	0.5
Almost all (96.9%) of the health facilities had no system for monitoring and reporting PV activities. The yellow forms, green forms, blue forms and electronic systems were found in only in a very few healthcare facilities assessed (Fig. 2). Furthermore, only (36.7%) of the healthcare facilities assessed had a focal person for PV activities. None of the healthcare facilities surveyed had guidelines for documenting and reporting PV activities to TMDA.		
Of the respondents (55.7%), (27.6%) and (51.1%) had observed ADRs, poor quality products and ME, respectively in their practice. Even though, almost all of the respondents did not report these problems to TMDA (Table 3).		
Types of ADRs observed by HCPs are shown in Fig. 3 skin rashes and itching had high prevalence of occurrence than the others with percent frequencies of 33 and 22, respectively.		
Types of defects seen on products as encountered by the healthcare professionals are shown in Fig. 4. Colour change, drug solution with particles and poor labelling were some of the defects seen.		
Medication errors encountered by respondents are shown in Fig. 5. The most encountered error was prescribing the high doses of medicines.		

Action taken by participants after encountering the ADRs or ME or a poor quality products are shown in Table 3. Majority of participants reported that they would report to the supervisor or solve the problem by themselves rather than documenting and reporting to TMDA.

Table 3

Action taken by participants after encountering the ADRs or ME or poor quality products

Actions taken by respondents after encountering ADRs (n = 107)		Percentage
Reported to TMDA	10	9.3
Reported to the supervisor	1	0.9
Referred patient to higher level facility	20	18.7
Solved the problem himself/herself	76	71
Actions taken by respondents after encountering poor quality (n = 53) Products		
Reported TMDA	5	9.4
Reported to the supervisor	32	60.4
Discarded the product	8	15.1
Returned the product to supplier	8	15.1
Actions taken by respondents after encountering medication errors (n = 98)		
Reported TMDA	4	4.1
Solved the problem himself/herself	59	60
Returned the patient back to the prescriber	35	35.7

Regarding attitude towards pharmacovigilance activities majority of the respondents, (89.6%) agreed that reporting PV activities is part of the professional obligation. Equally, (81.3%) of respondents strongly agreed that establishment of PV center in healthcare facility may play a significant role in pharmacovigilance reporting. Albeit, only 47 (24.5%) of respondents agreed that PV activities should be done voluntarily as indicated in Table 4.

Table 4
Attitude towards pharmacovigilance activities reporting (N = 192)

ATTITUDE	Strongly agreed	Agreed	Disagreed	Strongly disagreed	Not sure
Reporting is part of professional role	89.6%	4.7%	1.6%	3.6%	0.5%
Reporting is part of community role	66.7%	10.4%	3.6%	17.2%	2.1%
Reporting should be voluntary	24.5%	4.2%	8.3%	59.9%	3.1%
Reporting is necessary for any suspected defect in PQPs	93.2%	5.2%	0.5%	1%	0%
Reporting of ADRs is very important for quality and safe medicines	95.8%	3.6%	0%	0.5%	0%
Reporting of MEs is important	84.9%	4.2%	3.6%	6.3%	1%
Establishing PV center in your facility is important	81.3%	9.4%	2.1%	4.2%	3.1%

Lack of knowledge on what where and when to report (69.8%), lack of PV reporting tools (60.9%), lack of training on PV (87%) and lack of feedback from TMDA (93.3%) were the major factors contributing to under- reporting of ADRs, ME and poor quality products. Figure 6.

Of the 47 respondents with systems for monitoring and reporting PV activities had a view that attending more training (74.5%), increase availability of PV tools such as yellow, green and blue forms (10.6%), use of electronic method (7.8%) and frequent supervision from TMDA (5%) and inclusion of PV training in undergraduate and postgraduate training curriculum (2.1%) may improve participation in pharmacovigilance activities.

Discussions

Private healthcare facilities participated poorly in PV activities in this study, this is evidenced by the under reporting of encountered ADRs, ME and poor quality products by HCPs. Almost all HCPs interviewed did not report the effects encountered to the PV center (TMDA) as required, rather they solved the problems themselves. These findings of under-reporting of ADRs, ME and poor quality products have been reported worldwide (6–8).

Poor participation in PV activities and low reporting rate in this study could be accounted for by poor knowledge of respondents in PV activities namely ADRs, ME and poor quality products This lack of knowledge is reflected by the high percentage of HCPs stating that they did not know what, how, when and where to report. The results are similar to those reported from previous studies conducted in Tanzania and elsewhere (16–19). A review carried out by Vallero FR also reported that lack of pharmacovigilance knowledge was the eighth factor contributing to under-reporting (6). The HCPs cadre

and training on PV activities were found to have significant effect on knowledge of health care professionals on PV activities. Equally, various studies have identified an association between training in PV, knowledge and reporting rates (19, 20). Significantly, non-pharmaceutical personnel were found to have poor knowledge on PV activities compared to pharmaceutical personnel. This can be partly explained by the education background, as pharmaceutical personnel have formal training on pharmacovigilance compared to other cadres. Level of awareness on where and whom to send PV activities reports was also very low amongst the respondents. These findings are similar to studies conducted in Tanzania and elsewhere (12, 17, 21–23). Lack of pharmacovigilance component in the curriculum for medical personnel in Tanzania may account for lack of awareness and poor involvement in PV activities (15). ADDO courses offered in Tanzania include a PV module, however, in this study HCPs working in ADDO were found to have poor knowledge on pharmacovigilance compared to those working in other health care facilities. The short duration of the training of ADDO workers could be a contributing factor.

Results in this study as well show that there were only a few healthcare facilities with a system and guidelines for monitoring and reporting PV activities. Similar findings have been reported in previous studies conducted in Tanzania (24).

Our findings show that lack of reporting tools, lack of knowledge on procedures for documenting and reporting PV activities, lack of supervision and feedback from TMDA, lack of training on PV, insecurity and worries of implicating other healthcare professionals, were some of the hindrances for carrying out PV activities. Insecurity and ignorance have been reported to have a strong correlation with professional low knowledge on Pharmacovigilance (6, 9, 17, 25–27). Majority of the respondents considered the reporting of PV activities to be part of their professional obligation. However, only 24.5% of them indicated their willingness to participate in PV activities voluntarily. Comparable finding were reported in a study conducted among physicians and pharmacists in Venezuela (28). The use of incentive such as salary increment or bonus has been reported to have no impact on increasing the involvement of professionals on PV activities (29).

In this study attending more training, availability of pharmacovigilance reporting tools and frequent supervision by regulatory authority and use of electronic methods were identified as the important factors for improving reporting rate among HCPs. Similar results have been reported in other studies (6, 31), where training and continuing education of professionals has been reported to allow the development of competencies and skills for behavior change in relation to improvement of spontaneous reporting. As well, easy access and availability of pharmacovigilance tools and use of electronic methods were reported to increase the reporting rate of ADRs (31,32).

Conclusion

The participation of private health facilities in pharmacovigilance activities was poor. Poor knowledge in pharmacovigilance services and procedures for spontaneous reporting, poor availability of reporting

tools,, insecurity, lack supervision from TMDA and fear of implicating other healthcare professionals were identified as contributing factors for poor involvement of healthcare facilities in PV activities. Training on PV, and availability of PV tools can help to improve the participation in pharmacovigilance.

Abbreviations

ADDO: Accredited Drug Dispensing Outlet; MSD: Medical Stores Department;

TMDA : Tanzania Medicines and Medical Devices Authority; HCPs: Healthcare professionals; ME: Medication errors; WHO: World Health Organization; ADRs: Adverse drug reactions; PQPs: Poor quality products; PV: Pharmacovigilance.

Declarations

Ethics approval and consent to participate

All HCPs were informed about the purpose of the study and informed consent was obtained from all study participants prior to involvement. Ethical clearance to conduct this study was sought from Muhimbili University of Health and Allied Science Research and Ethics Committee.

Consent for publication

Not applicable

Availability of data and materials

All relevant data generated and analyzed during this study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that no competing interests.

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Authors' contributions

BAM, GK and HC contributed in study conception, design, data collection, analysis, writing and proof reading manuscript. KM, AN, VBM and DM contributed in data analysis and manuscript writing and proof reading. All authors participated in reading and approving the final manuscript.

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Figures

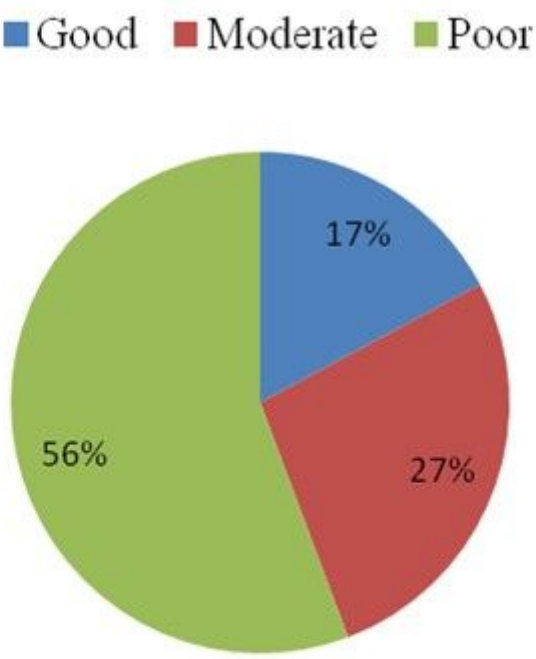

Figure 1

Knowledge of the participants on pharmacovigilance

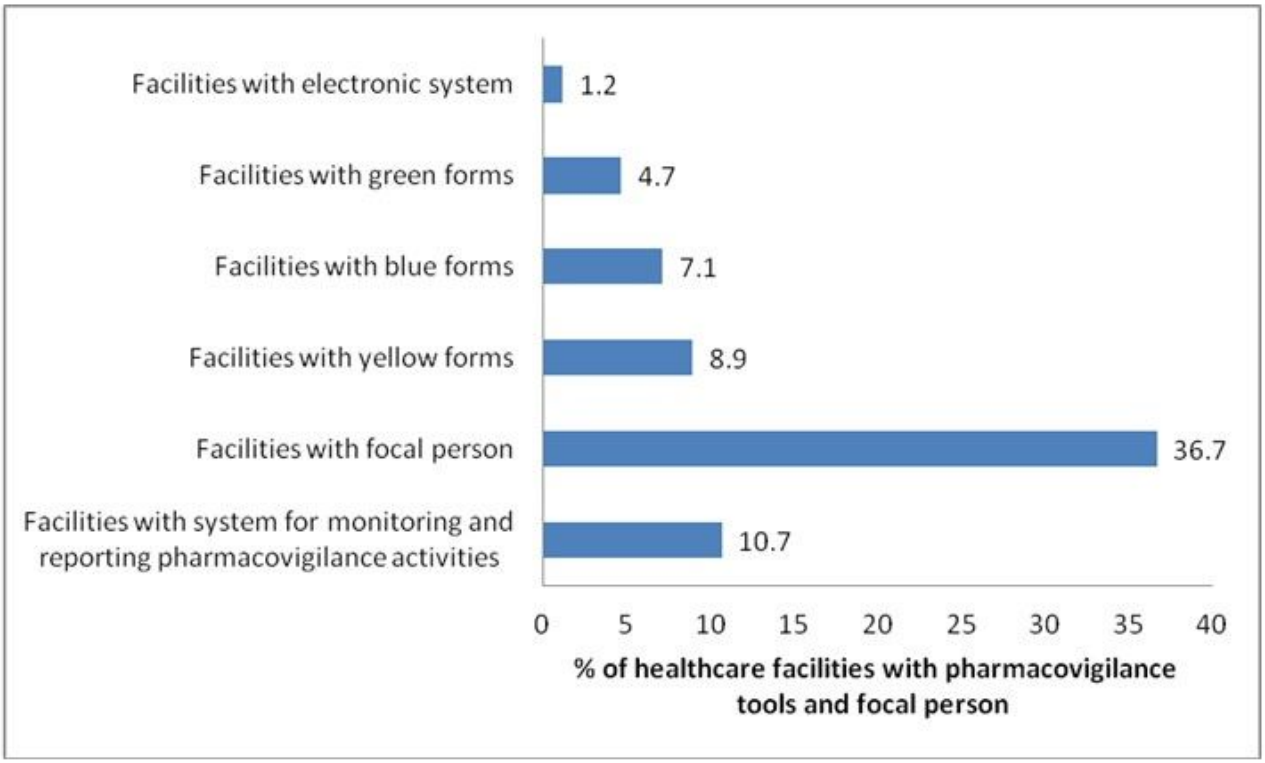

Figure 2

Healthcare facilities with pharmacovigilance tools and focal person

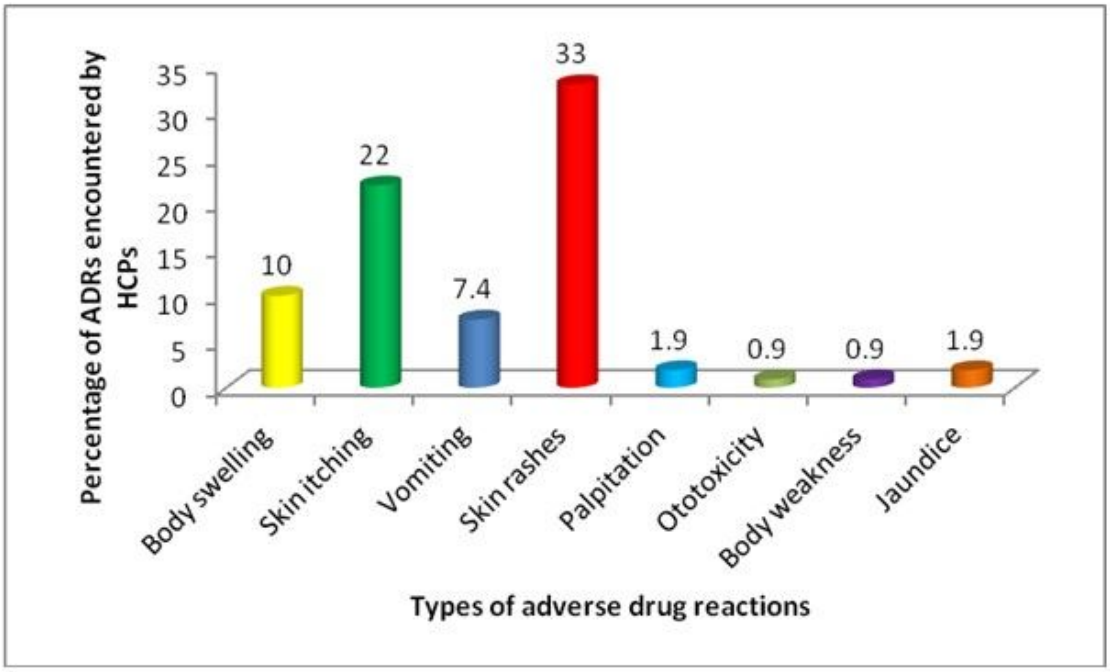

Figure 3

Types of the adverse drug reactions encountered by the respondents

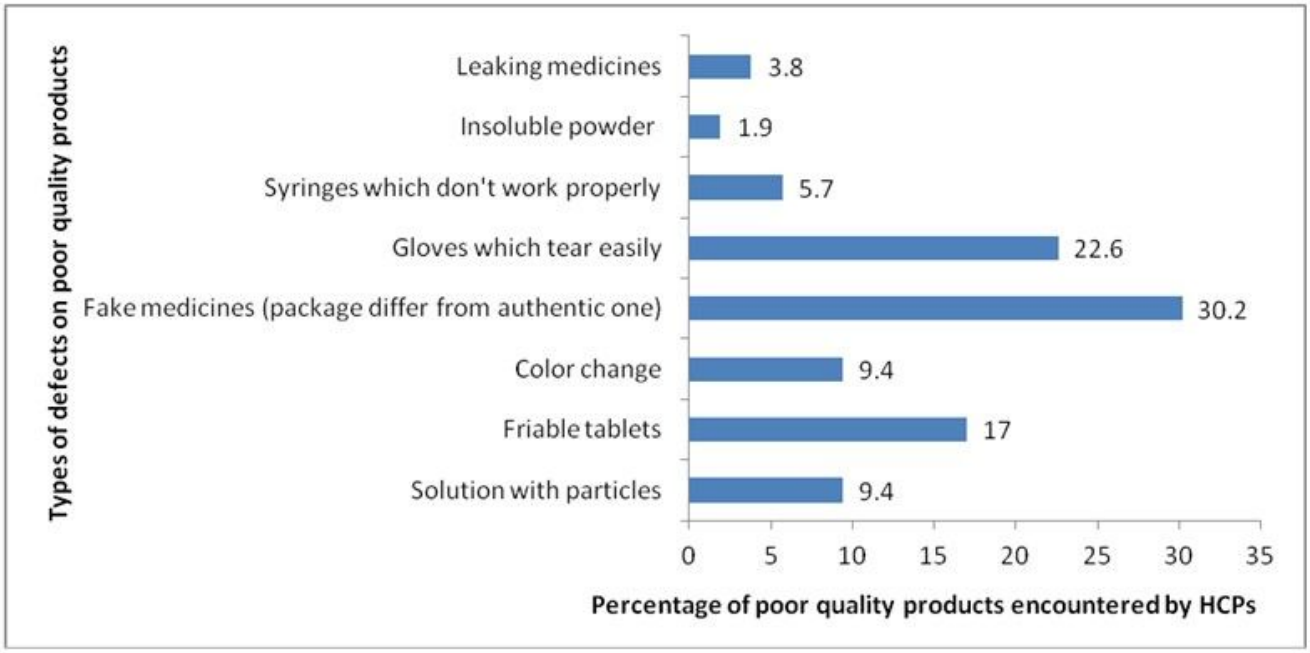

Figure 4

Types of defects seen on poor quality products

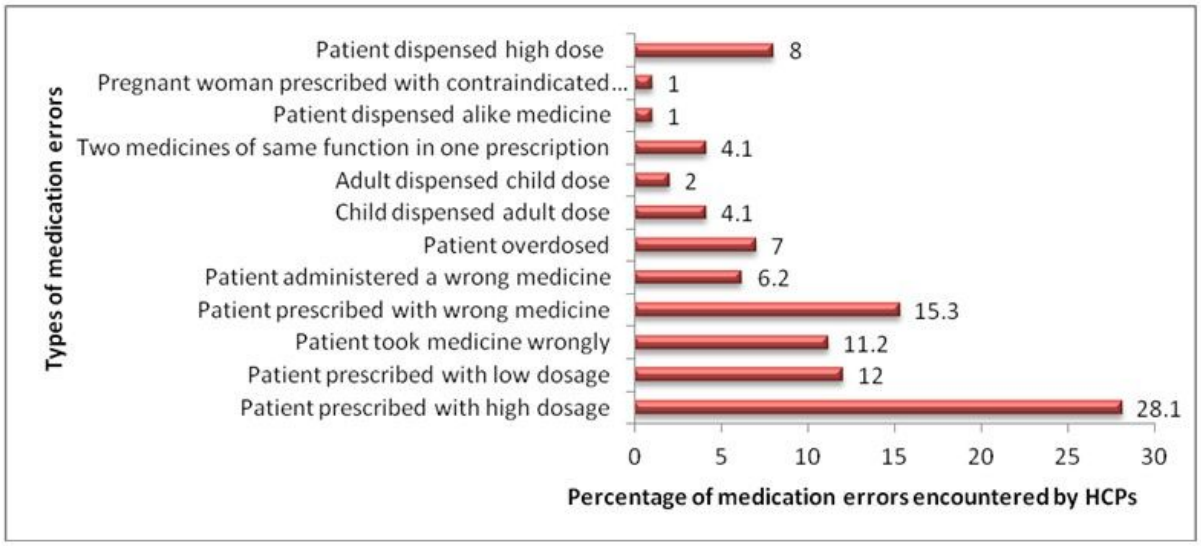

Figure 5

Types of the medication errors encountered by the healthcare professionals

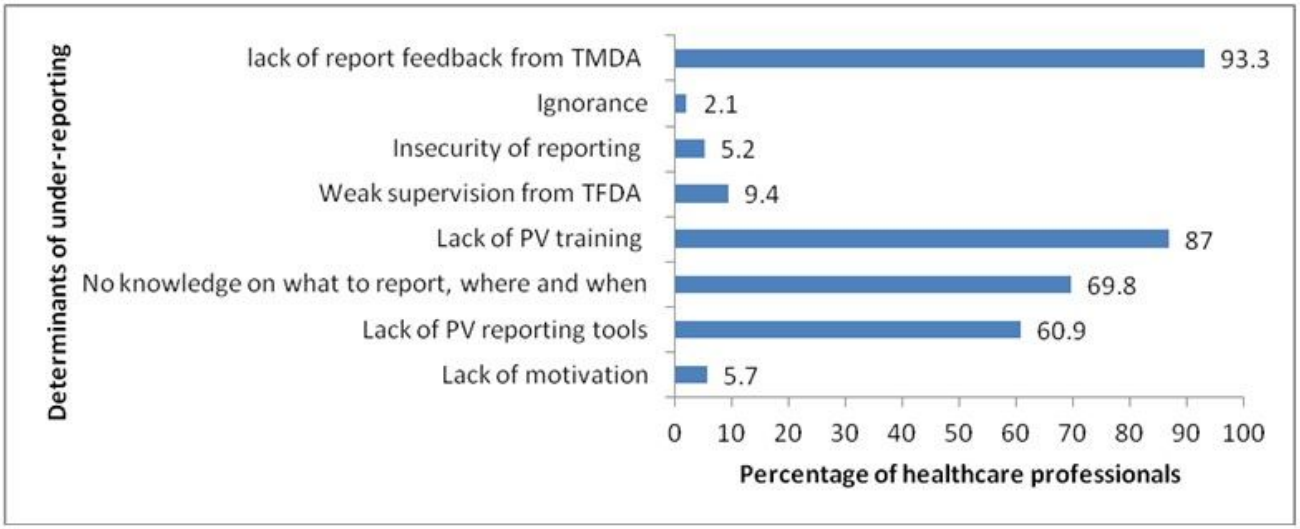

Figure 6

Determinants of under-reporting of adverse drug reactions, medication errors and poor quality products