ASSESSMENT OF KNOWLEDGE AND PRACTICE ON IDENTIFICATION AND REPORTING OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS AMONG HEALTH CARE PROVIDERS IN TANZANIA MAINLAND

Sayuni Steven Ndele, (B.PHARM)

Master of Pharmacy (Quality Control & Quality Assurance) Dissertation

Muhimbili University of Health and Allied Sciences

October 2021

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DEPARTMENT OF MEDICINAL CHEMISTRY

ASSESSMENT OF KNOWLEDGE AND PRACTICE ON IDENTIFICATION AND REPORTING OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS AMONG HEALTH CARE PROVIDERS IN TANZANIA MAINLAND.

By

Sayuni Steven Ndele

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Pharmacy in Quality Control and Quality Assurance of Muhimbili University of Health and Allied Sciences

October 2021

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences the dissertation entitled "***Assessment of knowledge and practice on identification and reporting of substandard and falsified medical products among health care providers in Tanzania Mainland"*** in partial fulfillment of the requirements for the degree of Master of Pharmacy (Quality Control and Quality Assurance) of Muhimbili University of Health and Allied Sciences.

_____

Dr. Vicky Manyanga

(Supervisor)

Date_____

_____

Prof. Eliangiringa Kaale

(Co-supervisor)

Date_____

_____

Mr. Innocent Daniel

(Co-supervisor)

Date _____

DECLARATION AND COPYRIGHT

I, Sayuni Steven Ndele, declare that, this dissertation is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature…… Date……..

ACKNOWLEDGEMENTS

All praise be to the almighty God for the gift of life and blessings throughout my academic journey to date.

I would like to extend my heartfelt gratitude to the School of Pharmacy of Muhimbili University of Health and Allied Sciences for providing the administrative supports to making this research work possible. My special gratitude is to my supervisors, Dr. Vicky Manyanga, Mr. Innocent Daniel, and Prof. Eliangiringa Kaale for their tireless efforts and support, dedication, and professional guidance during conducting and writing of this dissertation.

Moreover, I would like to acknowledge Mr. Manase Kilonzi for his support and effort in developing the data collection tools. Dr. Rogers Mwakalukwa for his assistance in creating google Forms together with Mr. Yohana Amon, Liberat Mroso, and Hamid Nassorro from the ICT office. More thanks are conveyed to Peter P. Kunambi, the statistical data analyst from MUHAS, for analyzing and making the data to be presentable.

Furthermore, many thanks go to the registrars of Medical doctors and dentists, Pharmacists, Nurses, and Midwifery, and Medical Laboratory Scientists councils for providing statistical data of registered personnel and allowing data collection amongst health care providers. I would like also to acknowledge the support from my colleagues, (postgraduate students) and the research participants for their willingness to engage in the study.

Lastly, I would like to acknowledge the support from my parents, my sisters and brothers, workmates, and my pastors for their valuable assistance, and encouragement during this period

.

DEDICATION

This work is dedicated to my Lovely mother Anitha Mbilinyi, Sister Grace Ndele, Brother Bariki Mandele, and my spiritual father Elia Mwinuka for their special help in prayers, encouragement, love, and endless support through this course.

ABSTRACT

Background: Substandard and falsified medical products are a global problem that affects both developed and developing countries. The existence of these products in the pharmaceutical supply chain undermines the efficiency of the healthcare delivery system due to their harmful effects and economic loss. Recently, studies from different countries have indicated the gap in knowledge and ability to handle substandard and falsified medical products among health care providers. Therefore, this study was done to assess the knowledge and practice of Tanzanian health care providers on the identification and reporting of substandard and falsified medical products.

Objective: This study aimed to assess the level of knowledge and practice among Tanzanian health care providers on the identification and reporting of substandard and falsified medical products.

Methodology: This was a descriptive cross-sectional study designed for 428 employed health care providers holding a minimum of a bachelor's degree in Tanzania mainland. The study participants were stratified according to their professions and sampled to participate in the study conveniently. The number of participants in each stratum was determined by its proportion of the study population. Data collection was done by using a questionnaire through an online method using Google forms. The collected data were analyzed by using the Statistical Package for Social Sciences (SPSS) version 23. The measure of association was done by Chi-square and Fisher's exact test at 95% Confidence interval (CI) with $P \leq 0.05$ considered statistically significant. Two-point Likert scales were used for knowledge and practice levels.

Results: A total of 773 HCP's participated in the study, the results were recorded from 767 (99.2%) HCPs who submitted complete filled responses. About 81.9% and 71.2% of respondents were found to have a good level of knowledge and practice on SF medical products identification and reporting respectively. However, 92.5% of pharmacists were having higher knowledge regarding SF medical products than other cadres (80.2) with *P*

=0.003. The knowledge of nurse officers was significantly different (74.6%) from other cadres (84.2%) with P = 0.004 and the practice of medical doctors was also significantly different (66.7%) from others (76.2%) with P =0.004. Furthermore, only 13.2% of the respondents reported having learned about SF medical products from universities. About 53.8% reported having no idea of reporting tools for SF medical products. The knowledge of the HCP's was significantly associated with age ($P < 0.001$), experience ($P = 0.001$), facility type ($P = 0.029$) and professional cadres ($P = 0.003$). Again, the respondents' practice on SF medical products identification and reporting was associated with age ($P < 0.001$), experience ($P < 0.001$), and professional cadres with $P = 0.009$. Moreover, the knowledge of respondents regarding SF medical products influenced respondents' practice with $P < 0.001$

Conclusions: The findings from this study show that 81.9% and 71.2% of HCP's have a good knowledge and practice regarding SF medical products identification and reporting respectively. The pharmacists' knowledge and practice were high than other cadres. Moreover, the knowledge of nurses was low whereas, the practice of medical doctors was also low. However, there is limited training from universities on SF medical products to only 13.2% of respondents who reported to have learned it from universities. Again, only 5.9% of the respondents reported using the right form to report SF medical products. The HCP's from health centers were found to have low knowledge than HCP's from other health facilities. The respondent's knowledge about SF medical products was found to influence practice.

Recommendations: Concerning the findings explored in this study, more interventions are recommended to be done by the regulatory authority. However, more efforts are required to make sure SOPs for identifying and reporting SF medical products are available in all health facilities. Moreover, capacity building to HCPs on how to identify and report any suspected medical product is recommended. Furthermore, Tanzanian higher learning institutions should include modules on substandard and falsified medical products.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ACTs	Artemisinin‐based Combination Therapies
ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ART	Anti-retroviral Therapy
ARV	Antiretroviral drug
BMC	Bugando Medical Centre
CHMT	Council Health Management Team
CI	Confidence Interval
DEG	Diethylene glycol
d4T	Stavudine
GMP	Good Manufacturing Practice
HCPs	Health Care Providers
HICs	High-Income Countries
HIV	Human Immunodeficiency Virus
ICN	International Council of Nurses
IRB	Institutional Review Board
HLPC	Health Laboratory Practitioners Council
KCMC	Kilimanjaro Christian Medical Centre
LMICs	Low-to-Middle-Income Countries
MCT	Medical Council of Tanganyika
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
MRDT	Malaria Rapid Diagnostic Test
MRH	Mbeya Referral Hospital
MSD	Medical Store Department
NMRA	National Medicine Regulatory Authority
RHMT	Region Health Management Team

SFM	Substandard and Falsified medicines
SOP	Standard Operating Procedure
SP	Sulphadoxine- Pyrimethamine
TBS	Tanzania Bureau of Standards
3TC	Lamivudine
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority
TNMC	Tanzania Nurses and Midwifery Council
TPI	Tanzania Pharmaceutical Industry
TT-VIR	Brand name for Nevirapine + Lamivudine + Stavudine
TZ	Tanzania
UNAIDS	Joint United Nations Program on HIV/AIDS
WHO	World Health Organization

DEFINITIONS

Counterfeit Medicines	Refer to illegal medicines that may contain wrong or no active ingredient, or may have the right active ingredient but at a wrong dose (high or low) produced deliberately to imitate the appearance of a genuine product.
Falsified medicines	These are medicines that may have the active pharmaceutical ingredient as claimed on the label but the source is not as stated or contain ingredient other than stated in the label.
Knowledge	This means a familiarity, awareness, or understanding about substandard and falsified medical products, their impacts on the patients, and the ways they are identified and reported.
Medical products	This means any products used to diagnose or manage patients (i.e medicines and medical devices.
Practice	This means any professional role played by a health care provider that has an impact on the effective delivery of health services.
Substandard medicine	These are medicines that fail to meet established specifications, the established limits may be below or above in the stated parameters.
Zone	Means an area separated from other areas in some artificial or natural manner.

1.0 INTRODUCTION

1.1 Background

Substandard and falsified medical products are a global problem that affects both developed and developing countries. The high demand for medical products and the high processing cost of genuine medications increase the risk of this falsification [1]. Reports have shown that both generic and innovator medical products can be falsified, starting with the most expensive anti-cancers to a very inexpensive pain killer [2]. This problem is widespread in countries with less stringent regulatory authorities (such as Africa and Asia) to those with stringent regulatory authorities such as Europe and America [3]. About two billion people in the world fail to access the necessary medicines, vaccines, and medical devices, such as *in vitro* diagnostic tools and other health products, which have created a huge gap that is normally filled by falsified and substandard medical products. This problem is increasing because the products are manufactured from one country, then packaged and consumed in other countries [1], [4]. The presence of substandard and falsified medical products in the pharmaceutical supply chain threatens both patients' health and the government due to economic loss, increased disease burden, frequent hospitalizations, disabilities, and deaths [5]. Research show that about 169,000 children die each year due to pneumonia as the result of the administration of substandard and falsified antibiotics and 158,000 deaths due to fake antimalarial in Africa [1], [6], [7].

The business of substandard and falsified medical products such as production, distribution, and sale is a huge market with several billions of money that represent more than 50% of products in the market, which has resulted in a loss of public confidence in medical products and health care delivery systems [8]. The World health organization (WHO) reported that about 32 billion US dollars were lost in 2004 due to the counterfeiting business involving medical products, and the amount increased to 40 billion US dollars in 2006 [9]. In 2018 a report from a study conducted in Tanzania to review the economic burden of substandard and falsified medical products by using 2005 to 2015 data from the regulatory authority (TMDA), showed that Tanzania has eliminated from the market substandard and falsified medical products worth $ 13.7 million [10]. This wastage of money and other threats associated with

the consumption of substandard and falsified medical products is a significant threat to the countries with weak health care delivery systems as it weakens their economic development and health sector. The business has also affected the development of many pharmaceutical industries due to unjustified competition in the markets since the quality products manufactured according to Good Manufacturing Practices (GMP) are much expensive [9]. The effect of substandard and falsified medical products has also been observed in Tanzania, such as the closure of the Tanzania Pharmaceutical industry (TPI) in 2012 due to a fake ARV scandal.

Currently, about 10-15% of the global medical products supplied are counterfeit, a significant proportion of these products are known to come from developing countries. A current report has shown that most of the substandard and falsified medical products circulating in the global market originate from India and China (35-75%) [11]. For instance, current reports from the Artemisinin Combination Therapy (ACT)- watch program (2009 through 2015) have shown that non-quality assured ACTs circulating in African countries are imported from India and China [5]. Moreover, another report from the Nigerian government showed a large consignment of fake anti-malaria drugs labeled 'made in India'; however, the drugs were made in China. The report also indicated that these products could be imported from other African countries [9]. This calls for stringent regulatory actions from African countries, including Tanzania which depends on imported medical products.

Substandard and falsified novel medicines such as hormones and supplements have been common in High-Income Countries (HICs). In contrast, Low to Middle-Income Countries (LMICs) reported being affected with falsified and substandard life-saving medicines such as anti-malaria, anti-TB, antiretroviral (ARV) drugs, and anti-cancer drugs. Other products like cough syrups, vitamins, and painkillers have also been reported [2]. The problem has proliferated to the anti-asthmatic drugs, and those used to treat blood pressure, heart conditions, and diabetes [12]. Substandard and falsified medical devices and diagnostic test kits such as Syringes, Malaria Rapid Diagnostic test (MRDT), and blood glucose test strips have also been reported [13]. Some cases of counterfeited test kits for COVID-19, hand sanitizers, disinfectants, and personal protective equipment (PPE) such as masks have also

been reported [14]. In Tanzania, a huge Consignment of 12,000 bottles of ARV's arrived at Medical Store Department (MSD) headquarter in 2012 being labeled as manufactured from Tanzania Pharmaceutical Industry (TPI) with a label claim of TT-VIR 30 (NVP 200 mg/3TC 150mg/d4T 30mg). The product was found to be repacked from expired ARV's within Dar Es Salaam region, and the label was designed to imitate the genuine product of TPI. Investigations from Tanzania Medicine and Medical Devices Authority (TMDA) ruled out that some containers contained Efavirency only and some contained different combinations from the stated combination in the label [15]. Due to the existence of these products in the country, there is a need for health care providers in Tanzania to be equipped with the appropriate knowledge necessary to identify and report these products [16].

1.2 Problem statement

Substandard and falsified medical products are a global challenge affecting all countries in the world. This problem affects both patients' recovery from treatment and countries in terms of trade relationships and economic development [8]. Some current reports have shown that an inadequate level of knowledge of the health workers about SF medical products contributes to the failure of their identification and subsequent administration to patients [9]. This practice normally leads to deaths, and other health effects such as drug resistance, treatment failure, toxicity, and prolonged illnesses. Therefore, this study assessed the level of knowledge and practice on the identification and reporting of substandard and falsified medical products among health care providers in Tanzania. So far, there is no report in the literature about the gap between the knowledge and practice of Tanzanian health care providers towards substandard and falsified medical product identification and reporting.

1.3 Rationale

The findings of this study reveal the level of knowledge and practice on the identification and reporting of substandard and falsified medical products among Tanzanian health care providers with an education background of a bachelor's degree. This study, therefore, paves a way towards understanding what actions should be taken to get rid of the prescribing or dispensing of the substandard and falsified medical products during patient care. The results

indicate a gap between knowledge and practice on the identification and reporting of SF medical products. Therefore these findings suggest further similar investigations involving large sample sizes. Those studies may help to make educational plans such as training programs for health care providers to raise their awareness of the existence of these products and their impact on patients and the public.

1.4 Research Questions

1. Are the health care providers equipped with enough knowledge on the identification and reporting of substandard and falsified medical products?
2. How do the Tanzanian health care providers handle substandard and falsified medical products?
3. Is there a difference within and between the professionals in the knowledge and practice towards the identification and reporting of substandard and falsified medical products among Tanzanian health care providers?

1.5 Objectives

1.5.1 Broad objectives

To determine the level of knowledge and practice regarding the identification and reporting of substandard and falsified medical products among health care providers in Tanzania's mainland.

1.5.2. Specific objectives.

1. To determine the level of knowledge of the Tanzanian health care providers towards substandard and falsified medical product identification and reporting.
2. To determine the practice of Tanzanian health care providers on handling substandard and falsified medical products.
3. To determine the difference in professional knowledge and practice towards identification and reporting of substandard and falsified medical products within and between the health professional cadres in Tanzania mainland.

2.0 LITERATURE REVIEW

2.1 Knowledge of the health care providers towards substandard and falsified medical product identification.

The assessment of knowledge among health care providers regarding SF medical products is based on whether they know what are the products, why the products are circulating, what are the health and economic effects to the patients and the public, how the product may be assessed with labels, packaging materials, expiration dates and appearance [4]. With labeling, a product can be mislabeled concerning identity or source. The packaging materials of one product can be used to pack other products, eg a tin of paracetamol tablets may contain aspirin tablets. Moreover, the leaflet may have different information like expiration date from what is in the label or the expiration date on the label may be extended to deceive. The appearance of the product can be different from the stated color, shape, or markings. In addition to that, the price of the medication can also be an indicator, where substandard medical products are usually associated with cheap prices and falsified medical products are associated with high price medical products. An example is the falsified ARVs in Tanzania [15] and WHO reported falsified Avastin anti-cancer drug that had a cost of around US$ 2400 per injection [4]. Furthermore, SF medical products can be identified through unexpected treatment outcomes. When substandard and falsified medical products of the same original are taken by more than one patient, all patients tend to develop the same unexpected outcome [4]. Thus, knowledge and technical skills among HCP's on identifying and reporting SF medical products for confirmation by chemical analysis are of paramount important.

The reports from different studies among health care professionals revealed an alarming limited knowledge on identifying and reporting SF medical products [17]. Low knowledge about the existence and identification of substandard and falsified medical products among health professionals seems to be a common problem hindering the efforts to combat the distribution of these products even in the developed world [18]. The literature show several incidences of health hazards associated with the consumption of substandard and falsified medical products by patients. The evidence to this irrational prescription of dispensing that results in the administration of substandard and falsified medical products are always from

unpredictable physiological reactions (mild or severe) and sometimes death [19]. For example, the recurrence of seizures and deaths from using falsified antiepileptic medicines have been reported in Guinea-Bissau and Nigeria [3]. Other reports have shown patients' failure to respond to antibiotics due to the previous intake of fake antibiotics [9]. Recently, there has also been a report on lethal bacterial meningitis in Uganda associated with substandard ceftriaxone consumption, which contained 0.455gm of the API on assay instead of 1gm as stated on the label [3]. A report from UNAIDS on patient's response to ARVs in Sub-Saharan Africa show that about 6% of clients taking first-line ART are switched to second-line regimens per year due to poor quality of medical products, where health care providers continue switching medications without performing a physical check of those products [20]. In China, it is also reported that medicines used traditionally as a remedy for diabetes were found to have up to six times the standard dose of Glibenclamide, where reports showed that two patients died and nine were hospitalized due to its consumption. This could have been prevented if the product had been identified before use [2].

The literature show that these problems happen to the patients when the health care providers lack the knowledge for timely identification before administering such medicines to the clients [17], [21]. A study conducted in Tanzania at Bugando Medical Centre show an increase in drug resistance for ceftriaxone and cefotaxime from 26.5% in 2014 to 57.9% in 2015 and that could be contributed by continued use of substandard/falsified products not identified by health care providers [22]. Another recent study conducted in three hospitals in the Kilimanjaro region show that the prevalence of antimicrobial resistance is high [23].

More studies have been conducted in different countries to assess the knowledge and practice of different health care providers concerning substandard and falsified medical products. The findings indicated a gap in knowledge regarding SF medical products [8], [17], [24], [25]. A recent study done in Qatar has reported that only 18% of the pharmacists were aware of these products, indicating that substandard and falsified medical products circulating could not be identified as they are unaware of that [18]. On the other hand, a study conducted in Sweden amongst physicians showed that 78.5% of the participants had heard about substandard and falsified medical products, and 36.5% had seen patients suspected to have taken those

products [26]. Again, a study conducted among Nurses working at Medina in Faisalabad showed that about 96.6% had an idea about counterfeit products, 55.5% misinterpreted that product as expired products, and 15.3% thought the products were made from herbs [8]. Furthermore, a recent study conducted among Iranian pharmacists on knowledge and practice concerning counterfeit medical products has revealed that only 13.6% of the pharmacists could correctly identify substandard and falsified medical products [24]. Due to the knowledge gap seen in these studies, Tanzania health care providers are assessed to find out if they have adequate knowledge on this.

2.2 The practice of the health care providers on handling substandard and falsified medical products.

The medical products being used in health facilities need to have quality assured distribution and supply chain channels. The medical products being supplied need frequent physical checks by health care providers for early detection of any fraudulent feature. The shortage of essential medical products in health facilities has exposed the supply of SF medical products by distributors and suppliers. Thus, the health care providers need to ensure that adequate medical products are available and being procured in a transparent system [27]. Health care providers have a role in educating the public on safety concerns related to the use of SF medical products and discourage a self-diagnosis and self-prescribing culture [28].

The chain on handling SF medical products is as follows. First, health care providers or any other personnel identify SF medical products. Second, reporting the encountered SF medical product to the regulatory authority. Third, the regulatory authority act on the information reported and investigates the reported medical products. Fourth, if the reported medical product is confirmed to be substandard or falsified, feedback is provided through media, and other ways to stop and segregate the products for recall. Fifth, more actions like sanctions are taken by the regulatory authority against wrongdoers. This helps to limit continuous penetration and circulation of SF medical products [29], [30].

In Tanzania, a study that was conducted in the Mwanza region to assess the ability of the general community in identifying fake antimalarial products has revealed that about 84% of the respondents with health professionals were able to distinguish genuine against counterfeit antimalarial drugs but were unaware of how to report them [11]. WHO reported that healthcare professionals usually report only the most severe cases, where less serious cases associated with consumption of substandard and falsified medical products are not reported [19]. Medical products not registered are used regardless of approval and normally no reports are available from the regulatory authorities [31]. A recent report from Sweden show that about 66.9% of physicians are not aware of the procedure for reporting identified SF medical products [26].

Current reports have shown that this problem is growing by about 10% annually, where reporting could help to reduce the distribution of these products [32]–[34]. Other recent studies have shown that the higher the demand for medical products with cheap prices without knowing the quality contributed to the procuring and using of substandard and falsified ones [2], [9]. Stockout and shortages of medical products, makes pharmacist find alternative cheap suppliers that could provide poor quality products which are not notified by the pharmacist [17], [35]. A nationwide web-based survey that involved Italian community pharmacists on perceptions and opinions about the online business of pharmaceutical products show low confidence among pharmacists in online business. This is another way of selling and distributing substandard and falsified medical products and it needs pharmacists and other health care providers to ensure those medical products procured through the internet are inspected and reported when suspected to be of poor quality [36]. Thus, these studies show that the ability among health care providers in handling substandard and falsified medical products is inadequate and needs to be addressed.

2.3 The differences within/between professional knowledge and practice on identification and reporting of substandard and falsified medical products.

According to the International Council of Nurses (ICN), the necessary knowledge among nurses about substandard and falsified medical product identification and reporting is inadequate.[35]. A study conducted at Madina Teaching Hospital in Faisalabad reported that the nurses working at that hospital could misinterpret substandard and falsified medical products as herbal products or expired products [8]. Other studies have shown that pharmacy workers' knowledge of substandard and falsified medical products is limited despite being responsible for educating other health care providers in identification and reporting [16], [37], [38]. Medical laboratory scientists failed to identify fake diagnostic kits for malaria, by repeating testing several times without assessing the quality of the kit [4]. Moreover, most medical doctors and dentists are also reported to have limited knowledge on identifying these products, they mainly concentrate on treatment outcomes [3]. Furthermore, the available reporting systems are not known to many health care providers [25], [26]. Therefore, the knowledge and practice among health care providers on identifying and reporting substandard and falsified medical products before reaching patients are of paramount importance as timely interventions would save many precious lives [8].

3.0 MATERIALS AND METHODOLOGY

3.1 Study design

This is a descriptive cross-sectional study designed to assess the knowledge and practice on identifying and reporting SF medical products among health care providers holding a bachelor's degree and licensed to practice in various medicine outlets in all administrative regions of Tanzania mainland.

3.2 Study area and population

This study involved Medical doctors, Pharmacists, Nurse officers, Dentists, and Medical Laboratory Scientists holding a bachelor's degree. Involved participants were only those who are licensed to prescribe, dispense, administer medical products to patients and perform laboratory investigations for diagnosis, in hospitals, community laboratories, dental clinics, health centers, community pharmacies, and other clinics. HCPs such as Radiologists were excluded from this study as they are mostly using medical equipment with few chemicals which are not directly consumed by patients for disease treatment. The participants were from seven zones of Tanzania's mainland. This includes the Western zone, Lake zone, Central zone, Eastern zone, Southern zone, Northern zone, and Southern highland zone.

3.3 Sampling Techniques and Sample size Calculation

A stratified sampling technique was used to get the study participants. Five strata groups were obtained with classification based on the cadres to which the health care providers belong i.e., Medical doctors, Pharmacists, Nurses, Dentists, and Medical Laboratory Scientists. The proportion sample from each cadre was calculated based on the total number of registered personnel from the registrar of each professional. The following are the registered personnel in each cadre, 9538 Medical doctors, 4200 Nurse Officers, 2329 Pharmacists, 1242 Medical laboratory scientists, and 264 Dentists, this makes a total population of 17,573. The participants from each cadre were obtained through snowball sampling techniques and participated the study conveniently.

Sample size calculation

$$n = \frac{Z^2 P (1-P)}{E^2}$$

Where by n = sample size

Z =confidence interval level, 95% CL (1.96)

P = Sample proportion, unknown from previous surveys, hence 50%

E = is a marginal error (5%)

The sample size (n) = 385. Adjustment for non-respondent (664/0.9) = 428 Participants

Sampling from each Cadre (n) = calculated sample size X No. of each cadre

Total number of all cadres (Total Population)

Where,

The calculated sample size (n) = 428

Total number of all cadres (N) = 17,573

Therefore, the targeted minimum number of the participants from each cadre was calculated as follows

For registered Medical doctors (9538) sample size (n) = $\frac{428 \times 9538}{17,573} = 233$

For registered Nurse officers (4200) sample size (n) = $\frac{428 \times 4200}{17,573} = 101$

For registered Pharmacists (2329) sample size (n) = $\frac{428 \times 2329}{17,573} = 56$

For registered Medical Laboratory Scientists (1242) n= $\frac{428 \times 1242}{17,573} = 30$

For registered Dentist (264) sample size (n) = $\frac{428 \times 264}{17,573} = 7$

Basing on the participants' responses, the results were from 767 which include 405 Medical doctors, 185 Nurse Officers, 106 Pharmacists, 53 Medical laboratory scientists, and 18 Dentists. The distribution of the participants is shown in the map (Figure 1).

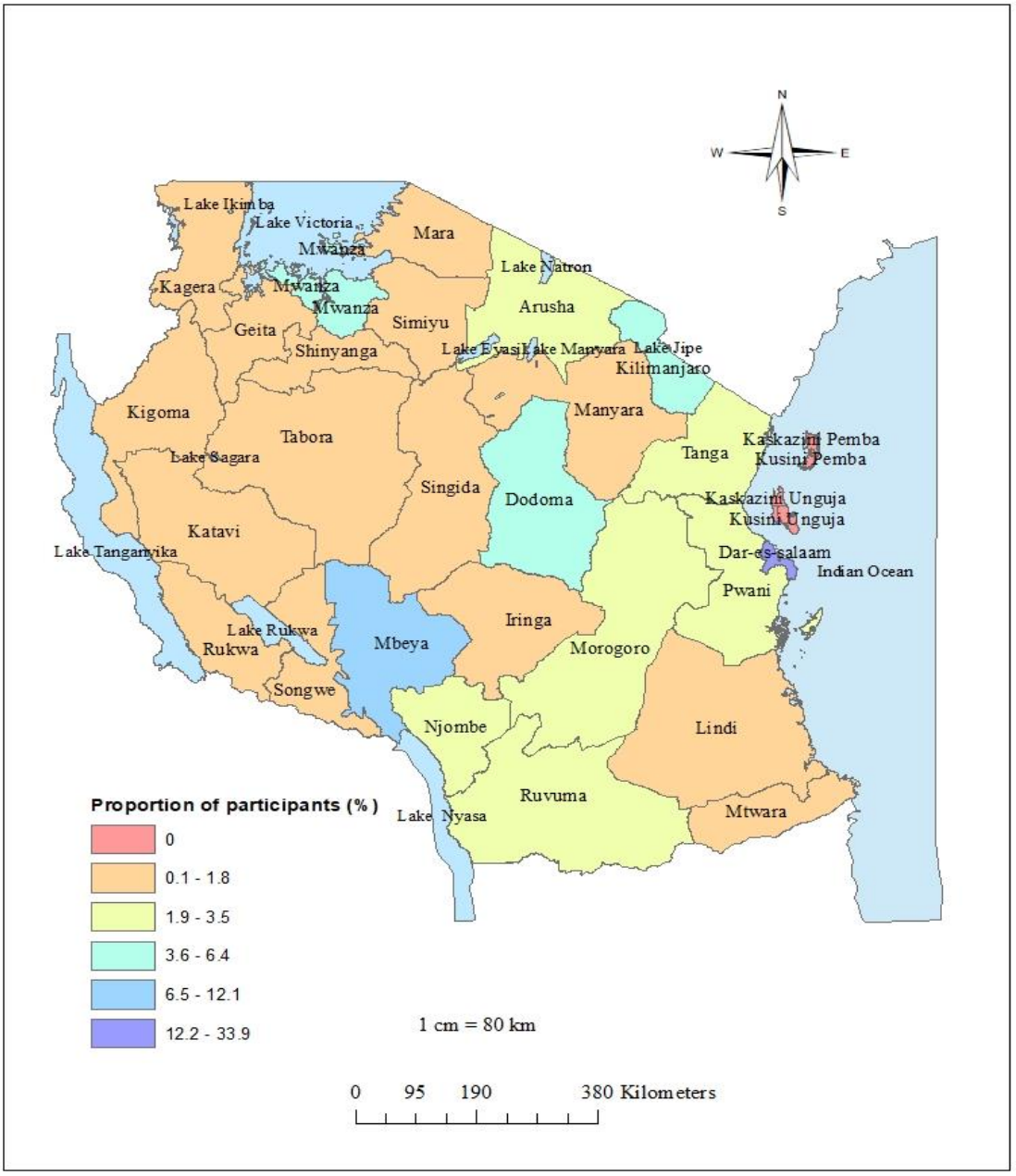

Figure 1: Proportion of participants from twenty-six (26) regions of Tanzania Mainland

3.4 Questionnaire and data collection method

The questionnaire (Annex II) was adopted from previous similar studies [4], [11], [25], [39]. The questions were entered into a Google form together with the informed consent form and then administered through the internet as an online survey. The principal research investigator introductory information about the study was provided to respondents along with instructions to open up the tool and use 5 to 10 minutes to fill out and submit responses. With the Snowball sampling method, the participants recruited other targeted HCP's providing health services everywhere within the country by forwarding the tool through What Sapp groups and emails as seen in the map (Figure 1). This made 773 of the health care providers opened up the tool, amongst which 767 (99.2%) filled out the tool completely, and 6 (0.8%) submitted an incomplete filled tool. Among 767, there were 405 (52.8%) Medical doctors, 185 (24.2%) Nurse officers, 106 (13.8%) Pharmacists, 53 (6.9%) Medical laboratory scientists, and 18 (2.3%) Dentists. Therefore 767 health care providers conveniently participated fully in the study as compared to the targeted sample size of 428 HCPs.

3.5 Description of variables

From this study, the main dependent variables were knowledge and practice among health care providers on identifying and reporting substandard and falsified medical products. These were assessed by Chi-square and Fisher's exact test at $P \leq 0.05$ i.e. those with good knowledge vs poor knowledge and those with good practice vs. bad practice. Those being knowledgeable and practicing were coded 1 (YES) for the minimum set of standards in the predefined set of knowledge and practice variables and those being un-knowledgeable and not practicing were coded zero, 0 (NO) for the knowledge and practice less than a defined minimum set of standards in the predefined set of variables. Independent variables such as age, sex, type of health facility where participants are working, zones where the facilities are located, bachelor degree studied, level of education attained, and the number of years of working experience were assessed to determine their association on knowledge and practice among health care providers.

3.6 Data processing and analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 23. The level of knowledge and practice were assessed using a two-point Likert scale such as good knowledge and good practice for those who scored 7-12 questions, also poor knowledge and bad practice for those scored 0-6 questions as was done in the previous studies [24] [39]. Chi-square and Fisher's exact tests were used to determine association factors (independent variables) with knowledge and practice as dependent variables. 95% Confidence interval (95% CI) was used as a measure of effect with P value of ≤ 0.05 considered statistically significant. The two tests were also used to analyze data for knowledge and practice within and between professional cadre (Figure 3 and 5, Table 3, 4, 5, and 6). Frequency distribution tables, histograms, and a map were used for the demonstration of the findings (Figure 1, 2, 3, 4, 5, and 6, Table 1, 2, 3, 4, 5, 6, and 7).

3.7 Ethical clearance

The ethical clearance for conducting this study was obtained from the Senate Research and Publication Committee of the Muhimbili University of Health and Allied Sciences (MUHAS). Permission to collect data from health care providers working in various health care facilities within the country was requested from the registrar of the five cadres. An informed consent form was provided to the respondents. The privacy and confidentiality of the research participants' data were observed throughout conducting the study.

3.8 Study limitations

About 773 health care providers participated in the study as compared to the calculated sample size of 428 HCP'S. This is because the targeted participants recruited other HCP's by sharing and forwarding the tool after receiving (snowball sampling technique). However, 767 (99.2%) participated fully in the study. This is because of network problems in some areas around the country. The study covered the country, which is not easy by traditional surveys like face-to-face interviews. However, some of the responses may be from untargeted participants. Thus, the online survey is good for large sample sizes and large study areas but the results may be biased.

4.0 RESULTS

4.1 Demographic and professional characteristics of the study participants.

About 773 health care providers participated in this study. A total of 6 (0.8%) responses were excluded due to an incomplete filled questionnaire, therefore the results of this study were recorded from 767 (99.2%) health care providers. Among the respondents, 85.3% were having a bachelor's degree, 62.1% were males with only 37.9% females. The age of the majority was lying between 30-39 (47.5%) as compared to other age groups. About 557 (72.6%) of the participants were working in hospitals, the remaining percent were from health centers, dental clinics, community pharmacies, community laboratories, and other clinics (Table 1). The distribution of respondents show that a large number (38.7%) of health care providers with an education background of bachelor's degree and above were from the eastern zone (mostly from the Dar Es Salaam region). This is supported by the registrars' statistics, which showed that about 80% of registered health personnel with a minimum of a bachelor's degree work in Dar Es Salaam.

Table 1: Demographic and professional characteristics of the study participants

Variables	Category	Frequency (n)	Percentage (%)
Age group (years)	20 – 29	138	18.0
	30 – 39	364	47.5
	40 – 49	184	24.0
	50 – 59	66	8.6
	≥ 60	15	2.0
Sex	Males	476	62.1
	Females	291	37.9
Professional cadre	Pharmacist	106	13.8
	Medical Doctor	405	52.8
	Dentist	18	2.3
	Nurse officer	185	24.1
	Medical lab scientist	53	6.9
Education level	Bachelor degree	654	85.3
	Master degree	113	14.7
Working experience (in years)	≤ 5	298	38.9
	6 – 10	222	28.9
	11 – 15	116	15.1
	16 – 20	50	6.5
	21 – 25	42	5.5
	≥26	39	5.1
Health facilities	Hospitals	557	72.6
	Health centers	77	10.0
	Community pharmacies	37	4.8
	Community laboratory	3	0.4
	Dental clinics	4	0.5
	Other clinics	89	11.6
Zones	Northern zone	80	10.4
	Lake zone	84	11.0
	Southern highlands zone	153	19.9
	Eastern zone	297	38.7
	Western zone	39	5.1
	Southern zone	48	6.3
	Central zone	66	8.6

.

4.2 Knowledge among health care providers regarding substandard and falsified medical products in Tanzania Mainland.

The health care providers who responded to all knowledge questions were 767. About 63.4% said SF medical products are fake medical products, 26.9 % said the products are from an unknown source, 7% said they are placebo and 2.7% said are orphan products. Again, 69.2% said SF medical products are available in urban and rural areas. Moreover, on common SF medical products, 34.4% said lifestyle medicines, 26.6% said antimalarials and antibiotics, 25.9% said face mask, and 13% said diagnostics like blood glucose test strips. About 60.8 % of the respondents said high demand contributed for those products to be at risk. Furthermore, the factors contributing to the circulation of SF medical products were stated as, high price (76.7%), inadequate control (85.4%), poor reporting culture (91.5%), procuring medical products anywhere (75.9%), and lack of knowledge (88.9%). Again, 66.6% said SF medical products increase mortality and morbidity, drug resistance, and prevalence of diseases. Moreover, 53.1% said limited resources are wasted. Furthermore, only 13.2% of the respondents reported having learned about SF medical products from universities (Table 2).

Table 2: Proportion of responses of HCP's regarding SF medical products.

Questions.	Responses	Frequency	Percentages
What are substandard/falsified medicine, medical devices, and diagnostics products?	Are products from an unknown source	206	26.9
	Are placebo products	54	7.0
	Are orphan products	21	2.7
	Are fake medical products	486	63.4
In which areas do these substandard/falsified medical products are available?	Urban areas	112	14.6
	Rural areas	58	7.6
	Both urban and rural	531	69.2
	Don't know	66	8.6
The following are some of the medical products that may be falsified or produced as	lifestyle medicines	264	34.4
	Antimalarial and antibiotic medicines	204	26.6
	Diagnostics like blood glucose test strip	100	13.0
	Protective devices like face Masks	199	25.9

substandard, which ones are most common?			
What factor contribute to the product of your choice above being at high risk of being falsified or being out of standard?	Unavailable & unaffordable	132	17.2
	Highly demanded	466	60.8
	Highly promoted from internet	116	15.1
	Don't Know	53	6.9
The following are the health impact of using substandard and falsified medical products, which one is correct?	Increase in mortality and morbidity	95	12.4
	Promote drug resistance	146	19.0
	Prevalence of diseases increases	15	2.0
	All of the above	511	66.6
The following are the economic outcome of SF medical products, select the appropriate answer	Increase in productivity	116	15.1
	Reduced poverty	16	2.1
	Limited resources are wasted	407	53.1
	All of the above	228	29.7
From which source you became aware/learned about substandard and falsified medical products	During practice	532	69.4
	From university	101	13.2
	From conferences	38	5.0
	Not aware of it	96	12.5
What factors contribute to the circulation of SF medical products			
Highly-priced medical products	Yes	588	76.7
	No	179	23.3
Inadequate control of medical products by the regulatory authority	Yes	655	85.4
	No	112	14.6
Poor reporting culture of identified SF medical products by HCP's	Yes	702	91.5
	No	65	8.5
Allowing patients to buy medical products anywhere due to stockout.	Yes	582	75.9
	No	185	24.1
Lack of knowledge on SF medical products	Yes	682	88.9
	No	85	11.1

The two-point Likert scale was used, where 7 to 12 scores (81.9%) were having good knowledge and 0 to 6 (18.1%) were considered to have poor knowledge [24] [39] (Figure 2).

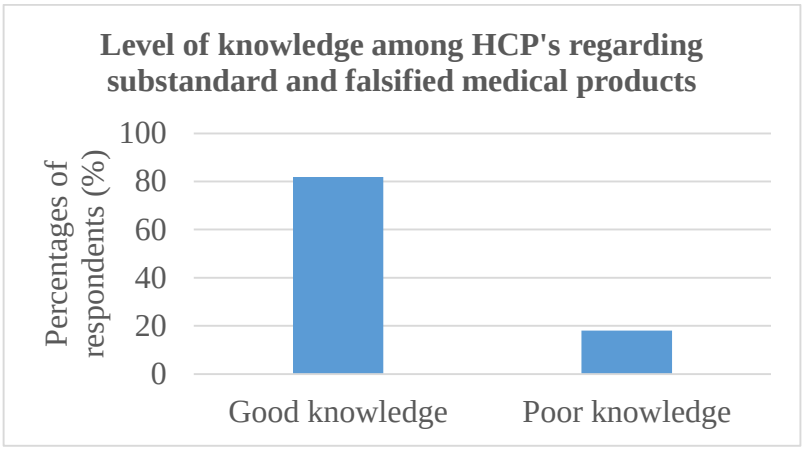

Figure 2: Knowledge on SF medical products among respondents

4.3 Knowledge on substandard and falsified medical products within the cadres

About 92.5% pharmacists, 88.9% dentists, 84.9% medical laboratory scientists, 81.7% medical doctors, and 74.6% nurses were having good knowledge. The differences in knowledge within the cadres were statistically significant with $P = 0.003$ (Figure 3).

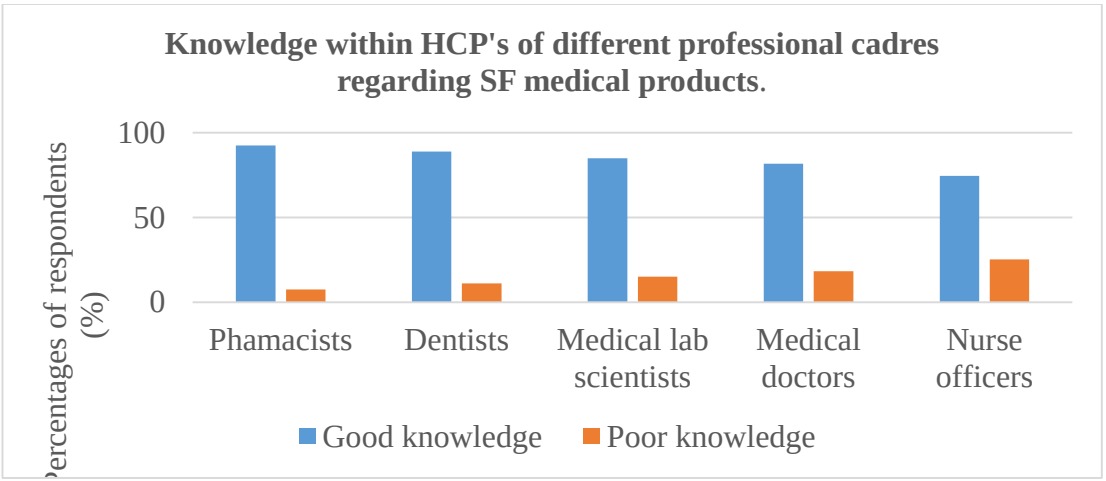

Figure 3: Knowledge within professional cadres on SF medical products.

4.4 Knowledge on substandard/falsified medical products between professional cadres

The knowledge on SF medical products between the five cadres was analyzed by both Chi-square and fisher's exact test. The findings show that the pharmacist knowledge regarding SF medical products was significantly higher (92.5%) than other cadres (80.2%) with $P = 0.003$. However, the difference in nurses' knowledge (74.6%) and other cadres (84.2%) was statistically significant with $P = 0.004$ (Table 3).

Table 3. The knowledge between health professional cadres on SF medical products.

Variable	Category	Knowledge frequency(n)		P value
		Poor	Good	
Pharmacists	Pharmacists	8 (7.5 %)	98 (92.5%)	0.003
	Other cadres	131 (19.8%)	530(80.2%)	
Medical doctors	Medical doctors	74 (18.3%)	331(81.7%)	0.925
	Other cadres	65 (18.0%)	297 (82.0%)	
Dentists	Dentists	2 (11.1%)	16 (88.9%)	0.755
	Other cadres	137 (18.3%)	612 (81.7%)	
Nurse officers	Nurse officers	47 (25.4%)	138 (74.6%)	0.004
	Other cadres	92 (15.8%)	490 (84.2%)	
Medical lab scientist	Lab scientist	8 (15.1%)	45 (84.9%)	0.589
	Other cadres	131 (18.3%)	583 (81.7%)	

Key: Variables with $P < 0.05$ have a significant difference concerning knowledge of other health care providers about SF medical products, while variables with $P > 0.05$ imply the opposite.

4.5 Factors associated with the knowledge regarding SF medical products among HCP's

The association variables with the knowledge of the respondents regarding substandard and falsified medical products were analyzed by both Chi-square and fisher's exact test. The age, experience, professional cadres, and facility level were significantly associated with respondents' knowledge regarding SF medical product with $P< 0.05$(Table 4).

Table 4: Factors associated with knowledge of the respondents on SF medical products.

Variables	**Category**	**Knowledge of SF medical products**		**P-Value**
		Poor n (%)	Good n (%)	
Age groups (years)	20-29	14 (10.1)	124 (89.0)	<0.001
	30-39	55 (15.1)	309 (84.9)	
	40-49	52(28.3)	132(71.7)	
	50-59	14 (21.2)	52 (78.8)	
	≥ 60	4(26.7)	11(73.3)	
Sex	Males	86 (18.1)	390 (81.9)	1.000
	Females	53 (18.2)	238 (81.8)	
Professionals	Pharmacists	8 (7.5)	98 (92.5)	0.003
	Medical Doctors	74 (18.3)	331 (81.7)	
	Dentists	2 (11.1)	16 (88.9)	
	Nurse officers	47 (25.4)	138 (74.6)	
	Medical lab scientists	8 (15.1)	45 (84.9)	
Education level	Bachelor degree	124 (19.0)	530 (81.0)	0.185
	Master degree	15 (13.3)	98 (86.7)	
Experience (years)	≤5	32 (10.7)	266 (89.3)	0.001
	6-10	42 (18.9)	180 (81.1)	
	11-15	32 (27.6)	84 (72.4)	
	16-20	13 (26.0)	37 (74.0)	
	21-25	10 (23.8)	32 (76.2)	
	≥ 26	10 (25.6)	29 (74.4)	
Zones	Northern zone	15 (18.8)	65 (81.3)	0.053
	Lake zone	21 (25.0)	63 (75.0)	
	Southern highland zone	25 (16.3)	128 (83.7)	
	Eastern zone	40 (13.5)	257 (86.5)	
	Western zone	10 (25.6)	29 (74.4)	
	Southern zone	13 (27.1)	35 (72.9)	
	Central zone	15 (22.7)	51 (77.3)	
Health facilities	Hospitals	101 (18.1)	456 (81.9)	0.029
	Health centers	21 (27.3)	56 (72.7)	
	Community pharmacy	1 (2.7)	36 (97.3)	
	Community laboratory	0	3 (100)	
	Dental clinics	0	4(100)	
	Other clinics	16(18)	73 (82)	

Key: Variables with $P < 0.05$ statistically affect the knowledge of the health care providers regarding SF medical products, while variables with $P > 0.05$ imply the opposite.

4.6 The practice of the Tanzanian HCP's on identification and reporting of substandard and falsified medical products.

The health care providers who responded to all practice questions regarding substandard and falsified medical products identification and reporting were 767. About 28.8% of the respondents reported to have encountered SF medical products, 22.3% heard from patients and colleagues, 40.8% heard from media and advertising material, and 8.1% were found to never have heard about it. Moreover, respondents were required to state how they identify SF medical products. In this, 81% said through the label, 59.3% said through the leaflet, 73.7% said through expiration dates, 79.5% said through reporting treatment outcomes like toxicity to the regulatory authority, 60.2% said through the cost/price of the medical products, 68.3% said the wrong diagnosis through laboratory results. However, 79.5% said through the unexpected adverse event in few patients that have used the same medical product of the same original (Table 5).

Furthermore, 86.7% of the respondents said if or when they encounter SF medical products they report or they will report to the regulatory authority. However, only 5.9% of the respondents reported using the right tool (blue form) for reporting SF medical products. Moreover, about 26.5% of the respondents said the problem in Tanzania regarding SF medical products is big, 44.8% said the SF medical products are existing but not identified and reported, 27% said the detection of SF medical products is increasing but reporting is a problem and 1.7% said SF medical products do not exist in Tanzania. The respondents suggested the action to be taken to reduce the problem. In this, 65.6% of the respondents suggested that public sensitization regarding SF medical products, adhering to ethics by the HCP's, reporting identified SF medical products and strictness in the entry points are required to overcome the problem (Table 5).

Table 5: Proportion of responses of HCP's on handling practice of SF medical products

Questions	Responses	Frequency	Percent
What is the source of information you heard about the presence of substandard and falsified medicines, medical devices, and diagnostic tools?	Media and advertising materials	313	40.8
	Patients and Colleagues	171	22.3
	Encountered in routine work	221	28.8
	Never heard	62	8.1
How do you identify substandard/falsified medicine/medical devices/diagnostics from original?			
Through label	Yes	621	81.0
	No	146	19.0
Through packaging materials	Yes	578	75.4
	No	189	24.6
Through expire date	Yes	565	73.7
	No	202	26.3
Through cost/price of medical products	Yes	462	60.2
	No	305	39.8
Through package insert(leaflet)	Yes	455	59.3
	No	312	40.7
Through unexpected adverse reactions to few patients after using the same medical product of the same batch.	Yes	610	79.5
	No	157	20.5
Wrong diagnosis through laboratory results	Yes	524	68.3
	No	243	31.7
Through reporting treatment outcomes to regulatory authority eg toxicity	Yes	610	79.5
	No	157	20.5
(When/if) you encounter SF medical products (do you/will you) report them?	Yes	665	86.7
	No	102	13.3
	Yellow form	273	35.6

Which form (do you use/will you use) to report them to the regulatory authority?	Green form	36	4.7
	Blue form	45	5.9
	Don't know	413	53.8
In your opinion, what is the current situation regarding the circulation of substandard and falsified medicine, medical devices, and diagnostics in Tanzania?	It is a big problem	203	26.5
	Substandard and falsified medical products are not existing	13	1.7
	The products are existing but not identified and reported	344	44.8
	Detection of SF medical products is increasing but reporting is a problem.	207	27.0
In which action do you suggest can help to reduce the penetration of substandard and falsified medical products in our country?	Through public sensitization to raise their awareness against SF medical products.	146	19.0
	Adherence to ethics and reporting the identified SF medical products	72	9.4
	The strictness of entry points(Borders)	46	6.0
	All of the above	503	65.6

The practice among HCP's was graded by the same number of scores as was done in the knowledge level. About 71.2% were having good and 28.8% have a bad practice (Figure 4).

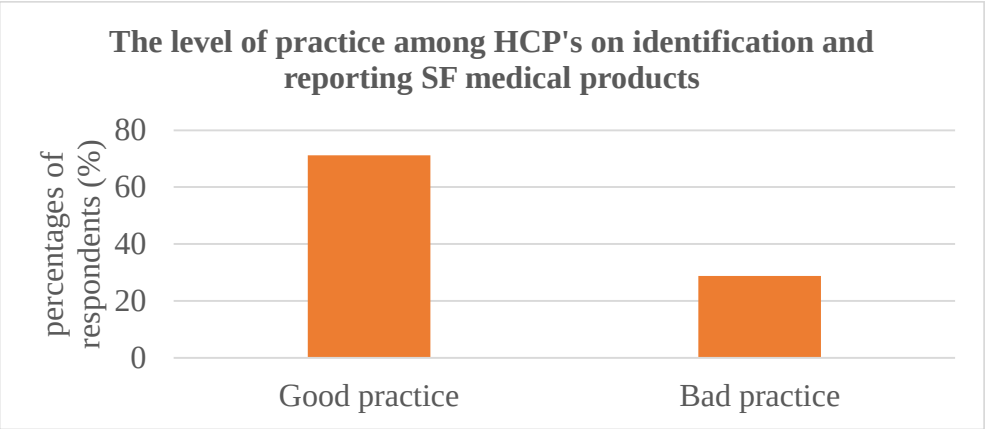

Figure 4: Practice among health care providers on handling SF medical products

4.7 The practice on SF medical products identifying and reporting within the cadres

About 84% of the pharmacists, 75.5% of medical laboratory scientists, 73% of nurse officers, 66.7% of dentists, and 66.7% of the medical doctors were found to have a good practice on substandard and falsified medical product identification and reporting. The differences in practice within the cadres were statistically significant with $P = 0.009$ (Figure 5).

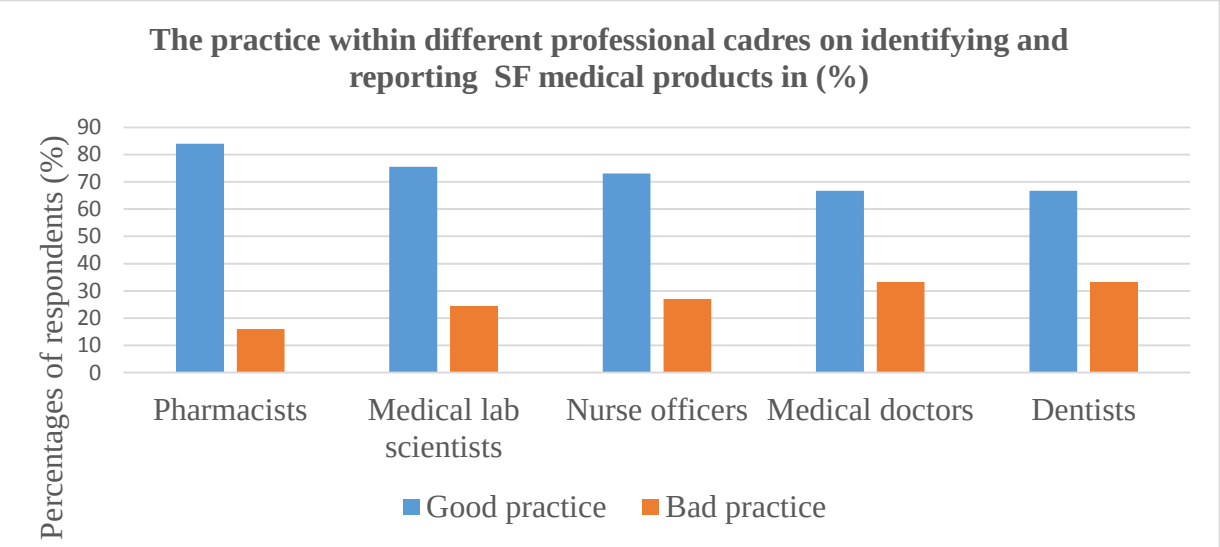

Figure 5: Practice on handling SF medical products within professional cadres

4.8 Assessment of SF medical products identification and reporting practice between the professional cadres

The practice of pharmacists was significantly higher (84%) than other cadres (69.1%) ($P = 0.002$). However, the practice of medical doctors was significantly low (66.7%) than other cadres (76.2%) with $P = 0.004$ (Table 6).

Table 6. Practice on identifying and reporting SF medical products between the cadres

Variable	Category	Practice frequency(n)		P value
		Bad practice	Good practice	
Pharmacists	Pharmacists	17 (16.0%)	89 (84.0%)	0.002
	Other cadres	204 (30.9%)	457(69.1%)	
Medical doctors	Medical doctors	135 (33.3%)	270 (66.7%)	0.004
	Other cadres	86 (23.8%)	276 (76.2%)	
Dentists	Dentists	6 (33.3%)	12 (66.7%)	0.792
	Other cadres	215 (28.7%)	534 (71.3%)	
Nurse officers	Nurse officers	50 (27.0%)	135 (73.0%)	0.577
	Other cadres	171 (29.4%)	411 (70.6%)	
Medical lab scientists	Lab scientist	13 (24.5%)	40 (75.5%)	0.533
	Other cadres	208 (29.1%)	506 (70.9%)	

Key: Variables with $P < 0.05$ have a significant difference in the practice between the cadres on the identification and reporting of SF medical products, while variables with $P > 0.05$ imply the opposite

4.9 Factors associated with practice on identifying and reporting substandard and falsified medical products among respondents.

The age, experience, professional cadres revealed a significant association in identifying and reporting SF medical products among the respondents with $P < 0.05$. However, the gender, zones where the facilities are located, educational level, type of health facility where respondents are working were found to have no association with $P > 0.05$ (Table 7).

Table 7: Factors associated with HCP's practice on handling SF medical products

Variable	Category	Practice on handling SF products		P – value
		Bad n (%)	Good n (%)	
Age (years)	20 – 29	31 (22.5)	107 (77.5)	< 0.001
	30 – 39	83 (22.8)	281 (77.2)	
	40 – 49	70 (38.0)	114 (62.0)	
	50 – 59	29 (43.9)	37 (56.1)	
	≥ 60	8 (53.3)	7 (46.7)	
Sex	Males	126 (26.5)	350 (73.5)	0.071
	Females	95 (32.6)	196 (67.4)	
Health facilities	Hospitals	175(31.4)	382 (68.6)	0.099
	Health centers	20 (26.0)	57 (74.0)	
	Community Pharmacies	6 (16.2)	31 (83.8)	
	Community Medical labs	1 (33.3)	2 (66.7)	
	Dental clinics	0	4 (100)	
	Other clinics	17 (21.3)	70 (78.7)	
Zone	Northern zone	31 (38.8)	49 (61.3)	0.237
	Lake zone	28 (33.3)	56 (66.7)	
	Southern Highland zone	37 (24.2)	116 (75.8)	
	Eastern zone	79 (26.6)	218 (73.4)	
	Western zone	14 (35.9)	25 (64.1)	
	Southern zone	13 (27.1)	35 (72.9)	
	Central zone	19 (28.8)	47 (71.2)	
Professional cadre	Pharmacists	17 (16.0)	89(84.0)	0.009
	Medical Doctors	135 (33.3)	270 (66.7)	
	Dentists	6 (33.3)	12 (66.7)	
	Nurse officers	50 (27.0)	135(73.0)	
	Medical Lab Scientists	13 (24.5)	40 (75.5)	
Experience(years)	≤ 5	67 (22.5)	231(77.5)	< 0.001
	6-10	56 (25.2)	166 (74.8)	
	11-15	46 (39.7)	70 (60.3)	
	16-20	16 (32.0)	34 (68.0)	
	21-25	17 (40.5)	25 (59.5)	
	≥ 26	19 (48.7)	20 (51.3)	
Education level	Bachelor degree	190 (29.1)	464 (70.9)	0.738
	Master degree	31 (27.4)	82 (72.6)	

Key: Variables with P <0.05 have a significant effect on the practice of HCP's on identifying and reporting of SF medical products, while variables with P > 0.05 imply the opposite.

4.10 Effect of knowledge on handling substandard and falsified medical products.

The knowledge of the respondents regarding substandard and falsified medical products was analyzed by Chi-square test to determine its effect on respondents' practice of identifying and reporting SF medical products. It was found that the respondents with good knowledge were having good practice and few of the respondents with good knowledge were having bad practice. However, the respondent with poor knowledge were having poor practice and few with poor knowledge were having good practice ($P < 0.001$) (Figure 6).

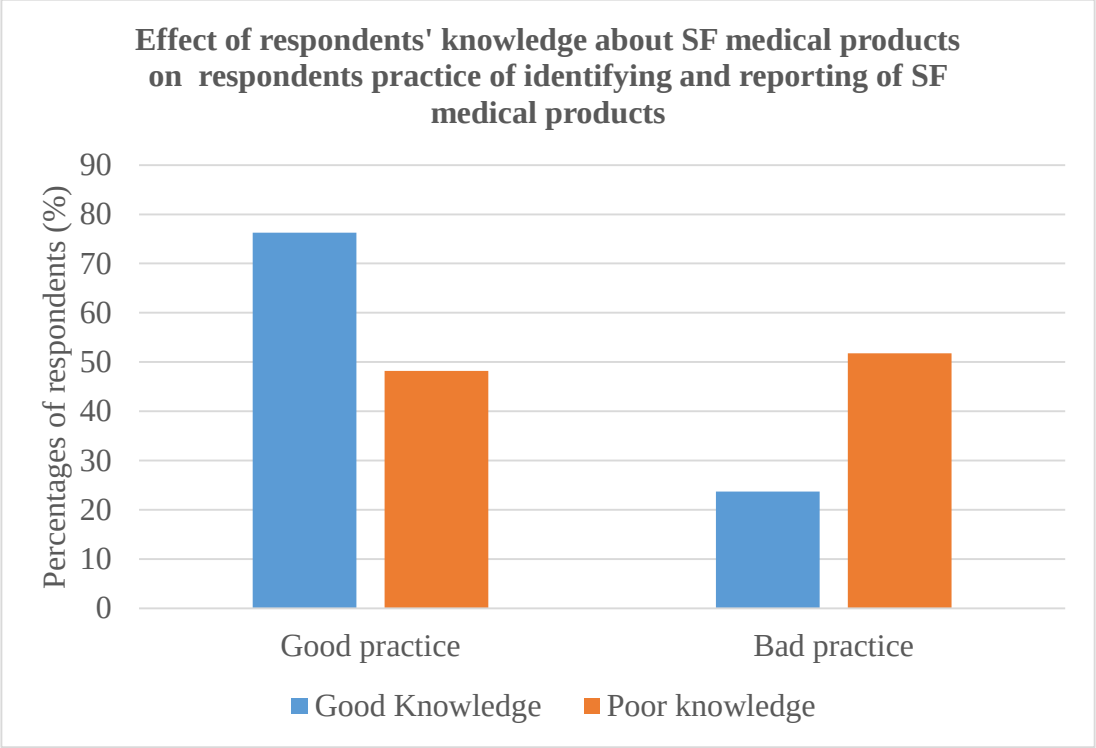

Figure 6: Effect of knowledge on handling SF medical products among health care providers

5.0 DISCUSSION

The WHO recommends the need for health care providers to have high knowledge and practice on substandard and falsified medical products identification and reporting [4]. This study has explored Tanzanian health care providers on the knowledge and practice on the identification and reporting of substandard and falsified medical products. The findings have indicated that Tanzanian health care providers have a good level of knowledge (81.9%) and good practice (71.2%) regarding substandard and falsified medical product identification and reporting. Thus, more interventions are required to raise the understanding of all health care providers regarding substandard and falsified medical products identifying and reporting to save many precious lives [8].

5.1 Knowledge among health care providers regarding SF medical products.

The overall level of knowledge among health care providers on substandard and falsified medical products was good, with 81.9% of the respondents having good knowledge (Figure 2). This is contrary to other studies that have reported the knowledge on substandard and falsified medical products to be low among health care providers [17], [18], [25], [26], [36]. However, about 69.4% of the health care providers reported learning about substandard and falsified medical products during practice (Table 2). This indicates that content on substandard and falsified medical products are not included in the curriculum of the most health training institution. The same finding has been reported from Lebanon [21] and in Sudan where 76% of HCP's learned SF medical products during practice [39].

The knowledge of the respondent's was statistically associated with age ($P < 0.001$), experience ($P = 0.001$), professional cadres ($P = 0.003$), and health facilities type with $P = 0.029$ (Table 4). The association of knowledge regarding substandard and falsified medical products with age and experience is due to changes in the cognitive process. This includes cognitive deterioration, the working memory, performance, and attention become slower as a person gets older with more experience. This has been stated by theories of mind [40]–[43] and the WHO [44]. The same findings were also reported in other studies from Iran [24], Lebanon [21], and Italy [36]. Furthermore, the association of knowledge of the respondents

with health facility type show that health care providers from health centers have low knowledge than HCP's from other facilities. This is because medical products are grouped by health facility levels. In this the higher the facility level the large the number of medical products groups being used. Therefore the health centers have limited groups of medical products used for patient care. This limits the exposure to challenges associated with substandard and falsified medical products to health care providers working in health centers.

5.2 Practice among health care providers on handling SF medical products

Concerning practice, the findings show that 71.2% of the respondents had a good practice of identifying and reporting substandard and falsified medical products (Figure 4). This is because the respondents' knowledge regarding SF medical products was also good. This has been compared with other studies, where in Iran the practice of health care providers on handling SF medical products was reported to be low [17], [24], [36]. The same gap was also observed in Qatar [18], and in Sweden [26]. Moreover, 28.8% of the respondents reported encountering SF medical products during routine work, and 22.3% heard from patients and colleagues (Table 5). The identified substandard and falsified medical products are to be reported by health care providers for investigation. In this, about 53.8% of the respondents reported having no idea of the tool to use for the encountered SF medical products. Only 5.9% of the respondents reported using the correct tool (blue form) which is the right form for reporting poor quality medical products to the regulatory authority (Table 5). Again, this is due to limited training from universities where respondents have learned about SF medical products through experience gained during practice. The same observation was reported in Sweden with 66.9% of health care providers who reported to have no idea of the reporting tools for substandard and falsified medical products [26]. However, other studies have reported that most of the HCP's are usually in a hurry and do not bring out time to report identified SF medical products [9], [17], [31].

Furthermore, the practice among health care providers was significant associated with age ($P < 0.001$), years of working experience ($P < 0.001$), and difference in professional cadres with $P = 0.009$ (Table 7). The association of practice among respondents on identifying and reporting SF medical products with age and experience is due to cognitive changes[40]–[44].

The same observation was also reported in Iran [24], where an increase in working time affected the practice of health care providers on identifying and reporting SF medical products ($P = 0.041$). Furthermore, it was reported in Lebanon that, health care providers with the age of ≥ 50 years were less likely to identify and report SF medical products than the young age of ≤ 40 years [21].

5.3 Knowledge and practice within and between health professional cadres on identification and reporting of substandard and falsified medical products.

The knowledge regarding substandard and falsified medical products within professional cadres was good (Figure 3). The findings are contrary to other studies where health care providers were reported to have limited knowledge of SF medical products [8], [18], [24], [25]. However, the knowledge of pharmacists was high (92.5%) than other cadres (80.2%) with $P = 0.003$ (Table 3). This is contrary to a study done in Qatar which showed that only 18% of the pharmacists have sufficient knowledge about SF medical products [18]. Furthermore, Iranian pharmacists were reported to have low knowledge to only 21.5% having good knowledge [24]. On the other side, the knowledge of nurse officers was low (74.6%) than other cadres (84.2%) with $P = 0.004$ (Table 3). The same gap in nurses' knowledge regarding SF medical products was reported to be low in Madina [8] and by the International Council of Nurses (ICN) [35].

Moreover, the practice within professional cadres was good (Figure 5). This has also been reported in other studies where about 88.2% of health care providers were reported to face the SF medical products phenomenon and they encountered health complications related to SF medical products in Sweden [26]. Furthermore, about 92.2% of health care providers reported being ready in handling SF medical products in India [25]. Again, the practice of pharmacists was significantly higher (84%) than other cadres (69.1%) with $P = 0.002$ (Table 6). This is because pharmacists have an active role in preventing the entry, distribution, dispensing of SF medical products [16]. However, the practice of medical doctors was significant low (66.7%) than other cadres (76.2%) with $P = 0.004$ (Table 6). In this, doctors are usually in a hurry with patients work load and do not bring out time to identify and report substandard and falsified medical products [9].

6.0 CONCLUSION

The findings from this study show that 81.9% and 71.2% of HCP's have a good knowledge and practice regarding SF medical products identification and reporting respectively. The pharmacist's knowledge and practice were high than other cadres. Moreover, the knowledge of nurses was lower, similarly, the practice of medical doctors was also lower than other cadres. However, there is limited trainings from universities on SF medical products to only 13.2% of respondents reporting to have learned it at universities. Again, only 5.9% of the respondents reported using the right form (blue form) to report SF medical products. The HCP's from health centers were found to have more low knowledge than from other health facilities. Moreover, age, experience, and professional cadres were associated with both respondents' knowledge and practice regarding identification and reporting SF medical products. Furthermore, the respondent's knowledge about SF medical products was found to influence practice. Therefore attention and concentrated efforts are required to raise the knowledge of health care providers so that the performance can be increased on identifying and reporting of SF medical products as one step towards fighting against the circulation of SF medical products.

7.0 RECOMMENDATIONS

Concerning the findings explored in this study, more interventions are recommended to be done by the regulatory authority. Basing on this more efforts are required to make sure Standard Operating Procedures (SOP's) on identifying and reporting SF medical products are available in all health facilities. Moreover, capacity building to HCPs on how to identify and report any suspected medical product is recommended. Furthermore, Tanzania academic institutions should include modules on substandard and falsified medical products. This will be one step towards fighting against the penetration of SF medical products on the market through timely identification and reporting for investigation. In addition to that, health care providers should be able to educate patients on choosing reliable sources to acquire medical products. Moreover, the patients will be encouraged to report any undesirable and unexpected side effects occurring after consuming medical products.

8.0 REFERENCES

[1] Naira G. Substandard and falsified medicines: Global and local efforts to address a growing problem. *Pharm. J.* 2019;1-11

[2] Yadav S, Rawal G. Counterfeit drugs : the problem of developing and developed countries. *J Pharm Anal.* 2015;2(1):46-50

[3] Poc MA. Unveiling the peril of substandard and falsified medicines to public health and safety in Africa: Need for all-out war to end the menace. *Wichtig International.* vol. 1, no. 1, pp. 145-154, 2017, DOI: 10.5301maapoc.0000023.

[4] Goyena R. WHO Global Surveillance And Monitoring System For Substandard And Falsified Medical Products. *J. Chem. Inf. Model.* vol. 53, no. 9, pp. 1689–1699, 2019.

[5] Nayyar GML, Breman JG, Mackey TK, Clark JP, Hajjou M, Littrell M, et al. Review Article Falsi fi ed and Substandard Drugs : Stopping the Pandemic. *Am. J. Trop. Med. Hyg*. vol. 00, no. July 2013, pp. 1–8, 2019, DOI: 10.4269/ajtmh.18-098.

[6] Beargie SM, Higgins CR, Evans DR, Laing SK, Erim D, Ozawa S. The economic impact of substandard and falsified antimalarial medications in Nigeria. *PLoS One*, vol. 14, no. 8, pp. 1–16, 2019, DOI: 10.1371/journal.pone.0217910.

[7] Syafri, Edi; Endrizal N. A study on the public health and socioeconomic impact of substandard and falsified medical products. *J. Chem. Inf. Model.*, vol. 53, no. 9, pp. 1689–1699, 2013.

[8] Imam SH, Khan ZM. Knowledge, Attitude and Practices Regarding Counterfeit Drugs among Nurses of Madina Teaching Hospital Faisalabad. *Ann. Punjab Med. Coll*. 2014;8(1):45-50.

[9] Ubajaka CF, Obi-okaro AC, Emelumadu OF, Azumarah MN, Ukegbu AU, Ilikannu SO. Factors Associated with Drug Counterfeit in Nigeria : A Twelve-Year Review. *BMJ*, vol. 12, no. 4, pp. 1–8, 2016, DOI: 10.9734/BJMMR/2016/21342.

[10] Mori AT, Meena E, Kaale EA. The economic cost of substandard and falsified human medicines and cosmetics with banned ingredients in Tanzania from 2005 to 2015 : a retrospective review of data from the regulatory authority. *BMJ Open*, pp. 1–7, 2018, DOI: 10.1136/bmjopen-2018-021825.

[11] Mhando L, Jande MB, Liwa A, Mwita S, Marwa KJ. Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs. *Adv. Public Heal*, vol. 2016, pp. 1-8, 2016, DOI: 10.1155/2016/6254157.

[12] Karunamoorthi K. The counterfeit anti-malarial is a crime against humanity : a systematic review of the scientific evidence. *Malar. J.* 2014; 13(209): 1-13.

[13] Hagan AO, Garlington A. Counterfeit drugs and the online pharmaceutical trade, a threat to public safety. *FRCIJ*, vol. 6, no. 3, pp. 151–158, 2018, DOI: 10.15406/frcij.2018.06.00200.

[14] Health G. Medical Product Quality Report – COVID-19 Issues. *Med. Qual. Res. Gr., University OXFORD*, no. 5, pp. 1–72, 2020.

[15] Welfare S. Who's lying in the fake ARVs scam ? *AJAAT, vol* no. 195, pp. 1–8, 2012.

[16] Chambliss WG, Carroll WA, Kennedy D, Levine D, Moné A, Ried LD, et al. Role of the Pharmacist in Preventing Distribution of Counterfeit Medications. *J. Am. Pharm. Assoc*. 2012; 52(2):195-199.

[17] Liu R, Lundin S. Falsified Medicines : Literature review. *Med Humanit*, vol. 2, no. 1, pp. 1–25, 2016.

[18] Alfadl AA, Ibrahim MIM, Maraghi FA, Mohammad KS. General public and community pharmacists perception on counterfeit medicines: A preliminary cross-sectional study in Qatar. *J. Clin. Diagnostic Res.*, vol. 12, no. 1, pp. IC01–IC06, 2018, DOI: 10.7860/JCDR/2018/28451.11136.

[19] FIP (International Pharmaceutical Federation). Curriculum for pharmacy students on substandard and falsified medicines. *Pharm. Res*, 2021;85(1) 1-80.

[20] Mziray S. Quality Of Selected Anti-retroviral Medicines : Tanzania Mainland Market As A Case Study Current Status : Under Review. *BMC Pharmacol. Toxicol.* pp. 1–27, DOI: 10.21203/rs.3.rs-18179/v1.

[21] Sholy L, Gard P, Williams S, MacAdam A. Pharmacist awareness and views towards counterfeit medicine in Lebanon. *Int. J. Pharm. Pract.*, vol. 26, no. 3, pp. 273–280, 2018, DOI: 10.1111/ijpp.12388.

[22] Moremi N, Claus H, Mshana SE. Antimicrobial resistance pattern : a report of microbiological cultures at a tertiary hospital in Tanzania. *BMC Infect. Dis*, pp. 1–7, 2016, DOI: 10.1186/s12879-016-2082-1.

[23] Horumpende PG, Mshana SE, Mouw EF, Mmbaga BT, Chilongola JO. Point prevalence survey of antimicrobial use in three hospitals in North-Eastern Tanzania. *Antimicrob*, vol. 3, pp. 1–6, 2020.

[24] Shahverdi S, Hajimiri M, Pourmalek F, Torkamandi H, Gholami K, Hanafi S, et al. Iranian pharmacists' knowledge, attitude, and practice regarding counterfeit drugs. *Iran. J. Pharm. Res.*, vol. 11, no. 3, pp. 963–968, 2012, DOI: 10.22037/ijpr.2012.1118.

[25] Yadav V, Budania N, Mondal A, Kumar N, Kumar R, Kumar Bhardwaj V, et al. A

questionnaire-based study on knowledge and attitude towards counterfeit medication among the doctors in tertiary care hospital. *Int. J. Basic Clin. Pharmacol.*, vol. 7, no. 4, p. 802, 2018, DOI: 10.18203/2319-2003.ijbcp20181190.

[26] Funestrand H, Liu R, Lundin S, Troein M. Substandard and falsified medical products are a global public health threat. A pilot survey of awareness among physicians in Sweden. *J. Public Health (Oxf.),* vol. 41, no. 1, pp. 95–102, 2018, DOI: 10.1093/PubMed/fdy092.

[27] WHO Member State mechanism on substandard and falsified medical products, *Online* Handbook on existing training resources and reference documentation for the prevention, detection, and response to SF medical products. 2019.

[28] Callister C.L, Substandard and Falsified Medical Products.*MCN Am. J. Matern. Nurs.*, vol. 44, no. 6, pp. 361–361, 2019, DOI: 10.1097/nmc.0000000000000579.

[29] Sheets F and Market F.O.R. WHO Global Benchmarking Tool For Evaluation Of National Regulatory System of Medical Products: MC01 Legal provisions, regulations and guidelines required," pp. 1–40.

[30] Hamill H, David-Barrett E, Mwanga J, Mshana G, and Hampshire K. Monitoring, reporting and regulating medicine quality: tensions between theory and practice in Tanzania," *BMJ Glob. Heal.*, pp. 1–8, 2020, DOI: 10.1136/bmjgh-2020-003043.

[31] Mcmanus D, Naughton BD. A systematic review of substandard, falsified, unlicensed, and unregistered medicine sampling studies : a focus on context, prevalence, and quality. *BMJ Global Health*, pp. 1–9, 2020, DOI: 10.1136/bmjgh-2020-002393.

[32] Almuzaini T, Sammons H, Choonara I. Substandard and falsified medicines in the UK: A retrospective review of drug alerts (2001-2011). *BMJ Open*, vol. 3, no. 7. 2013, DOI: 10.1136/BMJ open-2013-002924.

[33] Surur AS, Teni FS, Wale W, Ayalew Y, Tesfaye B. Health-related quality of life of HIV / AIDS patients on highly active antiretroviral therapy at a university referral hospital in Ethiopia. *BMC Health Serv. Res, vol* 17, no 737, pp. 1–8, 2017, DOI: 10.1186/s12913-017-2714-1.

[34] Blomberg B, Mwakagile DSM, Urassa WK, Maselle SY, Mashurano M, Digranes A, et al. Surveillance of antimicrobial resistance at a tertiary hospital in Tanzania. *BMC Public Health.* vol 4 ,no 45 ,pp1-12.May 2014, 2004, DOI: 10.1186/1471-2458-4-45.

[35] Ferrario A, Orubu ESF, Adeyeye MC, Zaman MH, Wirtz VJ. The need for comprehensive and multidisciplinary training in substandard and falsified medicines for pharmacists. *BMJ Global*

Health pp. 1–3, 2019, DOI: 10.1136/bmjgh-2019-001681.

[36] Lombardo S, Marino F, Cosentino M. A nationwide web-based survey of a sample of Italian community pharmacists' perceptions and opinions about online sales of medicines and falsified drugs. *Pharm. Pract. (Granada).*, vol. 17, no. 4, pp. 1–8, 2019, DOI: 10.18549/PharmPract.2019.4.1593.

[37] Hamilton WL, Doyle C, Halliwell-Ewen M, Lambert G. Public health interventions to protect against falsified medicines : a systematic review of international, national and local policies. *Health Policy and Plan.* no. June, pp. 1448–1466, 2016, DOI: 10.1093/heapol/czw062.

[38] Yousuf SA, Alshakka M, Badulla WFS, Ali HS, Shankar PR. Attitudes and practices of community pharmacists and barriers to their participation in public health activities in Yemen : mind the gap. *BMC Health Serv.Res*,vol.19 no 304, pp 1-8,2019.

[39] Wala W. Wagieall A, Shaza W. Shantie R, Imad O. Aburei D Elrasheed A. Community pharmacists Awareness and Attitude toward Counterfeit medicine in "Khartoum Locality : Cross-Sectional Survey," pp 1-14, 2020.

[40] Moran J.M, "Lifespan development: The effects of typical aging on the theory of mind. *Behav. Brain Res.*, vol. 237, no. 1, pp. 32–40, 2013, DOI: 10.1016/j.bbr.2012.09.020.

[41] Hess T.M and Smith B.T Aging and the impact of irrelevant information on social judgments. *Psychol. Aging*, vol. 29, no. 3, pp. 542–553, 2014, DOI: 10.1037/a0036730.

[42] Fischer A.L, Rourke N.O, and Thornton W.L. Age differences in cognitive and affective theory of mind: Concurrent contributions of neurocognitive performance, sex, and pulse pressure. *Journals Gerontol. - Ser. B Psychol. Sci. Soc. Sci.*, vol. 72, no. 1, pp. 71–81, 2017, DOI: 10.1093/geronb/gbw088.

[43] Grainger S.A, Steinvik H.R, Henry J.D, and Phillips L.H. The role of social attention in older adults' ability to interpret naturalistic social scenes. *Q. J. Exp. Psychol.*, vol. 72, no. 6, pp. 1328–1343, 2019, DOI: 10.1177/1747021818791774.

[44] WHO, World report on Ageing and Health. pp 1-260, 2015.".

9.0 TOOLS USED FOR DATA COLLECTION

9.1 ANNEX I: INFORMED CONSENT FORM

Introduction:
Greetings, my names are Sayuni Steven Ndele, a postgraduate student from Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting this research to assess the knowledge and practice on the identification and reporting of substandard and falsified medical products among health care providers in Tanzania. The study will involve Medical personnel with a minimum educational background of bachelor's degree (Medical Doctors, Pharmacist, Nurses, Dentist and Medical Laboratory Scientist) who are currently practicing in Tanzania.

Purpose
The main aim of this study is to collect information that will help to assess if health care providers are equipped with enough knowledge on the identification and handling of substandard and falsified medical products.

Participation requirements
If you agree to participate in this study, you will be required to kindly answer some questions that have been prepared for the study to obtain information relevant to the research objectives.

Confidentiality
All information given will remain for the research purpose only and will be confidential.

Risk
There is no risk/harm anticipated to participants from participating in this study

Benefits
There will be no direct benefit that the participant can get but the results obtained from this study will help to create awareness to the public about how the Health care providers deal with S/F medical products aiming at improving health services in Tanzania

Injury

It is not anticipated that any harm/injury will occur as a result of participating in this study

Termination

If you join this study and before completing answering the question, you feel like you need to stop, then you are allowed to stop.

Contact personnel

For any clarification about this study do not hesitate to contact the Principal Investigator, Sayuni Ndele, P.O. Box 65013 MUHAS, Telephone: +255 788 325 699. Or DR. Vicky Manyanga, the Research supervisor, P.O. Box 65013 MUHAS, Department of Medicinal Chemistry. Telephone: +255 755 566 055.

Signature of participant

Title……..

Signature…….

Date……

9.2 ANNEX II: QUESTIONNAIRE

SECTION I. DEMOGRAPHIC INFORMATION

1. **Circle your gender**; - a) Male b) Female

2. **Circle where your age lies(yrs)** a) 20-29 b) 30- 39 c) 40-49 d) 50-59 e) 60+

3. **Circle the type of health facility you are working/ you are leading position**

a) Hospital
b) Health Centre
c) Community Pharmacy
e) Community Medical Laboratory
f) Dental clinic
g) Other clinics
h) CHMT
i) RHMT

4. **Mention the name of the facility where you're working/ leading**……

5. **Mention the region where the facility you're working/leading is located**……

6. **Mention the zone where the region is located eg (lake zone)**……

7. **Mention bachelor degree you studied**……...……

8. **Circle the number of years of your working experience (yrs)**
   a) 1-5 b)6-10 c)11-15 d)16-20 e) 21-25 f) 26+

9. **Circle the highest educational level you have attained(graduated)**
   a) Bachelor degree
   b) Master degree
   c) Doctorate

SECTION II: KNOWLEDGE ASSESSMENT

1. What are substandard/falsified medicine, medical devices, and diagnostics products?

a) Are products from an unknown source
b) Are placebo products

c) Are orphan products
d) Are fake medical products

2. From which source you became aware of substandard and falsified medical products?

a) During practice
b) From university
c) From conferences
d) Not aware of it.

3. In which areas do these substandard/falsified medical products are available?

a) Urban areas
b) Rural areas
c) Both A and B
d) Don't know

4. The following are some of the medical products that may be falsified or produced as substandard medical products, which are most common

a) Lifestyle medicines
b) Ant malaria and antibiotic medicines
c) Diagnostic devices like blood glucose test strips
d) Protective devices like face masks

5. What factors contribute to the product of your choice above being at high risk of being falsified or being out of standard?

a) Unavailable and unaffordable
b) Highly demanded
c) Highly promoted from internet
d) Don't know

What factors contribute to the circulation of SF medicines, medical devices, and diagnostics? Please respond to question 6 to 10

6. Presence of some health care providers selling medical products to patients from their pockets, allowing patients to buy medical products anywhere out of health facilities due to shortage/stock out and procuring medical products from unknown sellers promoting to health facilities.

a) Yes
b) No

7. Inadequate control of medicines, medical devices, and diagnostics by the regulatory authority

a) Yes
b) No

8. Poor reporting culture by HCP's for the identified SF medical products and treatment outcomes associated with consumption of SF medical products to the regulatory authority.

a) Yes
b) No

9. Highly-priced medicines, medical devices, and diagnostic products

a) Yes
b) No

10. Lack of knowledge on substandard/falsified medicines/medical devices and diagnostic tools among health care providers.

a) Yes
b) No

11. The following may be the health impact of using substandard and falsified medical products i.e., medicines, medical devices, and diagnostic tools, which one is correct?

a) Increase in mortality and morbidity
b) Promote drug resistance
c) The prevalence of diseases increases
d) All of the above

12. The following are the economic outcome of substandard and falsified medicines, medical devices, and diagnostic tools, select the appropriate answer

a) Increased productivity
b) Reduced poverty
c) Limited resources are wasted
d) All of the above.

SECTION III: PRACTICE ASSESSMENT

13. What is the source of information you heard about the presence of substandard and falsified medicines, medical devices, and diagnostic tools?

a) Media and advertising materials
b) Patients and colleagues
c) Encountered by yourself in routine work.
d) Never heard if these products are present

Question 14 to 21, needs you to respond on how do you identify substandard/falsified medicine/medical devices/diagnostics from original

14. Through label

a. Yes
b. No

15. Through packaging materials

a) Yes
b) No

16. Through expire date

a) Yes
b) No

17. Through reporting treatment outcomes to regulatory authority eg treatment failure/toxicity.

a) Yes
b) No

18. Through cost/ price of medical products.

a) Yes
b) No

19. Through package insert (leaflet)

a) Yes
b) No

20. Through unexpected adverse reactions to few patients after using the same medical product of the same batch.

a) Yes
b) No

21. Wrong diagnosis through laboratory results

a) Yes
b) No

22. (When/if) you encounter a substandard/falsified medicine/medical device/ diagnostics (do you/ will you) report them?

a. Yes
b. No

23. Which form (do you use/will you use) to report them to the regulatory authority?

a) Yellow form
b) Green form
c) Blue form
d) Don't know

24. In your opinion, what is the current situation regarding the circulation of substandard and falsified medicine, medical devices, and diagnostics in Tanzania?

a) It is a big problem
b) Substandard/falsified medical products are not existing.
c) The products are existing but not identified and reported
d) Detection of SF medical products is increasing but reporting is a problem.

25. In which action do you suggest can help to reduce the penetration of substandard and falsified medical products in our country?

a) Through public sensitization to raise their awareness against SF medical products
b) Adherence to ethics and reporting the identified medical products
c) The strictness of entry points(borders)
d) All of the above

9.3 ANNEX III: ETHICAL LETTER

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

Ref. No.DA.282/298/01.C/ Date: 22/04/2021

MUHAS-REC-04-2021-568

SAYUNI STEVEN NDELE
School of Pharmacy
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: ASSESSMENT OF KNOWLEDGE AND PRACTICE ON IDENTIFICATION AND REPORTING OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS AMONG HEALTH CARE PROVIDERS IN TANZANIA.

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 22/04/2021
EXPIRATION DATE OF APPROVAL: 22/04/2022

STUDY DESCRIPTION:
Purpose:
The main purpose of this cross-sectional observational study is to determine the level of knowledge and practice regarding the identification and reporting of substandard and falsified medical products among health care providers in Tanzania

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20523.pdf and in the MUHAS archives.

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam; Tel. GiLine: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line. +255-22-2150302/8; Ext. 1038; Direct Line:+255-22-2152469;Telefax:+255-22-2152469;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz